



Skill India
कौशल भारत - कुशल भारत



सत्यमेव जयते
GOVERNMENT OF INDIA
MINISTRY OF SKILL DEVELOPMENT
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National
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Transforming the skill landscape



Facilitator Guide



Sector
Life Sciences

Sub-Sector
Pharmaceutical, Biopharmaceutical

Occupation
Manufacturing

Reference ID: LFS/ Q 0207, Version 1.0
NSQF level: 4

Production/ Machine Operator - Life Sciences



Shri Narendra Modi
Prime Minister of India

“ Skilling is building a better India.
If we have to move India towards
development then Skill Development
should be our mission. ”

Acknowledgement

Many individuals and organizations have contributed to developing this Facilitator Manual and all deserve to be thanked. Without their contribution, this participant manual would not have been written. The efforts by Team Talento Consulting, expert at LSSSDC and various subject matter experts, and prominent organizations like Dr. Reddy's Limited, Jubilant Generics Limited, Jamia Hamdard University has resulted in developing this manual for skilling Lab Assistants, therefore, aimed to plug a major loophole.

We would like to thank Dr. Vinay Umesh Rao, Mr. Sanjeev Kumar Sharma, Dr. M Saharyar, Mr. P K Gupta and all those who provided inputs to put together this manual— which we believe will make an invaluable contribution to Life Sciences sector.

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About this Guide

Life Sciences Sector is one of the primary engines of growth in the manufacturing space, and a leading player in the recently launched 'Make in India' campaign. With revenue in excess of \$30 bn, Life Sciences sector has been growing at over 16% per annum in the past few years. The sector currently provides employment to around 800,000. The Manufacturing job roles, comprise around 384,000 (approx. 48% of the total job volume).

Life Sciences Sector Skill Council is aiming for skilling about 30,000 Production/ Machine Operator- Life Sciences in next 3 years. This Facilitator manual dovetails with the National Occupation Standards for Production/ Machine Operator Assistant- Life Sciences, also developed by LSSSDC with Industry. The Manual will prove to be a vital tool in the skilling process. It will also be a boon for all fresh aspirants who wish to join the Life Sciences sector as Production/ Machine Operator. It is designed to enable theoretical and practical skilling on Production/ Machine Operator- Life Sciences Qualification Pack which mandates the below six (6) Occupation Standards for the job role:

- Prepare machines and accessories for the manufacturing process
- Perform manufacturing operations
- Ensure cleanliness in the work area
- Carry out reporting and documentation
- Carry out broad level quality checks before, in-process and post manufacturing
- Maintain a healthy, safe and secure working environment in the life sciences facility

The above six (6) occupational standards are covered under various units in the participant manual which comprehensively binds knowledge and skills related to these. It.

The book is designed keeping in mind the minimum education qualification of Production/ Machine Operator- Life Sciences to be 10+2 class Pass as stipulated by Industry. However, as part of this book, efforts have been made to put focus on practical learning in addition to all technical and manufacturing concepts required for the role. The Key Learning Objectives and the skills gained by the participant are defined in their respective units.

The contents of this book are in simple language. It is envisaged that this facilitator manual will provide the participants with the knowledge and skills required for Job role of Production/ Machine Operator- Life Sciences. It should enable participants to become effective and responsible Production/ Machine Operator for Life Sciences Industry.

Symbols used in the book have been listed below.

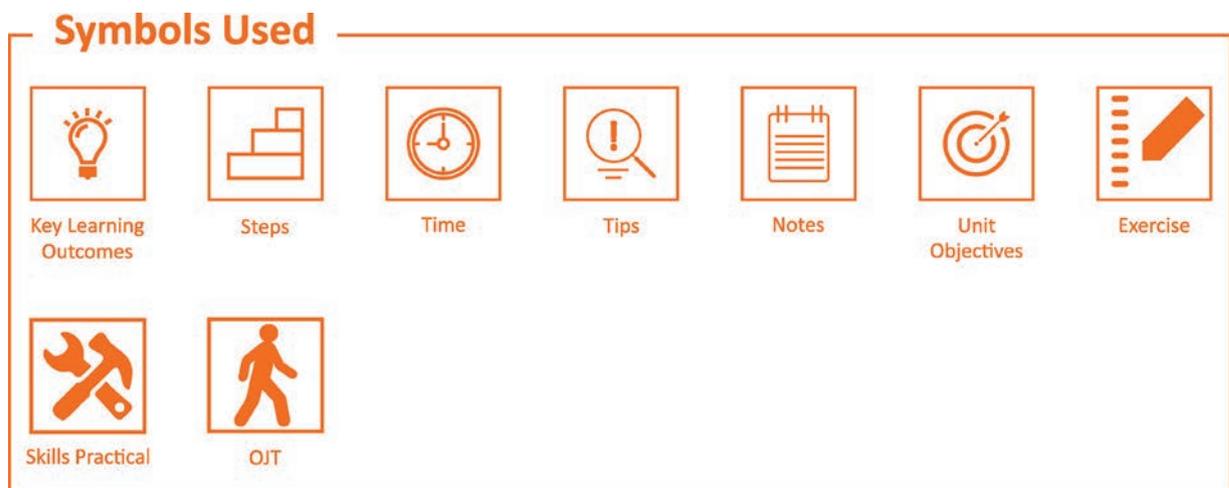


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Key Learning Outcomes

At the end of this module, you will be able to:

1. Gain brief knowledge about Life Sciences industry and its sub-sectors.
2. Gain knowledge about Regulatory Authorities and Government policies, rules and regulations and their impact on manufacturing in Life Sciences industry in India and emerging markets.
3. Know the standards for manufacturing in Life Sciences (cGMP and ISO).
4. Acquire knowledge about the organization structure in Life Sciences industry (Large / Medium / Small Enterprises).
5. Discuss on typical manufacturing function in a Life Sciences organization.
6. Learn about the role of a Machine Operator in Life Sciences industry.

UNIT 1.1: Life Sciences Industry and Its Sub-Sectors

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. About Life Sciences Industry, its sub-sectors.

Activity

- Ask the students about the expectations from the course.
- Invite students to participate. List their expectations on the whiteboard.
- Give the students a brief overview of what all will be covered in the program.

Do

- Divide the students into two groups.
- Call one from each group at a time and ask them to greet each other and introduce themselves to each other in front of the class, this will be helpful in judging their interpersonal skills.
- Select students randomly and ask them about their hobbies, interests, goal, etc.

Ask

Ask the learners to share:

- Their idea about Life Sciences Industry in India, its sub-sectors in Life Sciences Industry.
- Basic knowledge and their views on Pharmaceuticals
- Their views on Biopharmaceuticals.

Say

- Share facts and figures about Life Sciences Sector's growth consistent and remarkable growth to the economic growth of the country.
- Provide an overview of Machine Operator and the need for this job role in the sector.
- State the roles and responsibilities of Machine Operator.
- Brief the learners about the huge demand for trained personnel nationally, in life sciences industry.
- State different segments of life sciences industry.

Notes for Facilitation

- Encourage shy students to provide information about themselves by prompting them with questions such as 'what do you enjoy doing the most', 'what is your favourite movie or book' etc.
- Appreciate students for their participation
- Explain them required proficiency in communication in Lab Sciences Industry
- Discuss Contact Research
- Describe Organization Structure
- How to create a positive impression at the workplace

Resources to be Used

- Available objects such as a duster, marker, white board, pen, notebook etc.

Elaborate

1.1.1 General Instructions for the Participants

- Always be punctual for every class.
- Be regular. Candidates who fall short of the required attendance will not be certified.
- Inform your instructor if, for any reason, you need to miss class.
- Pay careful attention to what your instructor is saying or showing.
- In case you do not understand something do not hesitate to put up your hand and seek clarification.

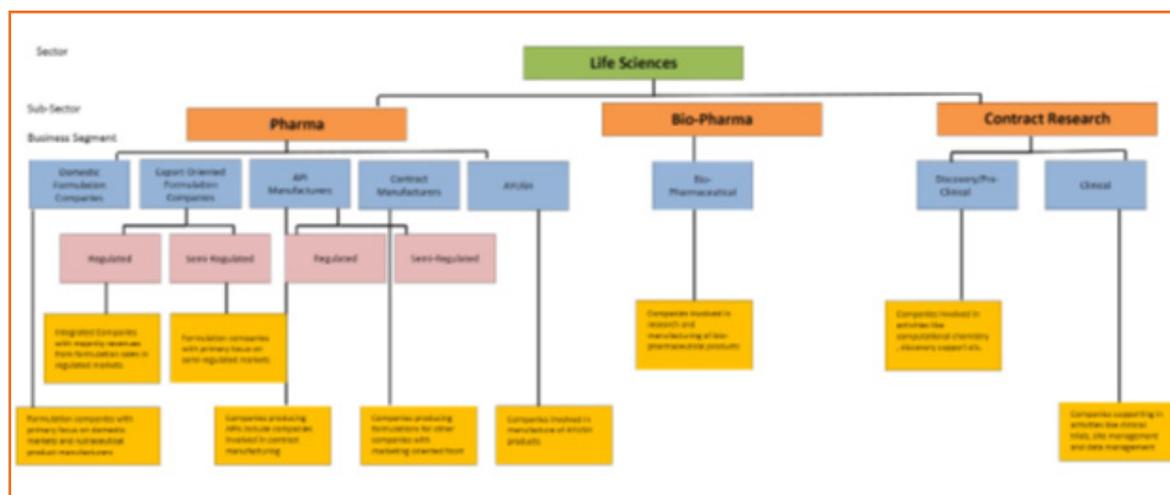
Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 3 and explain the learners' the concept.

1.1.2 Introduction to Indian Life Sciences Industry

Life Sciences Sector is one of the primary engines of growth in the manufacturing space, and a leading player in the recently launched 'Make in India' campaign. With revenue in excess of \$30 bn, Life Sciences sector has been growing at over 16% per annum in the past few years. The sector currently provides employment to around 800,000. The Manufacturing job roles, comprise around 384,000 (approx. 48% of the total job volume). Life Sciences Sector Skill Council is aiming for skilling about 30,000 Production/ Machine Operator- Life Sciences in next 3 years. This participant manual dovetails with the National Occupation Standards for Production/ Machine Operator Life Sciences, also developed by LSSSDC with Industry.

Life Sciences being a diverse and vibrant global industry encompasses a wide range of activities. The activities range from discovery, research & development and manufacture of therapeutics, medical devices, diagnostics and platform technologies. It also includes the specialist suppliers of products and services necessary for the functioning of various organizations related to Life Sciences. The increasingly ageing global population and their demand for improved longevity offers a very strong growth potential to Life Sciences industry.

1.1.3 Sub-Sectors in Life Sciences Industry



The life sciences industry in India is huge and has able to incorporate pharmaceutical companies, biopharmaceutical and contract research organization (CROs) with the support of specialized suppliers and organization. The pharmaceutical industry develops, produces, and markets drugs for use as medications.

1.1.3.1 Pharmaceuticals

Domestic Formulation companies: Formulation is the process that combines different chemical substances including the active drug in order to produce a final medicinal product. Tablets, capsules, liquid form, lyophilized, etc. are a few different forms of Pharmaceutical Formulations. A large number of companies are involved in processing and supplying of different types of pharmaceutical medicines across the domestic sector.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 4-5 and explain the learners' the concept.

1.1.1.2 Biopharmaceuticals

Biopharmaceutical business is engaged in discovering, developing and delivering innovative medicines to patients with serious diseases. Biopharmaceuticals are medical medication created victimization biotechnology. Biologics is composed of a mixture of sugars, proteins, or Nucleic acids or is also living cells or tissues. They're isolated from Natural sources—human, animal, or organism. Some leading Companies operating during this space embrace Biocon, Bodily Fluid Institute of India, Nostrum Biotec, Piramal care, GlaxoSmithKline.

Trainers note: *These are the supporting content to the participant manual, please adhere to the participant manual, page no. 4-6 and explain the learners' the concept.*

Program Overview

This program will facilitate an overview of:

- Prepare machines and accessories for the manufacturing process.
- Perform manufacturing operations
- Ensure cleanliness in the work area
- Carry out reporting and documentation
- Carry out broad level quality checks before, in process and post manufacturing.
- Maintain a healthy, safe and secure working environment in the life sciences facility.

Field Visit



- Take the students to Pharmaceutical industry, discuss Pharmaceutical industry with students.

Notes for Facilitation



Before leaving for the field visit, provide instructions to the learners about the following:

- Objectives of the field visit- what are they expected to learn during the field visit.
- Guidelines on appropriate behavior and appearance for the field visit.
- Importance of taking notes.
- Logistics of the visit- Location, time, duration, transport facilities, etc.

After the learner come back from the visit, have a joint experience sharing session to discuss what they learnt.

Team Activity

The trainer can conduct a Quiz to test the understanding of the learners as well as revise the main points of the course.

- Divide the learners into 3 teams
- Ask each team to formulate at least 10 questions from the complete introductory module including
- Conduct a QUIZ contest between the 3 teams, where one team asks questions on they made to the second team. The second team can earn a mutually agreed score if they get the answer correct. Then the second team asks questions on from the third team and then the third team will ask a question from the first.
- They can have 5-7 rounds
- Any question that is not correctly answered will pass on to the next team
- All questions and answers will be approved by the trainer
- The trainer can also throw questions to the teams that are important but not covered by any of the teams
- The trainer can ask one student to keep the score on the board

The winning team would get a standing ovation

Exercise 

1. Name any two activities of Life Sciences.

.....
.....

2. Formulation is the process that combines different chemical substances including the active drug in order to produce a final medicinal product.

- a. True
- b. False

3. What is the full form of API?

.....
.....

4. Biopharmaceutical industry is engaged in discovering, developing and delivering innovative medicines to patients with serious diseases.

- a. True
- b. False

5. What is the full form of CRO?

.....
.....

UNIT 1.2: Drug Regulatory Agencies

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. About drug regulatory agencies and authorities.

Ask

Ask the learners to share:

- What do they know about Drug Regulatory Agencies?

Say

- Brief the learners about Drug Regulatory Agencies.

Resources to be Used

- Available objects such as a duster, marker, white board, pen, notebook etc.

Elaborate

1.2.1 Drug Regulatory Agencies

Manufacturing and sales of Drugs and Pharmaceuticals is governed by government regulatory bodies of different countries. The Regulatory Affairs Department of Life Science companies should make it a point that the companies ought to follow the rules and laws regarding their business.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 8-9 and explain the learners' the concept.

Exercise 

1. Which regulatory authority does India come under?

.....
.....

2. Which is the regulatory authority of US?

.....
.....

3. Mention any one thing FDA is responsible for.

.....
.....

4. Name any two elements the FDA regulates.

.....
.....

5. What is the full form of CDER?

.....
.....

6. Mention any two roles of the agency.

.....
.....

7. What is TGA?

.....
.....

8. Name any two industries the TGA doesn't regulate.

.....
.....

UNIT 1.3: Impact of Rules and Regulations

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. Impact of rules and regulations of drug agencies.

Ask

Ask the learners to share:

- What do they know about ten principles of Good Manufacturing Practices
- What do they know about WHO GMP Protocols
- What do they know about Schedule

Say

- Describe Schedule M Compliance.
- Describe Pharmacopoeia.

Do

- Explain Pharmacopoeia.

Activity

- Select students randomly after the training session and ask them to extempore the standards of manufacturing in the class.

Elaborate

1.3.1 Ten Principles of Good Manufacturing Practices

Written Procedures

The first principle of GMP is to develop detailed step-by-step procedures, in writing, that provide a "road map" for consistency in performance. Written procedures allow for workplace standards to be clearly established,

ensuring that a job or procedure is performed in the same way each time, with each step followed as set out in the written instructions.

Following Procedures

The written procedures will only be effective if they are followed to the letter, so it is important that no short cuts or modifications be permitted. Any deviation from the written instructions may adversely affect consistency in product quality.

Trainers note: *These are the supporting content to the participant manual, please adhere to the participant manual, page no. 11 and explain the learners' the concept.*

1.3.2 WHO GMP Protocols

Instituted in 1975, World Health Organization GMP guidelines were instituted to assist regulatory authorities in different countries to ensure consistency in quality, safety and efficacy standards while importing and exporting drugs and related products. India is one of the signatories to the certification scheme. AWHO-GMP certification, with its validity for two-years, may be granted both by CDSCO and state regulatory authorities only after a thorough inspection of the manufacturing premises.

1.3.3 Schedule M Compliance

The production of drug products (drugs) in India is controlled under the Drugs and Cosmetics Rules (1945, last amended in 2005), which states that the holder of the license to manufacture drugs has to comply with the requirements of GMP as laid down in Schedule M. Schedule M is a part of the Drugs and Cosmetics Rules and embodies the Indian GMP regulations, which are based on the 1982 version of WHO GMP guidelines. Indian GMP regulations consist of eight parts: I, IA, IB, IC, ID, IE, IF and II. Part I covers the general requirements of GMP. It is divided into 29 chapters.

Trainers note: *These are the supporting content to the participant manual, please adhere to the participant manual, page no. 12-13 and explain the learners' the concept.*

1.3.4 Pharmacopoeia

Pharmacopoeia is a book containing directions for the identification of samples and the preparation of compound medicines published by the authority of a government or a medical or pharmaceutical society. It contains a list of drugs, their formulas, and methods for making medicinal preparations, requirements and tests for their strength and purity, and other related information.

Trainers note: *These are the supporting content to the participant manual, please adhere to the participant manual, page no. 13-16 and explain the learners' the concept.*

Exercise 

1. Machine operator is responsible for monitoring the events of a manufacturing of drugs/medicines.

.....
.....

2. What does ISO stand for?

.....
.....

3. Name any two pharmacopoeia.

.....
.....

4. What does 'standards' mean when defining the quality of drug product?

.....
.....

UNIT 1.4: Role of Machine Operator

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. Different role of machine operator.

Ask

Ask the learners to share:

- What do they know about the role of Machine Operator?
- What do they know about Key Competencies?

Say

- Discuss Key Competencies.
- Discuss the expected knowledge and skills.

Do

- Explain Career Path.

Activity

- Select students randomly after the training session and ask them to extempore the standards of manufacturing in the class.

Elaborate

1.4.1 Introduction

The Machine Operator is a person who handles and is responsible for

preparing the machinery before the manufacturing, performing the manufacturing activities and also doing the post manufacturing activities. Machine Operator is also called as the Production Operator. The Machine

Operator's task is to monitor the events of manufacturing of the drugs/medicines. The products and materials are being verified by the Machine Operator so as to give conformity of an ideal mixture that can be used.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 17 and explain the learners' the concept.

1.4.2 Key Competencies

- Knowledge about Life Sciences industry, and Regulations (cGMP, ISO) to enable themselves for establishing the Industry Standards in their performance.

Scientific knowledge about:

- Basic of Industrial Chemistry for API and Formulation Production.
- Production Process for API and Formulations.
- Use of equipment and machinery.
- QMS for Production.
- Detailed norms of cGMP.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 17 and explain the learners' the concept.

1.4.3 Knowledge and Skills

While performing the required activities to effectively supervise the production process, maintain a healthy, safe and secure working environment and communicating with colleagues and seniors, a Machine Operator is expected to have certain knowledge and skills.

Knowledge and Understanding

- Company's Quality policy.
- Production norms of the company.
- Safety and hygiene norms.
- Roles and responsibilities of others in the production area all relevant standard operating procedures(SOP) of the company.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 18 and explain the learners' the concept.

1.4.4 Career Path

Machine operator is a highly skilled job in Pharma sector. The joinee is first skilled on one particular activity or machine. Based on his performance, interest, Organizational needs, he is then skilled on other activities and machines within his area. Once he is multiskilled, then he may get supervisory role after attaining required skill set and gaining qualification for production supervisor.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 19 and explain the learners' the concept.

Activity

- Ask the students to write their name on a slip.
- Collect the slips from the students fold them and put them on the table/box/bowl.
- Randomly pick two slips and announce the name of students (the first student will ask question from the second student related to unit 1.6 and the second student will answer).
- Evaluate and explain the concept as per the students' performance.

Exercise

1. Machine operator is responsible for monitoring the events of a manufacturing of drugs/medicines.
 - a. True
 - b. False
2. What are the skills that a Machine Operator requires?

.....
.....

Key Learning Outcomes

At the end of this module, you will be able to:

1. Basics of Pharmaceutical Science.
2. Organic nomenclature system and reaction mechanisms.
3. Quality Management System for production in Life Sciences.
4. How to discuss productivity norms and to calculate the overall equipment efficiency (OEE).
5. Concepts and practical skills of Quality Risk Management and Data Integrity aligned to cGMP.
6. The documentation practices required by cGMP and its implementation on shop floor.

UNIT 2.1: IUPAC Rules for Naming of Organic Compounds

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. Basics of Pharmaceutical Science.
2. Different types of organic compounds.

Ask

Ask the learners to share:

- Knowledge about Alkanes
- Knowledge about Alkenes and Alkynes

Say

- State IUPAC rules for Naming of Organic Compounds.
- Discuss Alkyl Halides.

Do

- Discuss Alcohols.
- Discuss Ethers.
- Explain Aldehydes.

Activity

- Ask the students to write their name on a slip.
- Collect the slips from the students fold them and put them on the table/box/bowl.
- Randomly pick two slips and announce the name of students (the first student will ask question from the second student related to unit 2.1 and the second student will answer).
- Evaluate and explain the concept as per the students' performance.

Elaborate

2.1.1 Introduction

IUPAC (International Union of Pure and Applied Chemistry) has set rules for naming of any organic compound. Few basic names should be memorized in order to name organic compounds which is listed under naming alkanes. In general, the base part of the name reflects the number of carbons in what we have assigned to be the parent chain. The suffix of the name reflects the type(s) of functional group(s) present on (or within) the parent chain.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 23 and explain the learners' the concept.

2.1.2 Alkanes

The names of the straight chain saturated hydrocarbons for up to a 12 carbon chain are shown in the table. The names of the substituents formed by the removal of one hydrogen from the end of the chain is obtained by changing the suffix -ane to -yl.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 23-24 and explain the learners' the concept.

2.1.3 Alkenes and Alkynes

Double bonds in hydrocarbons are indicated by replacing the suffix -ane with -ene. If there is more than one double bond, the suffix is expanded to include a prefix that indicates the number of double bonds present (-adiene, -atriene, etc.).

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 24-25 and explain the learners' the concept.

2.1.4 Alkyl Halides

The halogen is treated as a substituent on an alkane chain. The halo-substituent is considered of equal rank with an alkyl substituent in the numbering of the parent chain.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 25-26 and explain the learners' the concept.

2.1.5 Alcohols

Alcohols are named by replacing the suffix -ane with -anol. If there is more than one hydroxyl group (-OH), the suffix is expanded to include a prefix that indicates the number of hydroxyl groups present (-anediol, -anetriol, etc.). The position of the hydroxyl group(s) on the parent chain is (are) indicated by placing the number(s) corresponding to the location(s) on the parent chain directly in front of the base name (same as alkenes).

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 26 and explain the learners' the concept.

2.1.6 Ethers

You are only expected to know how to name ethers by their common names. The two alkyl groups attached to the oxygen are put in alphabetical order with spaces between the names and they are followed by the word ether. The prefix di- is used if both alkyl groups are the same.



Examples of Ethers

2.1.7 Aldehydes

Aldehydes are named by replacing the suffix -ane with -anal. If there is more than one -CHO group, the suffix is expanded to include a prefix that indicates the number of -CHO groups present (-anedial - there should not be more than 2 of these groups on the parent chain as they must occur at the ends). It is not necessary to indicate the position of the -CHO group because this group will be at the end of the parent chain and its carbon is automatically assigned as C-1.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 27 and explain the learners' the concept.

2.1.8 Ketones

Ketones are named by replacing the suffix -ane with -anone. If there is more than one carbonyl group (C=O), the suffix is expanded to include a prefix that indicates the number of carbonyl groups present (-anedione, -anetrione, etc.). The position of the carbonyl group(s) on the parent chain is (are) indicated by placing the number(s) corresponding to the location(s) on the parent chain directly in front of the base name (same as alkenes).

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 28-30 and explain the learners' the concept.

Exercise

1. What is the formula of Alkane?

.....

2. What is the formula of Ethers?

.....

3. What is the longest carbon chain called?

.....
.....

4. A cyclic (ring) hydrocarbon is designated by the prefix cyclo- which appears directly in front of the base name.

- a. True
- b. False

UNIT 2.2: Organic Reactions Mechanism

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. Different types of organic reactions and their mechanism.

Ask

Ask the students to share:

- Knowledge about Organic Reactions

Say

- Discuss Mechanism of Organic Reactions.

Elaborate

2.2.1 Organic Reactions

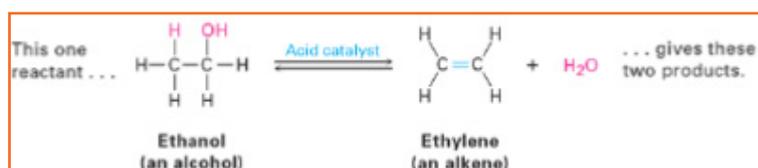
Organic chemistry is the chemistry of carbon compounds. Organic reactions are chemical reactions involving organic compounds. There are 5 basic types of organic reactions

1. Addition Reaction.
2. Elimination reaction.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 32 and explain the learners' the concept.

2.2.1.2 Elimination Reaction

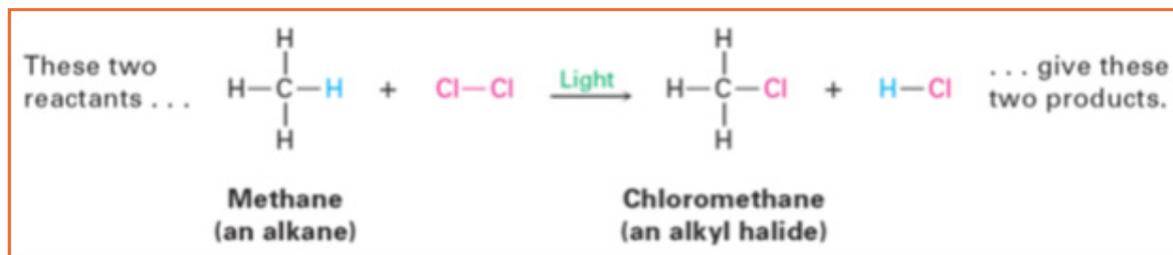
In this reaction type, one molecule splits into two molecules.



Elimination Reaction

2.2.1.3 Substitution Reaction

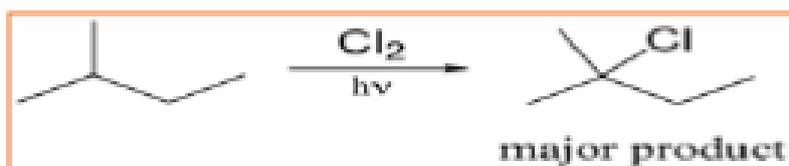
In this reaction type, parts from two molecules exchange some part.



Substitution Reaction

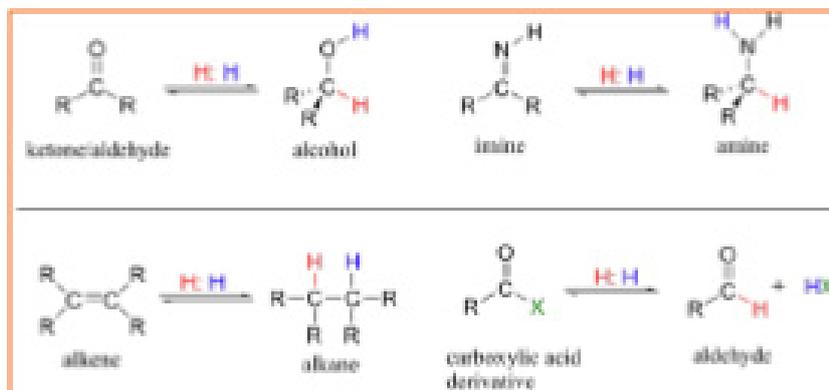
2.2.1.4 Radical Reaction

In this reaction a free radical gets added to the parent compound



2.2.1.5 Oxidation-Reduction Reaction

In one type of redox reaction, a hydrogen molecule (in the form of hydride anion plus a proton) is transferred to or from organic compound: these are called hydrogenation and dehydrogenation reactions.



2.2.2 Mechanism of Organic Reactions

In an organic reaction, we see the transformation that has occurred in defined steps that lead from reactant to product. The mechanism describes the steps behind the changes that we can observe. It provides the details of exactly which bonds break and which bonds form and in what order.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 33-35 and explain the learners' the concept.

Activity

- Select students randomly after the training session and ask them to extempore on the Organic Reactions.

Exercise

1. What is Organic Chemistry?

.....
.....

2. A radical can add to an alkene to give a new radical, causing an addition reaction.
 - a. True
 - b. False
3. The more electronegative atom has the greater electron density.
 - a. True
 - b. False
4. The more electronegative atom has the greater electron density.
 - a. True
 - b. False

UNIT 2.3: Quality Management System

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. The quality management system.
2. The Development of QMS.

Ask

Ask the students to share:

- What do they know about Quality management system

Say

- List and explain principles of QMS as per ISO 9000.

Elaborate

2.3.1 Introduction

According to Janet Woodcock (Director of the Centre for Drug Evaluation and Research of the US Food and Drug Administration) pharmaceutical quality means that a product is free of contamination and reproducibly delivers the therapeutic benefit promised in the label to the customer.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 37 and explain the learners' the concept.

2.3.2 Principles of QMS as per ISO 9000

The ISO 9000 guidelines lay down the following principles for QMS

- **Customer Focus:** understand needs, meet requirements, exceed expectations
- **Leadership:** unity of purpose, organizational direction, empowerment, achieve objectives
- **Involvement of People:** fully involved employees, to benefit the organization
- **Process Approach:** accomplishments by processes, resources must be managed

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 38 and explain the learners' the concept.

Activity 

- Select students randomly after the training session and ask them to extempore on the Quality management system.

Exercise 

1. Name any two systems in place to help Manufacturing Plants execute their production plans and schedules.

.....
.....

2. What is the full form of OEE?

.....
.....

UNIT 2.4: Productivity Concepts

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. The productivity concepts.

Ask

Ask the students to share:

- What do they know about productivity
- What do they know about prime causes of production losses
- What do they know about capturing production data

Say

- Discuss Overall Equipment Effectiveness.

Do

- Explain about Productivity.
- List prime causes of production losses.

Elaborate

2.4.1 Introduction

Production involves conversion of one type of material into another through chemical or mechanical method with a view to reinforce the utility of the product or services. Production is an organized activity. The system transforms the varied inputs into useful outputs. Production system does not operate in isolation from the opposite organizational systems.

“Production management deals with the decisions on production processes to produce goods and services according to specifications in the amounts and at the scheduled demanded and at minimum cost”.

2.4.2 Productivity

Productivity is defined as EFFECTIVE and EFFICIENT use of resources. Productivity means higher output with less resources. Concept of productivity calls for an attitude of continuous improvement. "There is no process which cannot be improved further". There is always scope for improvement even in the best of the processes.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 41 and explain the learners' the concept.

2.4.3 Prime Causes of Production Losses

A production line rarely operates at optimum speed. A myriad of reasons or negative performance impacts largely together, cause losses in productivity and thus loss of cash. These include:

- **Line Saturation:** There's no place for additional output from the machine. As an example, a paper machine runs out of empty tambours.
- **Equipment Failure:** Machines break down, wear out, not used properly so on. All finally ends up in lost production time.
- **Product changes:** Throughout the change over from one product to a different the machine settings should be modified, breakdown might occur and speed should be reduced.
- **Short Stops:** For instance, a bottle falls down during a bottling machine and therefore the operator picks it up. These short however frequent events may be the explanation for major time loss.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 40-42 and explain the learners' the concept.

Activity

- Divide students into two groups.
- Ask each group to create multiple choice question.
- The groups will ask questions to each other.
- Evaluate and explain the concept as per performance.

Exercise 

1. What is productivity defined as?

.....
.....

2. Mention any two factors affecting productivity.

.....
.....

3. Name any two reasons for production losses.

.....
.....

UNIT 2.5: Techniques of Improving Productivity

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. The techniques of productivity improvement.

Ask

Ask the students to share:

- What do they know about Six Sigma?
- What do they know about Lean?

Say

- Explain Quality control and Quality assurance.
- Discuss Quality risk management.

Do

- Discuss tips to reduce defects and improve quality in pharmaceutical manufacturing.

Activity

- Randomly select students and ask them to ask a question to his/her partner regarding techniques of improving productivity.

Elaborate

2.5.1 Six Sigma

Sigma is a term used in statistics to represent standard deviation, an indicator of the degree of variation in a set of measurements or a process or a product.

Six sigma is a statistical concept or a quality management approach that measures a process or a product in terms of defects at the six sigma level and offers a way to focus on developing and delivering perfect products and services.

Objectives

The key objective of the Six Sigma methodology is the implementation of a measurement-based strategy that focuses on process improvement and variation reduction through the application of various Six Sigma methodologies including the key processes like DMAIC and DMADV.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 43-44 and explain the learners' the concept.

2.5.2 Lean

Lean Manufacturing or Agile Manufacturing is an operating strategy that seeks to maximize operational effectiveness. This is achieved by creating value in the eyes of the customer. The focus is not on a department, area or process per-se, but on the optimization of the entire value stream.

Principles of Lean

Lean is a five-step thought process for guiding the implementation of its techniques:

1. Specify value as expected by end customer by product family.
2. The value stream is the set of activities across all parts of the organization involved in jointly delivering the product or service. It is essential to understand the wants of the customer and steps how to deliver (or not).

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 45 and explain the learners' the concept.

2.5.3 Quality Control and Quality Assurance

In the average manufacturing facility, the key units or departments that are of high regulatory concern are Production, Quality Control/Quality Assurance, Ware House and Engineering/Utilities. The mandate of the QA department is to maintain an oversight function over Production, Analytical laboratory, Warehouse, Utilities/ Water supply and the environment (hygiene) to assure that good manufacturing practices, good laboratory practices and good storage practices are in place.

The system of specifications and practice control measures in the industry, also known as standard operating procedures (S.O.P.s), designed by the scientific community and regulatory authorities, and localized by each industrial outfit into their own templates – ensures a good manufacturing practice (GMP) when put to use. The strict enforcement of these codes of GMP guiding the manufacture of medicines, plus the laboratory follow-up of

the manufacturing processes from start to finish, is termed QUALITY CONTROL. So, in broad terms, the elimination of error to the barest minimum through management control practices leads to a QUALITY ASSURANCE or certification of the product as good, safe, and fit for the intended use.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 45-49 and explain the learners' the concept.

Exercise

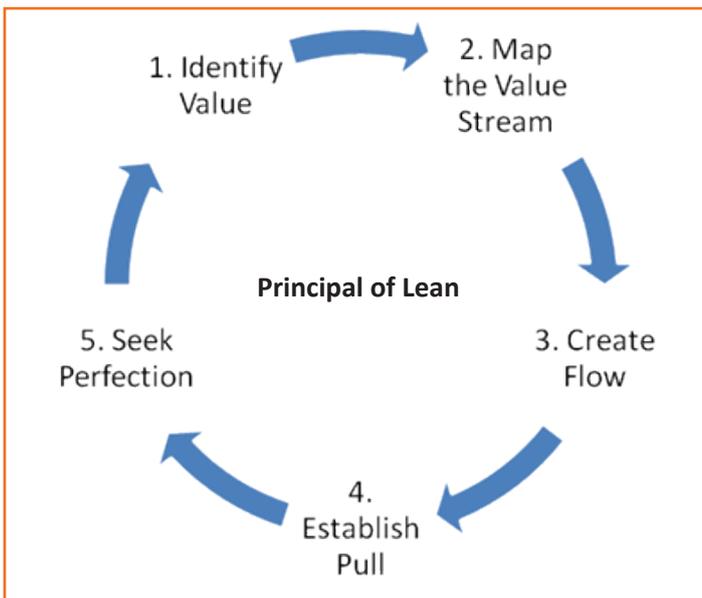
1. Sigma is a term use in statistics to represent standard deviation, an indicator of the degree of variation in a set of measurements or a process or a product.

- True
- False

2. Name any two objectives of the Six Sigma methodology.

.....
.....

3. Identify the principle in this diagram.



UNIT 2.6: Good Manufacturing Practices

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. The gmp practices
2. The commandant of CGMP.

Ask

Ask students to share:

- What do they know about CGMP Enforcement and guidelines.

Say

- Discuss CGMP rules.
- Discuss Data Integrity.

Do

- Explain Audits and self-inspection.
- Explain documentation practices required by CGMP.

Activity

- Select students randomly after the training session and ask them to extempore on the importance of Good manufacturing practices.

Elaborate

2.6.1 Introduction

A Good Manufacturing Practice (GMP) is that practice which helps to upgrade and provide top-most quality product. Several countries have caused out that the pharmaceutical companies should follow GMP Procedures and have commenced own GMP pointers coincide with their legislation. Basic ideas of all of those guidelines stay more or less similar to the ultimate goals of safeguarding the health of the patient moreover as producing good quality drugs, medical devices or active pharmaceutical products. If the drug passes all the specification tests but is found to be manufactured in such a condition that it violates the ongoing manufacturing pointers, that doing is regarded as adulterated. Therefore, it is necessary to oblige with the good manufacturing pointers in aspect in pharmaceutical manufacturing and every pointers follow a couple of basic principles.

- Manufacturing processes are clearly outlined and controlled. All the important processes are valid to make sure consistency and compliance with specifications.
- Manufacturing processes are controlled, and any changes to the method are evaluated. Changes that have a sway on the standard of the drug are valid as necessary.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 51 and explain the learners' the concept.

2.6.2 CGMP Enforcement and Guidelines

GMPs are enforced in the United States by the USFDA, under Section 501(B) of the 1938 Food, Drug, and Cosmetic Act (21USCS§351). The regulations use the phrase "current good manufacturing practices" (cGMP) (21CFR210and211) to describe these guidelines. Courts may theoretically hold that a drug product is adulterated even if there is no specific regulatory requirement that was violated as long as the process was not performed according to industry standards. As of June 2010, a different set of cGMP requirements apply to all manufacturers of dietary supplements.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 52-60 and explain the learners' the concept.

Exercise

1. What are the two kinds of Deviation?

.....

2. What is the full form of CAPA?

.....

3. Name any two steps of Preventive Action.

.....

Key Learning Outcomes

At the end of this module, you will be able to:

1. Gain knowledge of fundamental science in API production.
2. Learn about unit processes like oxidation, reduction, hydrogenation, sulfonation, nitration, and halogenation.
3. Learn about organic chemicals as building blocks for manufacture of drugs and drug intermediates.
4. Discuss role of catalysis and bio-catalysis in industrial production.
5. Gain knowledge of processes like filtration, centrifugation, extraction, evaporation, crystallization, drying and size reduction.
6. Identify the pharmaceutical manufacturing equipment's.
7. Learn the chemical technologies for selected drugs.

UNIT 3.1: Orientation with Machines and Manufacturing Concepts for API Manufacturing

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. The fundamental science in API production.
2. The IUPAC Rules for Naming of Organic Compounds

Ask

Ask the students to share:

- What do they know about API Manufactures
- What do they know about API Outsourcing

Say

- Discuss Size Separation.
- Discuss Size Reduction.

Do

- Explain mixing and homogenization process.
- Explain Mass transfer.
- Discuss Fluid flow.

Team Activity

- Divide the students into two groups.
- Ask both the groups to prepare multiple choice questions from unit 3.1 (minimum 5 questions from each group).
- Each group will then ask the question from the other group members in front of the class.
- Evaluate and give the feedback to students as per their explanations and performance.

Elaborate

3.1.1 Introduction

The chemicals used to manufacture pharmaceutical drugs are known as Active Pharmaceutical Ingredients (APIs) are. The active ingredient (AI) is the substance or substances that are biologically active within the drug and is responsible for the desired effect it has on the individual taking it.

Any drug or medicine is composed of two major components. The first is the API – which is the main ingredient. The second is known as the excipient, which is an inactive substance but serves as the vehicle for the API itself. If the drug is in a syrup form, then the excipient is the liquid that has been used to make it as such.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 63 and explain the learners' the concept.

3.1.2 Leading API Manufacturers

- TAPI (Teva Active Pharmaceutical Ingredients) it works in areas such as chemical synthesis, fermentation, chromatography and plant extraction and now has the industry's largest portfolio of over 300 API products
- Dr. Reddy's is another leading manufacturer with more than 60 APIs for drug use, diagnostic kits and biotechnology products.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 64 and explain the learners' the concept.

3.1.3 API Outsourcing

APIs are commonly considered as 'bulk pharmaceuticals'. These are usually made in places far from where tablets, suspensions and liquids are manufactured. If you look at the geographical distribution, the greatest concentrations of API manufacturers are located around Asia, specifically in India and China. These places get more projects of outsourced API manufacturing as it eliminates the need to invest in highly expensive equipment and infrastructure.

3.1.4 Size Separation

Size separation is a process in which particles of desired size are separated from other fractions.

Objectives of size separation

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 64-86 and explain the learners' the concept.

Exercise

1. APIs are commonly considered as 'bulk pharmaceuticals'.

- a. True
- b. False

2. Mention any two uses of Bag Filter.

.....
.....

3. Name any two factors related to nature of raw materials.

.....
.....

4. What are the three ways Mass transfer can be done?

.....
.....

5. What is a Rotameter?

.....
.....

UNIT 3.2: Perform Chemical Reactions and Manufacturing Operations for API

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. The production process of API.

Ask

Ask the students to share:

- What do they know about Unit process
- What do they know about Bulk organic chemicals

Say

- Discuss Catalysis and Biocatalysis in Industrial Production.

Explain

- Explain Downstream processes.

Do

- Explain Chemical technologies for selected drugs.

Activity

- Select students randomly after the training session and ask them to extempore on the production process of API.

Elaborate

3.2.1 Introduction

A chemical process is a process in which chemicals or chemical compounds are changed in some way. The basic reactions used in the chemical industry are: oxidation, reduction, hydrogenation, sulphonation, nitration, halogenations, dehydration,

The chemical industry is the one responsible of converting raw materials like water, oil, natural gas, air, metals, and minerals, into more valuable products. The United States and European Union have the most important chemical companies. Chemicals is calculated to be a \$3 trillion global enterprise.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 88 and explain the learners' the concept.

3.2.2 Unit Process

Unit processes may be defined as major chemical transformations which are important to the chemical industries e.g. Nitration, halogenation, sulfonation, oxidation, reduction etc.

The study of these processes includes: basic knowledge of reaction along with their equipment's, minimum cost, and minimum time.

3.2.2.1 Nitration

Unit process nitration

- The reaction is always almost exothermic
- The physicochemical principles of equilibrium and chemical kinetics are similar
- Nitration is the process of introduction of one or more nitro groups in a reacting molecule (called substrate), e.g.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 89-92 and explain the learners' the concept.

3.2.2.2 Hydrogenation

Hydrogenation is a chemical reaction between molecular hydrogen (H₂) and another compound or element, usually in the presence of a catalyst. The process is commonly employed to reduce or saturate organic compounds.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 92-95 and explain the learners' the concept.

3.2.2.3 Catalytic Hydrogenation

- Step 1: Hydrogen gets absorbed onto the metal surface.
- Step 2: Alkyne approaches the H atoms absorbed on the metal surface.
- Step 3: $C\equiv C$ reacts with the H atoms on the surface forming the two new C-H σ bonds generating the alkene.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 95-135 and explain the learners' the concept.

Exercise

1. Petrochemicals are also used for producing other organic chemicals and well as specialty chemicals.
 - a. True
 - b. False
2. What are the two processes for Nitration?
.....
.....
3. What is Hydrogenation?
.....
.....
4. Common catalysts used are insoluble metals such as palladium in the form Pd-C, platinum in the form PtO₂, and nickel in the form Ra-Ni.
 - a. True
 - b. False



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Transforming the skill landscape



4. Prepare for and Perform Manufacturing Operations of Formulations

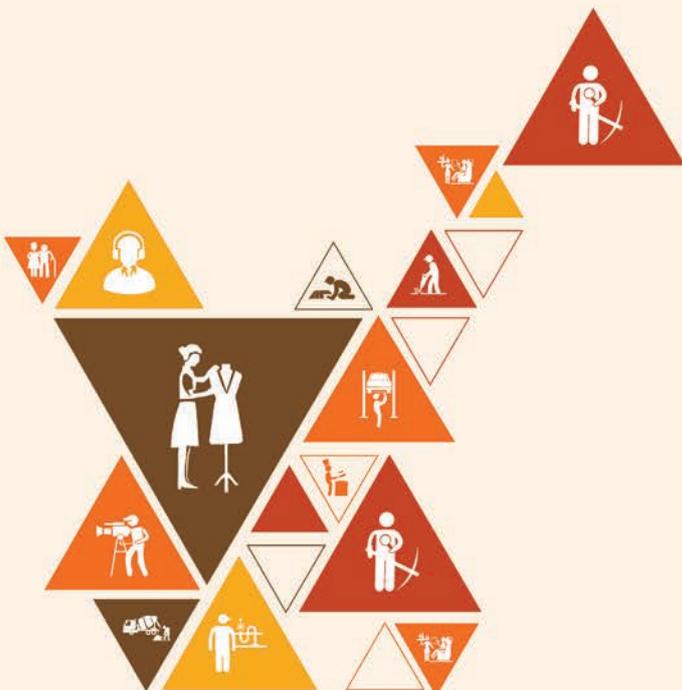
Unit 4.1 - Routes of Drug Administration

Unit 4.2 - Prepare for and Perform Manufacturing Operations of Oral Solid Dosage

Unit 4.3- Prepare for and Perform Manufacturing Operations of Liquid Oral Dosage

Unit 4.4 - Prepare for and Perform Manufacturing Operations of Sterile Dosage

Unit 4.5 - Prepare for and Perform Manufacturing Operations of Dermatological Formulation



LFS/N0213, LFS/N0214

Key Learning Outcomes

At the end of this module, you will be able to:

1. Basics of formulations including route of drug administration.
2. Benefits of various dosage forms.
3. The conceptual and practical skills about production process of Oral Solid Dosage, Liquid Oral Dosage, Sterile Dosage and Dermatological Formulations.

UNIT 4.1: Routes of Drug Administration

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. Routes of drug administration.
2. Different forms of dosage.

Ask

Ask students to share:

- Knowledge about Dosage form

Say

- Discuss Pharmaceutical manufacturing equipment.

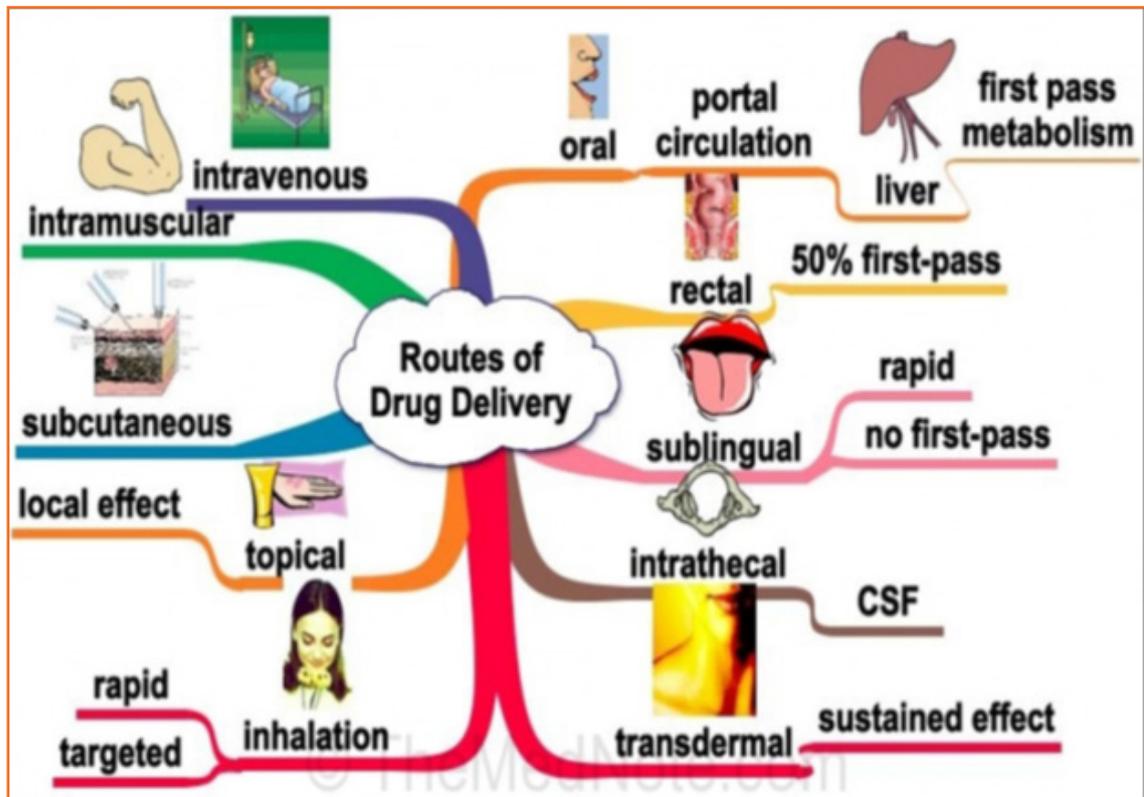
Activity

- Randomly pick students and ask them to summarize different forms of dosage.

Elaborate

4.1.1 Communication

A route of drug administration is the path by which a drug, fluid, poison or other substance is brought in contact with the body.



Routes of drug delivery

4.1.2 Dosage Form

Dosage forms are the means by which drug molecules are delivered to sites of action within the body. The need for dosage forms:

- Accurate dose
- Protection e.g. coated tablets, sealed ampoules
- Protection from gastric juice

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 141 and explain the learners' the concept.

4.1.3.1 Solid Dosage Forms

Unit dosage forms

Tablet: These are solid dosage forms of medicaments which are prepared by moulding or by compression with or without Excipients.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 142-143 and explain the learners' the concept.

4.1.3.2 Liquid Dosage Forms

Oral solution

Oral solutions are clear liquid preparations for oral use containing one or more active ingredients dissolved in a suitable vehicle.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 143-144 and explain the learners' the concept.

4.1.4 Pharmaceutical Manufacturing Equipment

The International regulatory requirements for the pharmaceutical machinery should be as per cGMP, US FDA, MCA standards. Every pharmaceutical company has its own system of procedures for manufacturing and maintenance of its machines, as an effort to meet the latest GMP compliance. The manufacturing facilities in India are being upgraded to the standards of the regulated markets. Today, India has the highest number of FDA approved facilities outside USA. An increasing number of foreign pharmaceutical-machine manufacturers also have recognized India's achievements and evolution in the industry. Indian machines are manufactured and used in accordance with international standards and do not hazard the inspection and approval of their facility. This is one of the many reasons that India has the most FDA-approved facilities in the world.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 144-149 and explain the learners' the concept.

Exercise

1. What is a route of drug administration?

.....

2. Mention any two advantages of oral drug administration.

.....

3. Mention any two needs of dosage forms.

.....

4. Oral solutions are clear liquid preparations for oral use containing one or more active ingredients dissolved in a suitable vehicle.
 - a. True
 - b. False

UNIT 4.2: Prepare for and Perform Manufacturing Operations of Oral Solid Dosage

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. Production Process for Oral Solids Dosage Form.

Ask

Ask the students to share:

- What do they know about Tablets
- What do they know about Granulation

Say

- Discuss Primary unit operation: Drying.
- Discuss Primary unit operation: Milling and Screening.
- Discuss primary unit operation: Blending.
- Explain tablet compression.
- Explain granule properties influencing compression.
- Explain Tablet coating.
- Discuss Coating equipment.

Explain

- Explain composition of coating dispersion.
- List the factors affecting film coating.
- Explain Capsules filling.
- Discuss tablet defects and remedies.
- List types of Capsules.
- Explain capsule filling operation.
- Discuss capsule defects.

Demonstrate

- Select students randomly after the training session and ask them to extempore on the importance of Timely Reporting and Time Management.

Elaborate

4.2.1 Introduction

One of the most popular and convenient method of drug delivery is Oral Solid dosage forms (Tablets and Capsules). Oral solid dosage requires a non-sterile environment for production. The processes, equipment's and technologies for production of tablets and capsules are well defined and known to mankind for many years. As the Oral Solid dosage form is used in high volumes, it is important that the unit operations for their production be thoroughly understood, developed and implemented.

Oral solids dosage form are the most common dosage form because they are:

- Convenient
- Easy to handle
- Have long shelf life
- Flexible

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 150 and explain the learners' the concept.

4.2.2 Tablets

Tablets are defined as solid preparation each containing a single dose of one or more active ingredients and obtained by compressing uniform volume of particles. They are used for local and systemic effect and are usually administered orally.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 150-151 and explain the learners' the concept

4.2.3 Granulation

Blends are made ready for compression either by Granulation or Direct compression. Granulation is the process of collecting particles together by creating bonds between them. Based on the mechanism of bond formation, granulation is classified as:

- Wet granulation: Bonds formed by using a binding agent
- Dry Granulation: Bonds are formed by compression

Steps involved in the wet granulation

1. Mixing of the drug(s) and excipients
2. Preparation of binder solution

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 152-159 and explain the learners' the concept.

4.2.4 Primary Unit Operation: Drying

It is another primary unit operation and is performed following the wet granulation process in order to reduce moisture levels.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 159-161 and explain the learners' the concept.

4.2.5 Primary Unit Operation: Milling and Screening

This is another primary unit operation which usually follows drying and is mainly performed to remove lumps and size the granules as per the target particle size requirement.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 161-162 and explain the learners' the concept.

4.2.6 Primary Unit Operation: Blending

Blending is the most critical operation in the manufacturing process since perfect homogeneity is practically impossible due to differences in size, shape and density of particles.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 163-178 and explain the learners' the concept.

Exercise

1. Mention any two reasons why oral solids dosage form are the most common dosage form.

.....

2. What are the three basic unit operations in tablets manufacturing?

.....

3. Based on the mechanism of bond formation, what is granulation classified as?

.....
.....

4. Coarse screening of wet mass using a suitable sieve - is a step of wet granulation.

- a. True
- b. False

UNIT 4.3: Prepare for and Perform Manufacturing Operations of Liquid Oral Dosage

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. The liquid orals dosage form.
2. Types of oral liquids.

Ask

Ask the students to share:

- What do they know about types of oral liquids
- What do they know about types of monophasic liquid dosage forms

Say

- Discuss manufacturing considerations.
- Discuss operation, cleaning and maintenance of filter press.
- Discuss mixing process.
- Discuss biphasic dosage forms: suspensions.
- Discuss types of suspension.
- Discuss preparation of suspensions.
- Discuss biphasic dosage forms: Emulsions.
- List types of Emulsions.
- List uses of Emulsions.

Explain

- Discuss Emulsifying agents.
- Discuss preservation of emulsions.
- Explain chemical parameters for formation of emulsion.
- Discuss HLB method for selection of Emulsifying agents.

Do 

- Discuss machineries required for preparation of Emulsions.
- Discuss parameters for assessing the emulsion stability.
- Explain Gels.

Activity 

- Select students randomly and ask them to list types oral dosages.

Elaborate **4.3.1 Introduction**

A solution is known as a liquid-preparation that contains one or more soluble chemical substances dissolved in a specified solvent.

4.3.2 Types of Oral Liquids

Liquid dosage forms are mainly divided into solution: Mono phasic and Biphasic dosage forms which are:

1. Syrups (Monophasic)
2. Suspensions (Biphasic)
3. Emulsions (Biphasic)

4.3.3 Types of Monophasic Liquid Dosage Forms

Monophasic dosage forms are the liquid dosage preparations in which there is only one phase and is represented by a true solution.

A true solution is one which is a clear homogenous mixture that is prepared by dissolving a solid, liquid or gas (solute) in a suitable solvent.

Advantages of Monophasic dosage form

- They are easier to swallow therefore easier for:
 - » It can be given to children, old age, and unconscious people.
 - » Fast absorption of the drug.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 180-181 and explain the learners' the concept.

4.3.4 Manufacturing Considerations

Raw Materials

The raw materials should be tested according to some specifications regarding identity, purity, uniformity and freedom from excessive microbial contamination.

Additional processing done if necessary

For e.g: size-reduction or sterilization before manufacturing process.

In oral liquid preparations, water is the main vehicle. So, it should meet the requirements for Purified water.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 182 and explain the learners' the concept.

4.3.5 Operation, Cleaning and Maintenance of Filter Press

Process flow: First addition of Raw materials into vessel: (Active+ excipients as per the formula of specific dosage and company).

Mixing of Materials: It is done in jacketed vessel with variable speed mixer which helps in controlling the speed.

Filtration: It is done by Filter Press or Cartridge Filter.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 182-184 and explain the learners' the concept.

4.3.6 Mixing Processes

- Mixing and storage tanks [Jacketed kettle / SS tank (steam, gas or electrically heated)]
- Mixer
- Colloid mill / homogenizers
- Filter press or suitable filtration equipment.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 184-186 and explain the learners' the concept.

4.3.7 Biphasic Dosage Forms: Suspensions

A Pharmaceutical suspension is outlined as coarse dispersion within which internal phase (therapeutically active ingredient) is distributed uniformly throughout the external phase. The internal phase consists of insoluble solid particles having a variety of size (0.5 to 5 microns) that is maintained uniformly throughout the suspending vehicle with aid of single or combination of suspending agent. The external phase (suspending medium) is mostly liquid in some instance, could also be an organic or oily liquid for non-oral use. The explanations for the formulation of a pharmaceutical suspension

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 187-206 and explain the learners' the concept.

Exercise 

1. What is Monophasic dosage?

.....
.....

2. Mention any two advantages of Monophasic dosage?

.....
.....

3. Mention any one type of suspension

.....
.....

4. Auxiliary (Secondary) emulsifying agents include those compounds that are normally incapable themselves of forming stable emulsion.

- a. True
- b. False

5. What is the full form of HLB?

.....
.....

UNIT 4.4: Prepare for and Perform Manufacturing Operations of Sterile Dosage

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. Overview of manufacturing of Parentrals
2. Production process of sterile dosage

Ask

Ask students to share:

- What do they know about Manufacturing of parentrals
- What do they know about terminal sterilization

Say

- Discuss Aseptic processing.
- Discuss Water for Injection (WFI).
- Discuss Gowning Procedures.
- Discuss Good Aseptic Technique.
- Discuss HVAC Design and Construction.
- Discuss basic Microbiology and Environmental Monitoring.
- Preparation and Filtration of Solutions.

Explain

- Explain Filter Integrity
- Explain Filter Integrity Testing
- Discuss Equipment/Container Preparation and Sterilization
- Explain Operation and Cleaning of Autoclave
- Explain CIP and SIP Process

- Discuss Component Preparation
- Explain Operation and Maintenance of Isolators
- Discuss filling of Ampoules, Vials, Prefilled Syringes, Bags Facility Design and HEPA System

Do

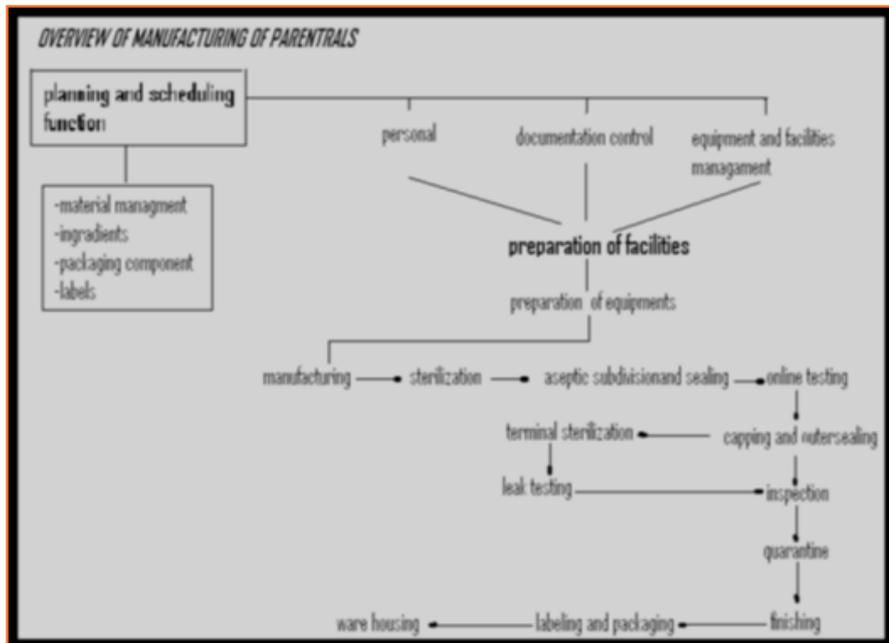
- Explain Environmental Monitoring.
- Explain SMED Concept.
- Discuss Good Documentation Practices.

Activity

- Select students randomly and ask them to explain the production process of sterile dosage.

Elaborate

4.4.1 Overview of Manufacturing of Parental's



Manufacturing of Parentrals

A Parentral dosage form is said to be sterile when it is free from:

- Free from microorganisms
- Any spores
- All types of pyrogens and pathogens

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 207-208 and explain the learners' the concept.

4.4.2 Terminal Sterilization

The terminal sterilization process usually involves filling and sealing product containers under high quality environmental conditions designed to minimize microbial and particulate contamination of the product. This minimization of upstream bioburden reduces the challenge to the subsequent sterilization process. In most cases, the product, container, and closure have low bioburden, but are not sterile at the time of filling. The product is then subjected to a sterilization process in its final container. There are various methods of terminal sterilization including: 1. Moist Heat Sterilization 2. Irradiation 3. Ethylene Oxide (typically for assembled components/kits) Types of sterilization cycles include:

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 208 and explain the learners' the concept.

4.4.3 Aseptic Processing

This processing presents a higher risk of microbial contamination of the product than terminal sterilization. In an aseptic filling process, the drug product, containers and closures are sterilized separately and then brought together under an extremely high quality environmental condition designed to reduce the possibility of a non-sterile unit. Aseptic processing involves more variables than terminal sterilization. Any manual or mechanical manipulation of the sterilized drug, containers, or closures prior to or during aseptic filling and assembly poses the risk of microbial contamination.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 208-209 and explain the learners' the concept.

4.4.4 Water for Injection (WFI)

Water for Injection is used as an excipient in the production of parenteral and other preparations where product endotoxin content must be controlled. It is also used during final cleaning of equipment and product-contact components.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 209-210 and explain the learners' the concept.

4.4.5 Gowning Procedures

Aseptic area is well designed to fulfill the global requirements of full sterilization.

- The area contains the main hall for compounding and dispensing the medicines, and other logistic rooms.
- All halls and rooms have one entrance, and one exist.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 210-233 and explain the learners' the concept.

Exercise

1. Mention any two different dosage forms that require to be sterile.

.....

2. Mention any one sterilization cycle.

- a. True
- b. False

3. What is the full form of WFI?

.....

4. HVAC is the technology of indoor and vehicular environmental comfort.

- a. True
- b. False

5. Mention any two physical parameters to monitor environmental.

.....

UNIT 4.5: Prepare for and Perform Manufacturing Operations of Dermatological Formulation

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. The production process of dermatological formulations
2. The classification and types of dermatological products.

Ask

Ask students to share:

- Their knowledge about classification and types of dermatological products

Say

- Discuss types of Ointment bases.
- Discuss dermatological product formulations.

Explain

- Explain common manufacturing and filling defects and trouble-shooting
- Discuss equipment and production control

Do

- Explain Critical Process Parameters (CPPs) and Critical Quality Attributes (CQAs).

Elaborate

4.5.1 Introduction

Semisolid dosage forms (Dermatological): products of semisolid consistency which are applied to skin or mucous membranes for therapeutic or protective action or cosmetic function.

4.5.2 Classification and Types of Dermatological Products

These preparations include ointments, pastes, cream, emulsions, gels and rigid foams:

Ointments are soft solid preparations meant for external application to the skin, rectum or mucous membrane. The bottom is typically anhydrous and incompatible with skin secretions. They typically contain medicament, that is either dissolved or suspended within the base. They need emollient and protecting action. Ointments could also be used as emollients or to use suspended or dissolved medicaments to the skin.

Creams are solid emulsions for external application and are usually of softer consistency and lighter than ointments. They are less greasy and are easily done.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 235-237 and explain the learners' the concept.

4.5.3 Types of Ointment Bases

Types of ointment bases are:

1. Oleaginous bases
2. Absorption bases
3. Emulsion bases.
4. Water-soluble (hydrophilic) bases.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 237-247 and explain the learners' the concept.

Exercise

1. Ointments are soft semisolid preparations meant for external application to the skin, rectum or mucous membrane.
 - a. True
 - b. False
2. Mention any two ideal properties of semi-solid dosage

.....

3. Mention any two characteristics of an ideal ointment

.....
.....

4. Mention any two types of Ointment bases

.....
.....

Key Learning Outcomes

At the end of this module, you will be able to:

1. Understand different Material, chemicals and equipment and their cleaning procedure.
2. Learn about Electronic and Optical Sensors in laboratory equipment and their operations.
3. Gain knowledge about methodology for storage area inspection with methods and materials required for cleaning variety of surfaces and equipment, disposal methods for waste, used/ unused solutions and relevant SOP, Procedures for reporting and escalating any unidentified soiling
4. Utilize Core Skills and Professional Skills.

UNIT 5.1: Deviations and Incidents

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. Understand the deviations and incidents.

Ask

Ask the students to share:

- Their knowledge about deviation handling

Say

- Discuss quality risk management and deviation.

Activity

- Select students randomly and ask them summarize the complete 5.1 unit.

Elaborate

5.1.1 Introduction

The aim of this section is to contribute to the understanding of a quality risk management approach in the handling of deviations from a practical perspective as per WHO expectations on the matter.

Among the essential elements of a well-established Quality Management System (QMS), deviation handling plays a key role in assuring quality in products and by contributing to continuous improvement. Manufacturers are expected to “establish processes and define appropriate controls for measurement and analysis to identify nonconformities and potential non-conformities; defining when and how corrections, corrective actions, or preventive actions should be undertaken. These actions should be commensurate with the significance or risk of the nonconformity or potential nonconformity”

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 251 and explain the learners’ the concept.

5.1.2 Deviation Handing

Quality Risk Management was mainly designed to be used prospectively when manufacturing operations are defined and validated. Therefore, potential deviations are identified and avoided by implementing risk control measures and preventive actions. QRM is based on the identification of product attributes and operational parameters which are critical to manufacturing operations in order to identify in advance their associated risks. A sequence of steps are be identified when handling events and possible deviations:

Trainers note: *These are the supporting content to the participant manual, please adhere to the participant manual, page no. 251 and explain the learners' the concept.*

5.1.2.1 Event Detection

As a basic requirement, Machine Operators are expected to be alert and aware of possible undesirable events and clearly know what to do in terms of documenting and communicating them. Normally Machine operators are provided with a decision tree to initially screen events based on their risk and impact on the product in order to categorize, record, and investigate them as needed.

5.1.2.2 Deviation Categorization

The decision tree described in Fig 5.1.1 is a simplified risk assessment that answers the following questions when an event is encountered:

- Can the event affect a product attribute, manufacturing operational parameter or the product's quality?
- Does the event contradict or omit a requirement or instruction contemplated in any kind of approved written procedure or specification?

Trainers note: *These are the supporting content to the participant manual, please adhere to the participant manual, page no. 252-259 and explain the learners' the concept.*

Exercise

1. What are the two kinds of Deviation?

.....

2. What is the full form of CAPA?

.....

3. Name any two steps of Preventive Action

.....

UNIT 5.2: Quality Checks in Pharma/Bio Pharma Manufacturing Operations

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. Quality checks in pharma and biopharma manufacturing operations.
2. IUPAC nomenclature of organic chemistry.

Ask

Ask the students to share:

- What do they know about Quality Control
- What do they know about Location of In Process Control

Say

- Discuss Sampling.
- Discuss Testing.

Explain

- Explain Post Manufacturing Checks.

Elaborate

5.2.1 In-Process Quality Check

In-process controls (IPC) are checks, which are carried out before the manufacturing process is completed. The function of in-process controls is monitoring and – if necessary – adaptation of the manufacturing process in order to comply with the specifications. This may include control of equipment and environment, too. In-process materials should be tested for identity, strength, quality and purity as appropriate and approved or rejected by the Quality Control unit during the production process. Rejected in-process materials should be identified and controlled under a quarantine system designed to prevent their use in manufacturing.

Written procedures are to be established and to be followed that describe the In-process controls and tests as specified:

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 260 and explain the learners' the concept.

5.2.2 Quality Control

Quality Control function is performed by documenting production parameters. In a broader sense, this includes the following in-process controls:

- measured values obtained from process equipment, e.g. temperatures
- measured values obtained by persons, e.g. times
- product attributes, e.g. weight, hardness, friability
- measured values obtained from the room environment, e.g. particle counts

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 260-263 and explain the learners' the concept.

5.2.3 Location of In Process Control

As per GMP guidelines, In-process controls may be carried out within the production area provided they do not carry any risk for the production. This means that particular care must be taken when carrying out sampling or testing. Examples of possible influences of in-process control methods on production are shown below:

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 264-267 and explain the learners' the concept.

Exercise

1. Define Pharmacology

.....

2. Define Pharmacognosy

.....

3. What is the full form of IUPAC

.....

4. Mention any two properties of an acid

.....

5. Stoichiometry is the calculation of relative quantities of reactants and products in chemical reactions.

.....



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6. Carry out Reporting and Documentation

Unit 6.1 - Documentation and Reporting for Machine Operator

Unit 6.2 - Introduction to Computer

Unit 6.3 - Basic Computer Knowledge

Unit 6.4 - Components of Computer

Unit 6.5 - Concept of Operating System

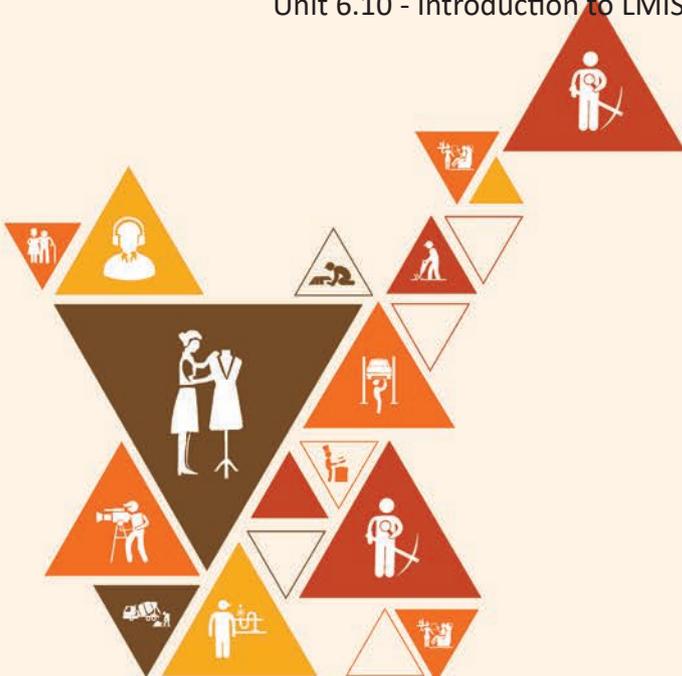
Unit 6.6 - MS Word

Unit 6.7 - MS Power Point

Unit 6.8 - MS Excel

Unit 6.9 - Internet Concepts

Unit 6.10 - Introduction to LMIS



LFS/N0102

Key Learning Outcomes

At the end of this module, you will be able to:

1. Different Material, chemicals and equipment and their cleaning procedure.
2. Electronic and Optical Sensors in laboratory equipment and their operations.
3. Methodology for storage area inspection with methods and materials required for cleaning variety of surfaces and equipment, disposal methods for waste, used/ unused solutions and relevant SOP, Procedures for reporting and escalating any unidentified soiling
4. How to utilize Core Skills and Professional Skills.

UNIT 6.1: Documentation and Reporting for Machine Operator

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. Good Documentation Practices
2. The documentation and reporting required for machine operator

Ask

Ask the students to share:

- What do they know about Good documentation practices
- What do they know about Attributable

Say

- Discuss Legible, traceable and permanent.
- Discuss Contemporaneous.

Explain

- Explain Original
- Explain Accurate
- Discuss Documentation for Machine Operator

Do

- Discuss Labelling for Life Sciences products.
- Explain how to maintain record in appropriate manner.
- Discuss how to follow the validation process of document.

Elaborate

6.1.1 Introduction

Good Documentation Practices (GDocP) are critical elements of the pharmaceutical quality system and a systematic approach are implemented to provide a high level of assurance that throughout the product life cycle, all GMP/GLP records and data are complete and reliable. To achieve robust decisions, the supporting data set are made to be reliable and complete. Hence GDocP are followed in order to ensure all records, both paper and electronic, allow the full reconstruction and traceability of GMP/GLP activities.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 271 and explain the learners' the concept.

6.1.1.1 Good Documentation Practices

The basic building blocks of good GXP data are to follow GDocP and then to manage risks to the accuracy, completeness, consistency and reliability of the data throughout their entire period of usefulness – that is, throughout the data life cycle.

Personnel should follow GDocP for both paper records and electronic records in order to assure data integrity. These principles require that documentation has the characteristics of being attributable, legible, contemporaneously recorded, original and accurate (sometimes referred to as ALCOA). These essential characteristics apply equally for both paper and electronic records.

6.1.1.2 Attributable

Attributable means information is captured in the record so that it is uniquely identified as executed by the originator of the data (e.g. a person or a computer system).

Attributable	
Expectations for paper records	Expectations for electronic records
Attribution of actions in paper records should occur, as appropriate, through the use of: <ul style="list-style-type: none"> • initials; • full handwritten signature; • personal seal; • date and, when necessary, time. 	Attribution of actions in electronic records should occur, as appropriate, through the use of: <ul style="list-style-type: none"> • unique user logons that link the user to actions that create, modify or delete data; • unique electronic signatures (can be either biometric or non-biometric); • an audit trail that should capture user identification (ID) and date and time stamps; • signatures, which must be securely and permanently linked to the record being signed.

Expectation for "Attributable" element of GDocP

6.1.1.3 Legible, traceable and permanent

The terms legible and traceable and permanent refer to the requirements that data are readable, understandable, and allow a clear picture of the sequencing of steps or events in the record so that all GXP activities conducted can be fully reconstructed by the people reviewing these records at any point during the records retention period set by the applicable GXP.

Trainers note: *These are the supporting content to the participant manual, please adhere to the participant manual, page no. 272-273 and explain the learners' the concept.*

6.1.1.4 Contemporaneous

Contemporaneous data are data recorded at the time they are generated or observed.

Trainers note: *These are the supporting content to the participant manual, please adhere to the participant manual, page no. 273-274 and explain the learners' the concept.*

6.1.1.5 Original

Original data include the first or source capture of data or information and all subsequent data required to fully reconstruct the conduct of the GXP activity. The GXP requirements for original data include the following:

Trainers note: *These are the supporting content to the participant manual, please adhere to the participant manual, page no. 274-276 and explain the learners' the concept.*

6.1.1.6 Accurate

The term "accurate" means data are correct, truthful, complete, valid and reliable.

Trainers note: *These are the supporting content to the participant manual, please adhere to the participant manual, page no. 276-290 and explain the learners' the concept.*

Exercise

1. ALCOA stands for
 - a. attributable, legible, contemporaneously recorded, original and accurate
 - b. actionable, left indented, contemporaneously recorded, original and accurate
 - c. attributable, legible, crisp, original and accurate
 - d. actionable, left indented, crisp, open and absolute
2. BMR stands for
 - a. Batch Manufacturing Report
 - b. Basic Manufacturing Requirement
 - c. Batch Manufacturing Record
 - d. Bare Minimum Record
3. In case of any mistake or wrong entry it can be corrected by
 - a. Using eraser/ white ink
 - b. A single cross line striking through the wrong entry with name, signature, date and time
 - c. Multiple cross lines on wrong entry so that none can see what the wrong entry was
 - d. A single cross line striking through the wrong entry

UNIT 6.2: Introduction to Computer

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. Know what computer is.
2. Recognise its various parts.
3. Understand the advantages of computer

Resources to be Used

- Participant Manual
- Computer Lab

Do

- Greet and welcome the participants to the next session of the program.
- Before starting the session ask them do they have any doubts pertaining to the previous unit.
- Acknowledge their responses and clear their doubts if any.
- Tell them they will learn about introduction to computer in this unit.

Say

- Tell participants about the computer. Computer plays a very important role in our personal and professional lives. It has become an integral part of our lives.
- Tell them about important characteristics and application of a computer.

Notes for Facilitation

- Summaries the main points of the unit.
- Ask participants if they have any doubts. Encourage them to ask questions.
- Answer their queries satisfactorily.
- Ask them to answer the questions at the end of unit given in the participant's manual.
- Ensure that every participant answer all questions.

Activity

- Tell participants to demonstrate the parts of computer.
- Give them 15 minutes to prepare.
- Tell them each participant will be given 10 minute to demonstrate the same.
- Once presentations are complete appreciate the efforts made by the group and summarize the highlights of the activity.

Skill Practice	Time	Resources
1. Demonstration of Computer Computer Lab	4 Hours	<ul style="list-style-type: none"> • Participant Manual • Computer Lab

Elaborate

6.2.1 What are Computers

Computer is the greatest technology of all times. An innovative electronic device that takes raw data as input from the user and processes these data under the control of set of instructions which is called program, to give the result the output. The first fully electronic computers, announced in the 1940s, were huge machines. The computer of today's time is thousands of times faster and in any size you want. They can fit on your desk, on your lap, or even in your pocket. Computers work through an interface of hardware and software.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 181 and explain the learners' the concept.

Exercise

1. When was the first fully electronic computer introduced?
 - a. 1930s
 - b. 1940s
 - c. 1950s
 - d. None of these
2. Give 3 examples of the hardware components of computers?

.....

3. What is an Operating System (OS)?

.....

4. Mention 3 advantages of computers

.....

UNIT 6.3: Basic Computer Knowledge

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. Know what is a computer.
2. Understand the web, e-mail and media.

Resources to be Used

- Participant Manual
- Computer Lab

Do

- Greet and welcome the participants to the next session of the program.
- Before starting the session ask them do they have any doubts pertaining to the previous unit.
- Acknowledge their responses and clear their doubts if any.
- Tell them they will learn about the introduction to a computer in this unit.

Say

Tell participants about the application of the computer in daily life. In the workplace, many people use computers to keep records, analyze data, do research, and manage projects. At home, you can use computers to find information, store pictures and music, track finances, play games, and communicate with others— and those are just a few of the possibilities. Tell them about important characteristics and application of a computer.

Now explain the concept of the web. The World Wide Web is an enormous warehouse of information. The web is the most prevalent part of the Internet, partly because it exhibits most information in a visually pleasing format.

Tell them about the application part of the web and introduce them to the use of different applications as email, instant messaging, picture music and movies with them.

Notes for Facilitation

- Summarise the main points of the unit.
- Ask participants if they have any doubts. Encourage them to ask questions.
- Answer their queries satisfactorily.
- Ask them to answer the questions at the end of unit given in the participant's manual.
- Ensure that every participant answer all questions.

Suggestive questions to ask students:

- Ask students to explain the concept of Web

Activity

- Tell participants to prepare an online report using web.
- Tell them they can choose any topic of their interest. Give them one hour to prepare.
- Tell them each participant will be given 10 minute to present their report to the class.
- Once presentations are complete appreciate the efforts made by the group and summarise the highlights of the activity.

Skill Practice	Time	Resources
1. Prepare Online report	4 Hours	<ul style="list-style-type: none"> • Participant Manual • Computer Lab with internet

Elaborate

6.3.1 The Web

The World Wide Web is an enormous warehouse of information. The web is the most prevalent part of the Internet, partly because it exhibits most information in a visually pleasing format. Headlines, text, and images can be combined on a single webpage—along with sounds and animation. A website is a collection of interconnected webpages. The web contains millions of websites and billions of webpages.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 183-184 and explain the learners' the concept.

Exercise 

1. Give 3 examples of how you can use computers?

.....
.....

2. All participants have to be on-line and in front of the computers for instant messaging to work?

- a. True
- b. False

UNIT 6.4: Components of Computer

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. Know what is pre housekeeping activities
2. Know the reasons for doing cleaning
3. Understand the principles of cleaning
4. Clean material, cleaning equipment and its maintenance

Resources to be Used

- Participant Manual
- Personal Protective Equipment (PPE)

Do

- Greet and welcome the participants to the next session of the program.
- Before starting the session ask them do they have any doubts pertaining to the previous unit.
- Acknowledge their responses and clear their doubts if any.
- Tell them they will learn about the components of the computer in this unit.

Say

- Tell them about different parts of the computer.
- Explain-them about different parts of motherboard in detail.

Notes for Facilitation

- Summarise the main points of the unit.
- Ask participants if they have any doubts. Encourage them to ask questions.
- Answer their queries satisfactorily.
- Ask them to answer the questions at the end of unit given in the participant's manual.
- Ensure that every participant answer all questions.

Suggestive questions to ask students:

- Ask students to explain the concept of Web.

Activity

- Tell participants to prepare an online report using web.
- Tell them they can choose any topic of their interest. Give them one hour to prepare.
- Tell them each participant will be given 10 minute to present their report to the class.
- Once presentations are complete appreciate the efforts made by the group and summarise the highlights of the activity.

Skill Practice	Time	Resources
1. Prepare Online report	4 Hours	<ul style="list-style-type: none"> • Participant Manual • Computer Lab with internet

Elaborate

6.4.1 Motherboard

The motherboard is the main element inside the case. It is a large rectangular board with combined circuitry this connects the several parts of the computer as the CPU, RAM, Disk drives (CD, DVD, Hard disk or any others) as well as any other peripherals linked via the ports or the expansion slots. Components directly attached to the motherboard include the following.

The central processing unit (CPU)

The central processing unit (CPU) performs most of the calculations that allow a computer to function and is sometimes referred to as the "brain" of the computer. It is usually cooled by a heat sink and fan.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 186 and explain the learners' the concept.

Exercise 

1. What is the full form of CPU?

.....
.....

2. What does the Chip Set do?

.....
.....

3. What is the full form of BIOS?

.....
.....

Unit 6.5: Concept of Operating System

Unit Objectives

At the end of this unit, you will be able to make the learners understand:

1. Understand the concept and good knowledge of the operating system.

Resources to be Used

- Participant Manual
- Computer System

Do

- Greet and welcome the participants to the next session of the program.
- Before starting the session ask them do they have any doubts pertaining to the previous unit.
- Acknowledge their responses and clear their doubts if any.
- Tell them they will learn about the introduction to a computer in this unit.

Say

- Tell them about windows XP. And explain that Windows XP lets you use different types of applications or software on the operating system.
- Familiarize them with the different versions of Windows.

Demonstrate

- Explain tools and parts of an operating system with the participants.
- Show them all these parts practically on the computer system.
- Then explain add or delete the desktop shortcut from the desktop.
- Also, explain how to create a new folder.
- Tell all participants to create a folder on the computer.
- Then explain how to work on multiple windows.
- Now demonstrate the keyboard to the participants and tell them the correct way to use the keyboard.

Notes for Facilitation

- Summarize the main points of the unit.
- Ask participants if they have any doubts. Encourage them to ask questions.
- Answer their queries satisfactorily.
- Ask them to answer the questions at the end of unit given in the participant's manual.
- Ensure that every participant answers all questions.

Suggestive questions to ask students:

- Ask students to define CPU.
- Ask students to explain tools & parts of an Operating system.

Activity

- Give one newspaper cutting to each student and tell them they need to type the same.
- Tell them they have to use correct fingers on keyboard and make sure work is free from errors.
- Give them one hour for typing practice and ensure that each participant is typing.
- Finally, share some tips for correct typing and summarise the highlights of the activity.

Skill Practice	Time	Resources
1. Typing Practice	2 Hours	<ul style="list-style-type: none"> • News paper • Computer Systems

Elaborate

6.5.1 Windows XP

Windows XP is a personal computer operating system created by Microsoft as part of the Windows NT family of operating systems. Basically it lets you use different types of applications or software on the operating system. For example; it allows you to use a word processing application to write a letter and a spread-sheet application to track your financial information. Windows XP is a graphical user interface (GUI).

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 188-195 and explain the learners' the concept.

Exercise 

1. Where is the taskbar located on your screen?

.....
.....

2. System Tray is an area where you can access programs that are running in the background?

- a. True
- b. False

3. To view sound settings, right click on the sound icon in task bar and left click on open volume control or double click on the sound icon.

- a. True
- b. False

Unit 6.6: MS Word

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. Learn the concept and practice MS-Word.

Resources to be Used

- Participant Manual
- Computer System with MS Word

Do

- Greet and welcome the participants to the next session of the program.
- Before starting the session ask them do they have any doubts pertaining to the previous unit.
- Acknowledge their responses and clear their doubts if any.
- Tell them they will learn about the introduction to a computer in this unit.

Say

- Most people who use a computer daily use word processing skills. word processing skills enable us to prepare text documents like letters, memos, and different correspondence.

Demonstrate

- Tell them to open MS Word in their respective systems.
- Show them how to create a word document in MS word software.
- Practically demonstrate how to perform different operations on MS Word document as:
 - » Saving a Document
 - » Change Font Type and Size
 - » Create Headers and Footers by Inserting Texts
 - » Indents and Spacing

- » Modifying Margins
- » Lists
- » Bulleted and Numbered Lists
- » Formatting Lists
- » Spelling and Grammar
- » Word Count
- » Different Editing Modes in Word
- » Inserting an Image and Table

Notes for Facilitation

- Summarize the main points of the unit.
- Ask participants if they have any doubts. Encourage them to ask questions.
- Answer their queries satisfactorily.
- Ask them to answer the questions at the end of unit given in the participant's manual.
- Ensure that every participant answers all questions.

Trainers Note: As per student give the practical question of your choice to understand the student's outcome.

Activity

- Give one news paper cutting to each student and tell them they need to type this in MS Word and perform different operations like saving documents, Saving a Document, Change Font Type and Size, Create Headers and Footers by Inserting Texts, Indents and Spacing
- Tell them they have to use correct fingers on key board and make sure work is free from errors.
- Give them one hour for typing practice and ensure that each participant is typing.
- Finally, share some tips for correct typing and summarize the highlights of the activity

Skill Practice	Time	Resources
1. Typing and Formatting – MS Word	3 Hours	<ul style="list-style-type: none"> • News paper • Computer Systems

Elaborate

6.6.2 Creating a Word Document

Once the document that has opened, type a short paragraph of why you are taking this mini-session. For example, are you new to Microsoft Word 2007 or are you up your software your skills? Keep in mind to purposely misspell some words. Later in the session you'll use this paragraph to learn the way to spell check and use basic Word 2007 functions.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 197-205 and explain the learners' the concept.

Exercise

1. What are things that MS word helps us with?

.....

2. Give any two features to proof read a document?

.....

3. You can insert a page break anywhere in the document, or you can specify where Microsoft Word positions automatic page breaks.

- a. True
- b. False

Unit 6.7: MS PowerPoint

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. Practice and understand MS-PowerPoint.

Resources to be Used

- Participant Manual
- Computer System with MS Office

Do

- Greet and welcome the participants to the next session of the program.
- Before starting the session ask them do they have any doubts pertaining to the previous unit.
- Acknowledge their responses and clear their doubts if any.
- Tell them they will learn about introduction to computer in this unit.

Say

Tell them about the power point. PowerPoint is the presentation graphics software in the Microsoft Office suite. PowerPoint has predefined layouts, themes, and templates to create dynamic and professional presentations.

Demonstrate

- Tell them to open MS power-point in their respective systems.
- Show them how to create a power point in MS Power-point software.
- Practically demonstrate how to perform different operations on MS Power-point presentation as:
 - » Saving a PowerPoint
 - » Working with slides
 - » View tabs
 - » Animating text and Images

- » Removing Animations
- » Working with Charts

Notes for Facilitation

- Ask participants if they have any doubts. Encourage them to ask questions.
- Answer their queries satisfactorily.
- Ask them to answer the questions at the end of unit given in the participant's manual.
- Ensure that every participant answer all questions.

Suggestive Note: As per student give practical question of your choice to understand the student's outcome.

Activity

- Tell participants they have to prepare a power-point presentation on MS PowerPoint Software.
- Tell them they need to perform following operations while working on this software, saving a PowerPoint, View tabs, animating text and Images and inserting Charts.
- Give them one and half hour to prepare the same.
- Finally share some tips for correct typing and summaries the highlights of the activity.

Skill Practice	Time	Resources
1. Presentation on MS PowerPoint	4 Hours	<ul style="list-style-type: none"> • Participant Manual • Computer Lab

Elaborate

6.7.2 Opening PowerPoint

To open PowerPoint in Windows, click on the:

Step 1: Start button --> Programs --> Microsoft PowerPoint. OR

Step 2: Double-click on the PowerPoint icon on the desktop.

When PowerPoint is opened, by default a blank Title slide appears as the first slide in your new presentation. However, to change the layout of an open slide, click on the Layout button in the Home tab.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 207-214 and explain the learners' the concept.

Exercise 

1. What does the office button in Power Point contain?

.....
.....

2. What is the Notes Panel?

- a. It's a new slide
- b. It's where you can enter notes on the slide

3. What are the three kinds of 'view buttons'?

- a. True
- b. False

UNIT 6.8: MS Excel

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. Practice MS-Excel.

Resources to be Used

- Participant Manual
- Computer System

Do

- Greet and welcome the participants to the next session of the program.
- Before starting the session ask them do they have any doubts pertaining to the previous unit.
- Acknowledge their responses and clear their doubts if any.
- Tell them they will learn about the introduction to a computer in this unit.

Say

- MS surpass stands for - Microsoft Excel is one of the foremost common electronic spreadsheet applications supported by both mack and computer platforms. as with a paper spreadsheet, you'll be able to use excel to prepare your data into rows and columns and to perform mathematical calculations.
- Discuss the application of Excel with the participants.

Demonstrate

- Tell them to open MS Excel in their respective systems.
- Show them how to create a spreadsheet in MS Excel software.
- Practically demonstrate how to perform different operations on MS Excel as:
 - » Zoom in and Zoom Out
 - » Page Views
 - » Change the default excel options
 - » Add Command to the quick access tool bar

- » Change the default excel options
- » Cell Addresses
- » Move Across a worksheet using key board
- » Formatting
- » Calculation and Analysis
- » Change page orientation
- » Aligning Text

Notes for Facilitation

- Summarise the main points of the unit.
- Ask participants if they have any doubts. Encourage them to ask questions.
- Answer their queries satisfactorily.
- Ask them to answer the questions at the end of unit given in the participant's manual.
- Ensure that every participant answers all questions.

Suggestive Note: As per student give the practical question of your choice to understand the student's outcome.

Activity

- Tell participants they have to prepare a spreadsheet on MS Excel Software.
- Share data of a class with the participants in which participants name, height, weight and age is given.
- Tell them they need to perform following operations while working on, Add Command to the quick access tool bar, Change the default excel options, Cell Addresses, Move Across a worksheet using key board, Formatting, Calculation and Analysis, Change page orientation
- Give them one and half hour to prepare the same.
- Finally share some tips for correct data typing and summarise the highlights of the activity

Skill Practice	Time	Resources
1. Preparing Spread Sheet on MS Excel	4 Hours	<ul style="list-style-type: none"> • Participant Manual • Computer Lab with MS Office Software

Elaborate

6.8.2 Exploring the Excel Environment

The tabbed Ribbon menu system is how you navigate through Excel and access the assorted Excel commands. If you have used previous versions of Excel, the Ribbon system replaces the traditional menus. On top of the Ribbon in the upper-left corner is the Microsoft Office Button. From here, you'll access important options like New, Save, Save As, and Print. By default, the short Access Toolbar is pinned next to the Microsoft Office Button and includes commands like Undo and Redo.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 216-231 and explain the learners' the concept.

Exercise

1. What are the things that MS Excel helps in?

.....

2. How does one Zoom out in MS Excel?

.....

3. The Save, Undo, and Redo commands appear by default in the Quick Access toolbar.

- a. True
- b. False

UNIT 6.9: Internet Concepts

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. Understand the internet concepts.

Resources to be Used

- Participant Manual
- Computer with Internet

Do

- Greet and welcome the participants to the next session of the program.
- Before starting the session ask them do they have any doubts pertaining to the previous unit.
- Acknowledge their responses and clear their doubts if any.
- Tell them they will learn about the introduction to a computer in this unit.

Say

- Tell them about the internet and its uses.
- Explain the concept of URL. The full form of URL is Uniform Resource Locator. It is the worldwide address of documents and other resources on the World Wide Web. The URL is divided into two different elements. The primary part of the URL is called a protocol identifier as it helps us distinguishing what protocol to use.
- Now tell them about different types of URLs.

Demonstrate

- Tell them now they will learn how to open an email account in outlook.
- Demonstrate the entire process to the participants. Make sure every student should open an e-mail account.
- Now tell them how to create and send an e-mail. Explain the entire steps in detail.
- Now show them how to read an email and reply email.
- Then explain attachment. The process of attaching a file or document.

Notes for Facilitation

- Summarize the main points of the unit.
- Ask participants if they have any doubts. Encourage them to ask questions.
- Answer their queries satisfactorily.
- Ask them to answer the questions at the end of unit given in the participant's manual.
- Ensure that every participant answers all questions.

Suggestive Note:

- Ask students to explain what is Internet & what are its uses.
- Ask students to explain the concept of URL.

Activity

- Tell participants they have sent emails to other participants with an attachment.
- Tell them first they need to create a word, excel or powerpoint. They can choose between any three of the formats.
- Give 2 hours for each participant for this entire activity.
- Once the activity is complete share some tips of e-mail etiquette with them and summarises the highlights of the activity.

Skill Practice	Time	Resources
1. Send e-mail with attachment	2 Hours	• Computers with Internet

Elaborate

6.9.1 URL Concepts

The full form of URL is Uniform Resource Locator. It is the worldwide address of documents and other resources on the World Wide Web. The URL is divided into two different elements. The primary part of the URL is called a protocol identifier as it helps us distinguishing what protocol to use. The second part of the URL is called a resource name and it indicates the IP address or the domain name where the resource is located.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 232-239 and explain the learners' the concept.

Exercise

1. What is the full form of URL?

.....
.....

2. The second part of the URL is called a resource name and it indicates the IP address or the domain name where the resource is located.

- a. True
- b. False

3. Choose a URL example from the below list.

- a. Messy
- b. Straight
- c. Constant

UNIT 6.10: Introduction to LMIS

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. The components and interfaces of a LMIS.

Ask

Ask the students to share:

- What do they know about Components and Interfaces of a LMIS
- What do they know about LMIS workflow

Say

- Discuss LMIS Screens.
- Discuss working on LMIS.

Explain

- Explain advantages of LMIS

Elaborate

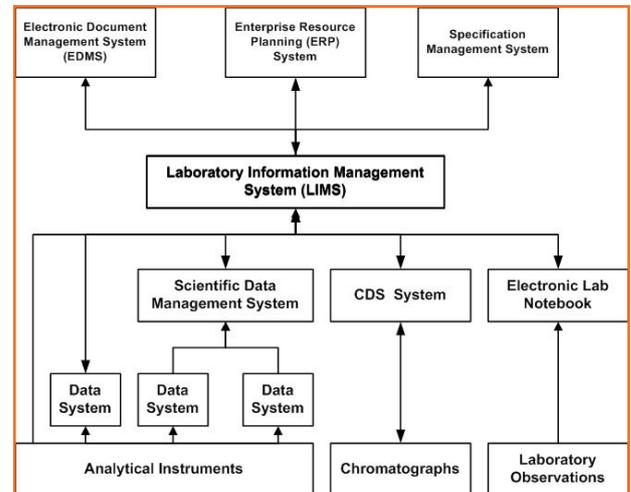
6.10.1 Introduction

LMIS or Laboratory Management Information System is software designed to electronically store laboratory data. It helps research laboratories simplify their day to day operations by managing data, resources and workflow. It helps in improving efficiency, productivity, consistency and quality by automating and integrating the lab with the business enterprise.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 352 and explain the learners' the concept.

6.10.2 Components and Interfaces of a LMIS

- The image below displays a more complex view than the above diagram and shows the primary components and interfaces of a LIMS.



Components and interface of LMIS

6.10.3 LMIS Workflow

Though each commercially available LMIS may have different features, in general a LMIS allows the user to "log-in" a sample into the system, record and then retrieve test results electronically. We will discuss the most common workflow of LMIS available in market.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 353 and explain the learners' the concept.

6.10.4 LMIS Screens

You can access a LMIS by accessing it through a login screen.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 354-355 and explain the learners' the concept.

LMIS Sample Screen

6.10.5 Working On LMIS

LMIS works as the center of every phase of laboratory operations. The following is a brief description of the major functions achieved using LMIS:

Sample receipt/Sample login

From the minute samples are received at a laboratory, LMIS assigns it a job and generate the bottle labels for all samples. Sample login completes the information by logging in all critical sample information, including the tests to be performed. Sample login is capable of capturing all information, including very lengthy client sample identifiers.

Trainers note: *These are the supporting content to the participant manual, please adhere to the participant manual, page no. 355-356 and explain the learners' the concept.*

6.10.6 Advantages of LMIS

Working with an LMIS will help you keep up with your dynamic laboratory. It allows you to track inventory and sample locations with barcoding capabilities.

- Tracks samples and products by name, date added, type, location, label and/or amount.
- Tracks parent/child relationships.

Trainers note: *These are the supporting content to the participant manual, please adhere to the participant manual, page no. 356 and explain the learners' the concept.*

Exercise

1. What is the full form of LMIS?

.....

2. What are the two functions of LMIS?

.....

3. Each user has access only to menu's that pertain to the organizational unit (or Team) to whom he/she belongs.

- a. True
- b. False

4. LMIS stores the analytical data collected from automated instruments, electronically or by manual entry.

- a. True
- b. False

5. Mention two advantages of LMIS.

.....



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7. Maintain a Healthy, Safe and Secure Working Environment

Unit 7.1 - Safety including Hazards, Accidents, Safety Signs and Signals and Heinrich Pyramid

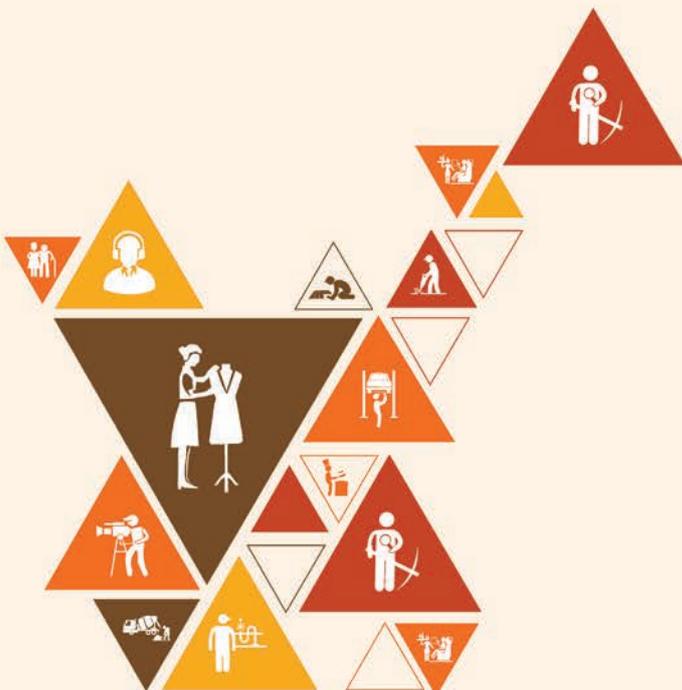
Unit 7.2 - Water Systems at Plant

Unit 7.3 - Clean Room: Classifications, Requirements and Behaviour Practices

Unit 7.4 - Process of Safety Analysis

Unit 7.5 - Job Safety Analysis (JSA)

Unit 7.6 - Managing Emergency Procedures and First Aid



LFS/N0101

Key Learning Outcomes

At the end of this module, you will be able to:

1. Gain knowledge about safety including hazards, accidents, safety signs and signals.
2. Understand the Heinrich Pyramid.
3. Orient with Water Systems at Plant, Engineering related tools and techniques to operate the machine safely.
4. Understand the clean room classifications and requirements.
5. Relate with the clean room behaviour practices.
6. Use Material Data Safety Sheet and Process of Safety Analysis.
7. Orient with Fire Safety concepts, PPEs action to be taken in case of fire emergency at shop floor.
8. Perform Job Safety Analysis for various production machines/ equipment and provide the critical information to concerned team members.
9. Manage emergency procedures and apply first aid.
10. Learn about basic professional and communication skills necessary to perform work successfully.

UNIT 7.1: Safety including Hazards, Accidents, Safety Signs and Signals and Heinrich Pyramid

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. The Heinrich Pyramid
2. Understand safety including hazards, accidents, safety signs and signals
3. How to orient with Water Systems at Plant, Engineering related tools and techniques to operate the machine safely.
4. Understand the clean room classifications and requirements.
5. How to relate to the clean room behaviour practices.
6. The usage of Material Data Safety Sheet and Process of Safety Analysis.
7. Orient with Fire Safety concepts, PPEs action to be taken in case of fire emergency at shop floor.
8. How to perform Job Safety Analysis for various production machines/ equipment and provide the critical information to concerned team members.
9. How to manage emergency procedures and apply first aid.
10. Understand about basic professional and communication skills necessary to perform work successfully.

Ask

Ask the students to share their views on:

- Views on the importance of safety, safety signs and Heinrich pyramid
- Probable hazards and accidents

Say

- Discuss accident.
- Describe accident prevention and the Domino theory.
- Discuss Heinrich's Loss Control Triangle.
- Discuss accident prevention and control.
- Describe safety signs.

Explain

- Explain Acoustic signals
- Explain usage of Hand signals
- Explain usage of verbal signals

Activity

- Ask the students to create a poster on various Safety signs.
- Each student should at least mention three safety signs.

Demonstrate

Safety Sign

			
Prohibition signs	Mandatory signs	Warning signs	Information or safe condition signs
Shape: Circular	Circular	Triangular	Square or rectangular
Colour: Red borders and cross bar. Black symbols on white background	White symbol on blue background	Yellow background with black border and symbol	White symbols on green background
Meaning: Shows what must NOT be done	Shows what must be done	Warns of hazard or danger	Indicates or gives information on safety provision
Example: No smoking	Wear eye protection	Danger electric shock risk	First-aid facilities

Various signboards

Below warning signs are used to identify different types of harmful substances:

Symbol	Meaning	Symbol	Meaning
	E Explosive		O Oxidising
	F Highly flammable		T Toxic
	Xn Harmful		Xi Irritating
	C Corrosive		N Harmful for the environment

warning signs of harmful substances

Prohibition Signs



Prohibition Signs

Warning signs – General



Warning signs -General

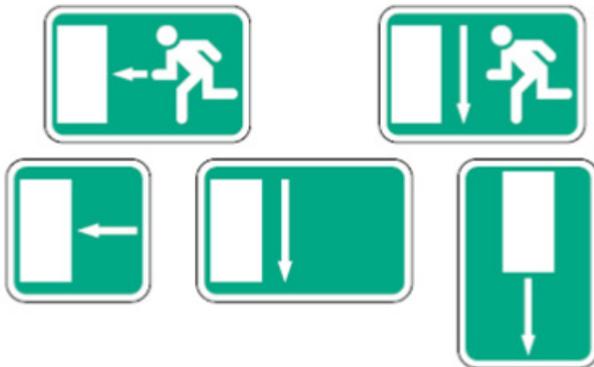
Mandatory Signs



Mandatory signs

Emergency Escape and First-Aid Signs

Emergency exit/escape route signs



Emergency escape and first-aid signs

First-aid signs



Tips

Share tips on:

- Using acoustic signals, hand signals, verbal signals.

Elaborate

7.1.2 What is an Accident?

The accident is defined as “An unplanned/undesired event giving rise to death, ill health, injury, damage or other losses to personnel or property”.



Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 243 and explain the learners' the concept.

7.1.3 Accident Prevention and the Domino Theory

The absence of an understanding of the causes of accidents makes it difficult to prevent accidents. Since a long time various attempts were made to populate a prediction theory of accident causation, but so far none has been accepted universally. Researchers from different fields of science and engineering have been trying to develop a theory of accident causation to help in identifying, isolate and ultimately remove the factors that contribute to or cause accidents.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 243-244 and explain the learners' the concept.

7.1.4 Heinrich's Loss Control Triangle

Heinrich collected the data about workplace injuries from insurance claims as well as from workplaces (usually Supervisors). From analysis of the data, Heinrich proposed that for every major injury there are 29 minor injuries and 300 no-injury accidents. Most people working in health and safety would have seen some variation of this formula in presentations containing triangles with different coloured horizontal bands representing the different severity of injuries and the ratios between them.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 245-250 and explain the learners' the concept.

Exercise

1. Name any two contaminant groups

.....

2. What are the types of water used in pharmaceutical processes

.....

3. Water is softened in a zeolite exchange column where the calcium and magnesium ions are exchanged for sodium.

- a. True
- b. False

UNIT 7.2: Water Systems at Laboratory

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. Water system at plant
2. Contamination of water
3. Understand about Minerals

Ask

Ask the students to share their views on:

- Natural water
- Contamination of water

Say

- Provide information about minerals, micro-organisms.
- Discuss physical and chemical contaminants.
- State types of water used in Pharmaceutical process.

Explain

- Explain about water for Pharmaceutical use

Activity

- Divide students into two groups.
- Ask each group to create multiple choice question.
- The groups will ask questions to each other.
- Evaluate and explain the concept as per performance.

Elaborate

7.2.1 Natural Water

Water is available on earth at the various source. The water has unique chemical properties, which makes it the “universal solvent”, there is no pure water in nature. A wide variety of organic compounds, minerals, metals may be present dissolved in water.

Raw water that is available in nature contains impurities:

- There is no pure water in nature, as it can contain up to 90 possible unacceptable contaminants.
- Contaminant groups include: Inorganic compounds
 - » Organic compounds
 - » Solids
 - » Gases
 - » Micro-organisms

7.2.2 Contaminants of Water

There a number of water contaminants. Some of the common contaminants are:

- Minerals
- Microbes
- Physical and chemical contaminants

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 252-255 and explain the learners’ the concept.

Exercise

1. What makes Water a universal solvent?

.....

2. Name two types of Water used in Pharmaceutical Processes?

.....

UNIT 7.3: Clean Room: Classifications, Requirements and Behaviour Practices

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. Understand clean room and its classifications
2. How to identify the personal behaviour of persons working in clean room.

Ask

Ask the students to share their views on:

- Clean room
- Classification of Clean Room

Say

- Discuss contamination transfer in clean rooms.
- Discuss clean room air filtration.

Explain

- Explain the selection criteria for cleanroom staff
- Explain personal behaviour of persons working in clean room
- List do's and dont's

Elaborate

7.3.1 Classification of Clean Room

A cleanroom is an environment, typically used in manufacturing or scientific research in an organization. It is maintained to have a low level of environmental pollutants such as dust, airborne microbes, aerosol particles, and chemical vapours and control other environmental parameters such as temperature, humidity and pressure. Clean room is equipped with a High Efficiency Particulate Air (HEPA) filter that is used to trap particles that are 0.3 micron and larger in size. All of the air delivered to a cleanroom passes through HEPA filters, and in some cases where stringent cleanliness performance is necessary, Ultra Low Particulate Air (ULPA) filters are used.

Cleanrooms are classified according to the number and size of particles permitted per volume of air

As per ISO — the International Standards Organization, the cleanrooms are ranked between ISO Class 1 (the cleanest) through ISO Class 9. The lower the ISO rating, the cleaner the environment. Measurement of contamination is done in “parts- per-cubic -meter.” An ISO Class 6 cleanroom, for example, is rated at 35,200 parts per cubic meter.



Cleanroom

Class	maximum particles/m ³						FED STD 209E equivalent
	≥0.1 μm	≥0.2 μm	≥0.3 μm	≥0.5 μm	≥1 μm	≥5 μm	
ISO 1	10	2					
ISO 2	100	24	10	4			
ISO 3	1,000	237	102	35	8		Class 1
ISO 4	10,000	2,370	1,020	352	83		Class 10
ISO 5	100,000	23,700	10,200	3,520	832	29	Class 100
ISO 6	1,000,000	237,000	102,000	35,200	8,320	293	Class 1,000
ISO 7				352,000	83,200	2,930	Class 10,000
ISO 8				3,520,000	832,000	29,300	Class 100,000
ISO 9				35,200,000	8,320,000	293,000	Room Air

Table: Clean Room Specifications

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 258-260 and explain the learners' the concept.

Exercise 

1. What is the full form of HEPA?

.....
.....

2. Name any two contamination carriers in Clean Rooms.

.....
.....

3. Name any two selection criteria for clean room.

.....
.....

4. Name any one Do's or Dont's.

.....
.....

UNIT 7.4: Process of Safety Analysis

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. Process of safety analysis
2. How to prepare material safety data sheet

Ask

Ask the students to share their views on:

- Material safety data sheet
- Process safety analysis

Say

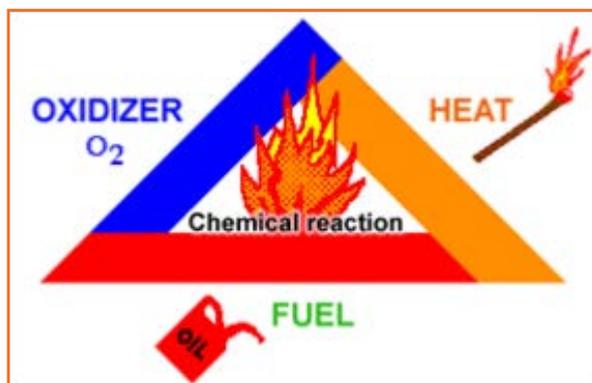
- Describe material safety data sheet.
- Discuss process safety analysis.
- Explain fire safety and emergency preparedness.
- List classes of fire.

Explain

- Explain fire extinguishers
- Fire prevention
- List firefighting rules
- Explain personal protective equipment (PPE's)

Demonstrate The Fire Triangle

Fire cannot occur without an ignition source, fuel and an oxidizing atmosphere (usually air), the three elements that comprise what is called the “fire triangle”.



The Fire Triangle

Elaborate

7.4.1 Material Safety Data Sheet

Material Safety Data Sheet (MSDS) is a document that provides detailed hazard, precautionary and emergency information of the product. Chemical manufacturers provide the MSDS to purchasing parties. Unless it is written on the purchase order, the MSDS is sent to the concerned user.

MSDS provides a variety of information to the chemical user. The American National Standards Institute (ANSI) recommends that MSDS have 16 sections. A description of each of these sections is outlined below.

Section 1 – Chemical Product and Company Identification

Section 1 identifies the product and its synonyms. Chemical and MSDS supplier name is also mentioned. It may also give the chemical abstracts service-identifying number. The manufacturer's name is required to be listed on the MSDS by OSHA.

Section 2 – Composition or Ingredients

It lists hazardous components as specified by the Occupational Safety and Health Act (OSHA) in their relative concentrations. Often significant non-hazardous components are listed. It may also include other information related to the chemicals such as personal exposure limits and time-weighted averages.

Section 3 - Hazards Identification and Emergency Procedures Overview

It gives an overview of emergency procedures and lists information on the potential adverse human health effects and symptoms that may result from exposure to the material.

Section 4 - First Aid Measures

It provides instructions to be taken if accidental exposure requires immediate treatment. It may also include instructions to medical professionals. Always provides an MSDS to the emergency medical care provider.

Section 5 - Fire fighting measures

It provides basic fire fighting guidance, including appropriate extinguishing media. It describes other fire and explosive properties useful for avoiding and fighting fires involving the material, such as flash point or explosive limits.

Section 6 - Accidental release measures

It describes actions to be taken to minimize the adverse effects of an accidental spill, leak or release of the material.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 261-263 and explain the learners' the concept.

7.4.2 Process Safety Analysis

Process Safety Analysis or Process Hazard Analysis is a systematic analysis of a specific job in a specific location to identify the potential hazards and determine the controls. This is a written document containing the potential hazards, consequences and their control. After completing this, the process/task can be planned in such a way to prevent the potential incident or to reduce the impact of hazard.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 263-268 and explain the learners' the concept.

Exercise 

1. What is the full form of MSDS?

.....

2. The manufacturer's name is required to be listed on the MSDS by OSHA.
 - a. True
 - b. False

3. What is the full form of OSHA?

.....

UNIT 7.5: Job Safety Analysis (JSA)

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. Job safety analysis
2. Hazard types
3. How to conduct the analysis

Ask

Ask the students to share their views on:

- Job safety analysis

Say

- Describe job safety analysis.
- Discuss hazard types.

Explain

- Explain how to conduct the analysis

Elaborate

7.5.1 Job Safety Analysis (JSA)

A job safety analysis (JSA) is a procedure to identify the potential hazards in each step of job and to recommend a written safest way to do that job.

Job Safety Analysis (JSA) is a procedure to make a job safe by:

- Identifying the hazards or potential accidents associated with each step of the job.
- Developing a solution for each hazard that will eliminate, reduce or control the exposure.
- Provide a step-by-step, written procedure for jobs.

UNIT 7.6: Managing Emergency Procedures and First Aid

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. How to identify types of emergencies
2. To follow the emergency procedures and perform first aid

Ask

Ask the students to share their views on:

- On managing various Emergencies

Say

- Describe emergency response in case of fire.
- Discuss emergency response in case of major Gas Leakage.

Explain

- Explain emergency response in case of chemical spill
- Explain response in case of Tremor/Earthquake
- State procedure to be followed in case of Riot, Bomb threat
- Explain weather alerts
- First aid and first aid boxes

Activity

The trainer can conduct a Quiz to test the understanding of the learners as well as revise the main points of the course.

- Divide the learners into 3 teams.
- Ask each team to formulate at least 10 questions from the complete introductory module including.

Conduct a QUIZ contest between the 3 teams, where one team asks ques on they made to the second team. The second team can earn a mutually agreed score if they get the answer correct. Then the second team asks ques on from the third team and then the third team will ask question from the first.

- They can have 5-7 rounds
- Any question that is not correctly answered will pass on to the next team
- All questions and answers will be approved by the trainer
- The trainer can also throw questions to the teams that are important but not covered by any of the teams
- The trainer can ask one student to keep the score on the board

The winning team would get a standing ovation.

Elaborate

“Emergency” means a situation leading to circumstances or set of circumstances in which there is a danger to the life of persons or which could result in major fire or explosion or any major environmental releases causing pollution to the works and outside environment. To mitigate and control such situation, Emergency Preparedness and Response Plan is formulated in industries considering all the possible hazards in the Premises.

The emergency procedures outlined are appropriate for round the clock coverage including holidays. The plan is designed in such a manner that it would avoid any confusion, panic among the lab personnel in case of emergency.

Emergency situation can arise due to the following:

- Fire
- Explosion
- Major gas leakage from cylinders / pipelines
- Major HSD / Solvent / Chemical spill
- Earthquake
- Riots
- Bomb threats
- Fatal /Major accident

7.6.2 Emergency Response in Case of Fire

In the event of a fire, immediate evacuation is essential. Everyone must be aware about the emergency exits and routes. On the way out of the building remember these safety precautions:

- Never enter a room containing a fire.
- Never enter a room that is smoke filled.
- Never enter a room in which the top half of the door is hot to the touch.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 272-277 and explain the learners’ the concept.

Exercise 

1. Name any two reasons why an emergency can arise.

.....
.....

2. Emergency response in case of fire.

- a. Enter a room filled with smoke
- b. Never enter a room that is smoke-filled

3. Do not apply any ointments, salves, or sprays on Thermal burns.

- a. True
- b. False

Key Learning Outcomes

At the end of this module, you will be able to:

1. Importance of housekeeping/ hygiene maintenance / Cleanliness at workplace.
2. Learning of level of hygiene.
3. Identification of dirty areas to be cleaned.
4. Material required for cleaning.
5. Efficient cleaning taking into account of risk, time.
6. Types of stains / soiling and their solutions.
7. Maintenance of cleaning equipment and supplies.
8. Planning the sequence for cleaning the area to avoid re-soiling clean areas.
9. Various signs used in while cleaning the area of cleanliness.
10. Various coding system in organization used during housekeeping.
11. Methodology for storage area inspection.
12. Optimum utilization of time & resources.

UNIT 8.1: Material, Chemical and Equipment and Cleaning Procedures

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. How to identify different material, chemicals and equipment and their cleaning procedure.

Ask

Ask the students to share views on:

- Housekeeping activities
- Managing emergency procedures

Say

- Provide knowledge of different materials and chemicals.
- Provide knowledge of equipment maintenance and their cleaning procedure.

Explain

- Explain the 5S System

Activity

- Randomly select students and ask them to ask a question to his/her partner regarding housekeeping activities and managing emergency procedure.

Elaborate

8.1.1 Introduction

What does it mean to be clean?

Insufficient or inadequate cleaning can have various consequences. From a health point of view, an absence of good cleaning can lead to contaminated drugs with a risk for patients, but also for the workers within the pharmaceutical company due to a lack of correct protection. The ecological problems can be summarized in pollution risks. The regulatory issues are linked with warnings from agencies up to possible authorization withdrawn. Economic problems start with a diminution of production and stock shortage which imply increased internal costs and financial loss. In addition, image problems for a company exist when patients must return medications to the pharmacy as in the case of batch recall. Agencies can increase inspections due to a lack in confidence, and financial institutions could rate a company as a higher risk due to profit diminution and poor predictability of the potential benefits.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 281 and explain the learners' the concept.

8.1.2 Housekeeping Activities & Managing Emergency Procedures

An important factor of quality assurance is good housekeeping. Manufacturing and other operational areas need regular cleaning and disinfection, in order to remove spillage powders, dust and dirt. Cleaning ensures avoidance of cross contamination and to maintain working environment tidy and safe. The main objectives of housekeeping activities are:

- To facilitate smooth movement of goods and personnel
- To prevent contamination of stored material

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 281-291 and explain the learners' the concept.

Exercise

1. Corrosive substance is a substance that causes visible destruction or permanent changes in human skin tissue at the site of contact.

- a. True
- b. False

2. Mention any two things that maintenance records should include

.....

3. What is Caliper?

.....

UNIT 8.2: Methodology for Storage Area Inspection

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. Methodology for storage area inspection

Ask

Ask the students to share their view on:

- Storage area inspection

Say

- Storage area guidelines.
- Methods required to clean surfaces.

Explain

- Materials required to clean the equipment
- Validation of cleaning
- Waste disposal

Activity

- Select students randomly after the training session and ask them to extempore on storage area guidelines.

Elaborate

8.2.1 Method Selection

Whenever possible, each piece of equipment should be dismantled into its individual components after cleaning and each part should be individually tested for cleanliness. In this manner, any inadequacies in the cleaning process will be more readily identified and localized. It may not be practical or desirable to dismantle large or Clean In Place (CIP) equipment. Regardless, validation sampling and testing should commence as soon as possible after the cleaning process is complete to reduce the chance for contamination by outside sources. Equipment that has just been cleaned should be covered immediately by appropriate means to protect it from any contamination.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 413-425 and explain the learners' the concept.

Exercise

1. There should be at least 15 m distance between the storage sheds.
 - a. True
 - b. False
2. In case of spills / leaks - dry adsorbents or cotton should be used for cleaning instead of water.
 - a. True
 - b. False
3. What are the two Analytical Techniques?

.....

UNIT 8.3: Core Skills and Professional Skills

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. Core skills and professional skills required for a machine operator in life science.

Ask

Ask the students to share:

- How to achieve the best

Say

- Discuss Case Study.

Explain

- Explain Case Study.

Elaborate

8.3.1 Introduction

Core skills and professional skills are critical to the Machine Operator for efficient coordination with the shift supervisor[s], cross functional teams and within the team. This includes:

- Communication and Interaction methods viz., Reading, Writing, Listening and Speaking.

Analytical Skills for different situations like:

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 426 and explain the learners' the concept.

8.3.2 How to Achieve the Best?

Establish Policies, Objectives, and Plans for the Organization as a Cross Functional Team

Policies, objectives, and plans under a modern quality system provide the means by which senior managers articulate their vision of and commitment to quality to all levels of the organization.

Train, Train, Retrain

Continued training is critical to ensure that the employees remain proficient in their operational functions and in their understanding of cGMP regulations.

Trainers note: *These are the supporting content to the participant manual, please adhere to the participant manual, page no. 426-427 and explain the learners' the concept.*

8.3.4 Case Study

Let us look at the scenario

Sending an Open part of the Drug Master File LDMF to a customer for Evaluation with respect to use of the API

[Say ABC] for his formulation to be launched in European Market

Issue: Delayed and held up by Regulatory Department who is adamant on not sending it across due to inadequacy/ doubt of stability studies results.

Problem: All Managers of Quality Assurance, Quality Control, Regulatory and Chemical Research [RnD] blaming each other for making an issue out of not so critical issue and not coming together to resolve and close the issue with an agreement to take precautions in future regarding this aspect.

Trainers note: *These are the supporting content to the participant manual, please adhere to the participant manual, page no. 428-429 and explain the learners' the concept.*

Exercise

1. Define a standard approach for cleaning.
 - a. True
 - b. False
2. Describe the Methods and materials required for cleaning variety of surfaces and equipment.
 - a. True
 - b. False

3. Define the elements for cleaning validation.

.....
.....

4. What is sampling for validation? Describe the Swab and Rinse sampling methods?

.....
.....

5. What are the various pharmaceutical waste management and disposal techniques used in India?

.....
.....

UNIT 8.4: Waste Disposal and Scrap Management

Unit Objectives

At the end of this unit, you will be able to make the students understand:

1. How and where disposal take place and what procedure is to be followed for safety purpose.
2. Methods of disposal of waste material.
3. Identification of the hazardous waste material.
4. Proper handling, storage, transportation of all hazardous material.
5. Chemical symbols and their meaning.
6. Damaged and expired labels.
7. Waste management, reusing of non-confirming products.
8. Disposal of garnered waste.
9. Dispose of chemical, their reactions.

Ask

Ask the students to share:

- What do they know about Waste Disposal
- What do they know about Listed Wastes

Say

- Discuss characteristics wastes.
- Discuss Pharmaceutical Waste Management.

Explain

- Explain Pharmaceutical Waste treatment & disposal

Do

- List standard operating policies and procedures.

Elaborate

8.4.1 Waste Disposal

Hazardous wastes are divided into two categories:

1. Listed wastes
2. Characteristic wastes

Listed wastes appear on one of four lists of hazardous waste (F, K, P and U). Pharmaceuticals are found on two of these lists, the P and U lists which both contain commercial chemical products. Characteristic wastes are regulated because they exhibit certain hazardous properties – ignitability, corrosivity, reactivity and toxicity.

8.4.1.1 Listed Wastes

P- Listed Wastes

Pharmaceuticals are chemicals first and therapeutic agents second. P-listed wastes are commercial chemical products that are categorized as acutely hazardous under RCRA. One of the primary

criteria for including a drug on the P-list as acutely hazardous is an oral lethal dose of 50 mg/kg (LD50) or less. LD50 is the amount of a material, given all at once, which causes the death of 50% of a group of test animals. Eight chemicals on the P-list are used as pharmaceuticals.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 430-431 and explain the learners' the concept.

8.4.1.2 Characteristics Wastes

Characteristic Hazardous Waste are:

- Ignitability
- Corrosivity
- Reactivity
- Toxicity

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 431 and explain the learners' the concept.

8.4.2 Pharmaceutical Waste Management

There are four (4) categories of pharmaceutical waste that need to be managed and they are defined as follows:

1. RCRA Hazardous Waste: Waste Pharmaceuticals that meet the definition of a hazardous waste and must be segregated and managed as hazardous waste. These include nine antineoplastic agents.
2. Non-RCRA Antineoplastic Hazardous Waste: Non-RCRA antineoplastic hazardous waste includes all antineoplastic agents used for the treatment of cancer that are not regulated by RCRA.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 432 and explain the learners' the concept.

8.4.3 Pharmaceutical Waste Treatment & Disposal

Pharmaceutical Waste Treatment and Disposal Technologies Specified in India's Pharmaceutical Waste Rules:

1. **Incineration:** Incineration is a disposal method in which solid organic wastes are subjected to combustion so as to convert them into residue and gaseous products. This method is useful for disposal of residue of both solid waste management and solid residue from waste water management. This process reduces the volumes of solid waste to 20 to 30 percent of the original volume.

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 432-433 and explain the learners' the concept.

8.4.4 Standard Operating Policies and Procedures

At a minimum pharmaceutical waste management policies and procedures should be developed to detail the organization's approach to:

- Identifying drugs that must be managed as hazardous waste.
- Determining which non-regulated drugs will be managed as hazardous waste.
- Labeling drugs to facilitate segregation of hazardous waste.
- Segregating waste streams.
- Training staff (e.g., which staff, what information and how often).

Trainers note: These are the supporting content to the participant manual, please adhere to the participant manual, page no. 433 and explain the learners' the concept.

Exercise 

1. What are the two kinds of hazardous wastes?

.....
.....

2. Name any two characteristics of hazardous waste.

.....
.....

3. Reactive wastes are unstable under “normal” conditions.

- a. True
- b. False

Introduction: Employability and Entrepreneurship Skills

This Facilitator's guide includes various activities which will help you as a facilitator to make the sessions participative and interactive.

Ice breaker

- You can begin the module with the following ice breaker:

Five of Anything Ice Breaker Steps:

- Divide the participants into groups of four or five by having them number off. (You do this because people generally begin a meeting by sitting with the people they already know best.)
- Tell the newly formed groups that their assignment is to share their five favourite movies of all time, their five favourite novels or their five least liked films. The topic can be five of anything - most liked or disliked.
- This ice breaker helps the group explore shared interests more broadly and sparks lots of discussion about why each person likes or dislikes their selected five.
- Tell the groups that one person must take notes and be ready to share the highlights of their group discussion with the class upon completion of the assignment.

Expectation Mapping

1. During the first session and after ice breaker session, ask the participants to answer the following question: "What do I expect to learn from this training?"
2. Have one of the participants write their contributions on a flip chart sheet.
3. Write down your own list of covered material in the training on another flip chart sheet.
4. Compare the two sheets, commenting on what will and what will not be covered during the training.
5. Set some ground rules for the training sessions. Ask the participants to put these rules on a flipchart and display it in the class.
6. You may get back to those sheets once again at the end of the last session of the training.
7. Benefits of doing this activity:
 - Participants feel better as their opinions are heard.
 - Participants get to know what they should expect from the training.
 - The facilitator gets to know which points to emphasize, which to leave out, and which to add during the training.
8. Expectations from the participants:
 - Must sign the attendance sheet when they arrive for class.
 - Conduct themselves in a positive manner
 - Be punctual, attentive, and participative
9. Explain the contents that are going to get covered one by one and connect it with the expectation mapping done earlier.
10. By the end of this exercise, the participants should have a clear understanding of what to expect from the session and what are the areas that will not get covered.

Defining Objectives

1. Defining the objectives in the beginning of the units sets the mood for the unit.
2. To begin with the end in mind sets the expectations of the participants as what could be the important takeaways from the session.
3. It is also a way of making participants take responsibility of their own learning process.
4. For the facilitator, the objectives decide a designed path to progress on so that the learning stays aligned and on track.

5. Read the objectives slowly, one by one, and ask the participants to explain what they think it means.
6. At the end of the session, you could again revisit the objectives to find out from the participants about how many objectives have been achieved.

In order to effectively facilitate this workshop:

1. You must have thorough knowledge of the material in the Participant Handbook, and be prepared to answer questions about it.
2. You may also wish to read other material to enhance your knowledge of the subject.
3. There may be issues raised with which you are not able to deal, either because of lack of time or knowledge. You can either state that you will obtain answers and get back to the participants with the information. In case the query can be turned to an assignment to the class, do so. You can work with the the participants on the assignment.
4. You must have a very clear understanding of what the participants want to accomplish by the end of the workshop and the means to guide the participants.
5. As the facilitator, it is your responsibility to make sure that all logistical arrangements are made for the workshop. This may involve doing it yourself or confirming that someone else has made all necessary arrangements associated with the workshop. Assume nothing and check everything before the workshop begins.
6. To break the monotony and boredom during sessions, introduce mini breaks in the form of stretching exercises, jokes, some group songs or games.
7. Invite discussion from the participants.
8. Probe the participants further and lead them to come to affirmative conclusions.
9. Let the participants answer. No answer is incorrect.
10. Ask one participant to write all the points on the whiteboard.
11. Build the sessions from the answers provided by the class.
12. Prepare for the sessions in advance so that the resources like flipcharts, handouts, blank sheets of paper, marker pens, etc. can be kept ready.
13. Ensure that resources like board, markers, duster etc. is available before your session starts.

General instructions for role playing:

1. You are not being asked to be an actor or to entertain. The purpose of the role play is to provide a situation in which you can practice certain skills.
2. When you read the brief, try to imagine yourself in the situation described and behave in a way you feel to be natural – but be conscious of the fact that your role may require a different approach from that which you might normally use.
3. You (and others) may benefit from the change in approach and behaviour. Therefore, try to use the approach you feel to be most appropriate for the circumstances described in your brief.
4. The brief is just the starting point. It simply sets the scene and the tone of session or activity. Try not to keep referring to the brief as this will affect the spontaneity of the meeting. Allow the role play to develop as you think it might in real life and change your reactions in line with the behaviour and responses of others involved.
5. If you find that you have too little information to answer questions or to describe what has happened in the situation, do feel free to add your own thoughts and ideas. Try to keep these within the framework of the role you are taking and try to make your improvisations as realistic as possible.

UNIT 9.1: Personal Strengths & Value Systems

Key Learning Outcomes



At the end of this unit, participants will be able to:

1. Explain the meaning of health
2. List common health issues
3. Discuss tips to prevent common health issues
4. Explain the meaning of hygiene
5. Discuss the purpose of Swacch Bharat Abhiyan
6. Explain the meaning of habit
7. Discuss ways to set up a safe work environment
8. Discuss critical safety habits to be followed by employees
9. Explain the importance of self-analysis
10. Discuss motivation with the help of Maslow's Hierarchy of Needs
11. Discuss the meaning of achievement motivation
12. List the characteristics of entrepreneurs with achievement motivation
13. List the different factors that motivate you
14. Discuss the role of attitude in self-analysis
15. Discuss how to maintain a positive attitude
16. List your strengths and weaknesses
17. Discuss the qualities of honest people
18. Describe the importance of honesty in entrepreneurs
19. Discuss the elements of a strong work ethic
20. Discuss how to foster a good work ethic
21. List the characteristics of highly creative people
22. List the characteristics of highly innovative people
23. Discuss the benefits of time management
24. List the traits of effective time managers
25. Describe effective time management technique
26. Discuss the importance of anger management
27. Describe anger management strategies
28. Discuss tips for anger management
29. Discuss the causes of stress
30. Discuss the symptoms of stress
31. Discuss tips for stress management

UNIT 9.1.1: Health, Habits, Hygiene: What is Health?

Unit Objectives

At the end of this unit, participants will be able to:

- Explain the meaning of health
- List common health issues
- Discuss tips to prevent common health issues
- Explain the meaning of hygiene
- Discuss the purpose of Swachh Bharat Abhiyan
- Explain the meaning of habit

Resources to be Used

- Participant Handbook

Ask

- What do you understand by the term “Health?”
- According to you, who is a healthy person?

Say

- Discuss the meaning of health and a healthy person as given in the Participant Handbook.

Ask

- When did you visit the doctor last? Was it for you or for a family member?

Say

- Discuss the common health issues like common cold, allergies etc. Refer to the Participant Handbook.
- Let us do a small activity. I will need some volunteers.

Role Play

- Conduct a small skit with volunteers from the class. Consider one of the villagers has been appointed as a health representative of the village, what measures will you as a health representative suggest to the common villagers to prevent common health issues discussed.
- You will need at least 4 volunteers (Narrator, Health Representative, Head of the Village, Doctor).
- Explain the health concerns of the village to the Narrator. The Narrator will brief the class about the skit.
- Give the group of volunteers, 5 minutes to do discuss.
- At the end of 5 minutes, ask the group to present the skit to the class assuming them as the villagers.
- The class can ask questions to the group as a common villager.

Summarize

- Through this activity we got some tips on how can we prevent these common health issues.

Say 

- Let us now see how many of these health standards we follow in our daily life.

Activity 

- Health Standard Checklist from the Participant Handbook.

Ask 

- How many of you think that you are healthy? How many of you follow healthy habits?

Say 

- Let's do an exercise to find out how healthy you are.
- Open your Participant Handbook section 'Health, Habits, Hygiene: What is Health?', and read through the health standards given.
- Tick the points which you think are true for you.
- Try to be as honest as possible as this test is for your own learning.

Do 

- Ensure that all the participants have opened the right page in the Participant Handbook.
- Read aloud the points for the participants and explain if required.
- Give them 5 minutes to do the exercise.
- At the end of 5 minutes, ask the participants to check how many ticks have they got.

Summarize 

- Tell them that they need to follow all the tips given in this checklist regularly in order to remain healthy and fit.

Ask **Discuss:**

- Is it necessary to practice personal hygiene every day? Why?
- How does a person feel when they do not practice good personal hygiene? Why?
- Can good personal hygiene help a person feel good about his/her self? How?

Say 

- Discuss the meaning of hygiene as given in the Participant Handbook.

Activity 

- Health Standard Checklist: Hygiene

Say

- Let's do an exercise to find out if we maintain good hygiene habits or not.
- Open the Participant Handbook and read through the Health Standard checklist given.
- Tick the points which you think are true for you.
- Try to be as honest as possible as this test is for your own learning.

Do

- Ensure that all the participants have opened the right page in the Participant Handbook.
- Read aloud the points for the participants and explain if required.
- Give them 5 minutes to do the exercise. .
- At the end of 5 minutes, ask the participants to check how many ticks have they got.
- Ask them to calculate their score.
- Tell them what each score indicates by reading aloud what has been mentioned in the Participant Handbook.

Ask

- How many of you have heard about “Swachh Bharat Abhiyan”?
- Can you tell the class what it is about?

Summarize

- Tell them about Swachh Bharat Abhiyan as given in the Participant Handbook and request them to take a pledge to keep our country clean.

Ask

- What is a habit?

Say

- Discuss some good habits which can become a way of life.

Summarize

- Tell them about good and bad habits and the reasons to make good habits a way of life.

UNIT 9.1.2: Safety

Unit Objectives

At the end of this unit, participants will be able to:

- Discuss ways to set up a safe work environment
- Discuss critical safety habits to be followed by employees

Resources to be Used

- Participant Handbook
- Safety signs and symbols
- Safety equipments
- Blank papers
- Pens

Say

- There are many common safety hazards present in most workplaces at one time or another. They include unsafe conditions that can cause injury, illness and death.
- Safety Hazards include:
 - Spills on floors or tripping hazards, such as blocked aisles or cords running across the floor.
 - Working from heights, including ladders, scaffolds, roofs, or any raised work area.
 - Unguarded machinery and moving machinery parts; guards removed or moving parts that a worker can accidentally touch.
 - Electrical hazards like cords, missing ground pins, improper wiring.
 - Machinery-related hazards (lockout/tag out, boiler safety, forklifts, etc.)

Team Activity

Safety Hazards

- There are two parts to this activity.
- First part will cover the potential safety hazards at work place.
- Second part will cover a few safety signs, symbols and equipments at work place.
- Use this format for the first part of the activity.

PART 1		
Hazard	What could happen?	How could it be corrected?

Ask

- How could you or your employees get hurt at work?

Say

- Let's understand it better with the help of an activity. You will be given a handout within your groups. You have to think about the possible hazards of your workplace, what damage these hazards could cause and about the corrective action.

Do

- Divide the class into five to six groups of four participants each.
- Put the format on the board for the activity.
- Give blank papers and pens to each group.
- The group is expected to think and discuss the potential safety hazards in the workplace.
- Ask the group to discuss and fill the format using the blank sheet.
- Give the groups 5 minutes for the activity.
- For the second part of the activity, show the class some pictures of safety signs, symbols and equipments.
- Now they will put down a few safety symbols, signs or equipment against the safety hazards identified.
- Give them 5 to 10 minutes to discuss and draw/note it.
- At the end of 10 minutes the groups will present their answers to the class.

Say

- Now, let's discuss the answers with the class.
- All the groups will briefly present their answers.

Do

- Ask the audience to applaud for the group presentation.
- Ask de-brief questions to cull out the information from each group.
- Keep a check on time.
- Tell the group to wind up the discussion quickly if they go beyond the given time limit.

Ask

De-briefing

- What did you learn from the exercise?
- As an entrepreneur, is it important to ensure the safety of your employees from possible hazards? Why?

Summarize

- Ask the participants what they have learnt so far.
- Ask if they have any questions related to what they have talked about so far.
- Close the discussion by summarizing the tips to design a safe workplace and non-negotiable employee safety habits.

UNIT 9.1.3: Self Analysis- Attitude, Achievement Motivation: What is Self Analysis?

Unit Objectives

At the end of this unit, participants will be able to:

- Explain the importance of self- analysis
- Discuss motivation with the help of Maslow's Hierarchy of Needs
- Discuss the meaning of achievement motivation
- List the characteristics of entrepreneurs with achievement motivation
- List the different factors that motivate you
- Discuss the role of attitude in self- analysis
- Discuss how to maintain a positive attitude
- List your strengths and weaknesses

Resources to be Used

- Participant Handbook
- Old newspapers
- Blank papers
- Pencils/ pens

Activity

- This is a paper pencil activity.

What are the three sentences that describe you the best?
What do you need to live happily?
What are your strengths and weaknesses?

Do

- Write the three questions on the board/ flipchart before the session begins.
- Give plain papers and pencils/ pens to each participant.
- Tell participants to write the answer for the three questions on the paper.
- Tell them the purpose of this activity is not to judge anyone but to understand more about self.

Say

- Discuss the concept of Self Analysis and motivation with reference to Maslow's Hierarchy of Needs as discussed in the Participant Handbook.

Team Activity

Tower building

- Each group which will create tower using the old newspapers.

Do 

- Divide the class into groups.
- Give them some old newspapers.
- The task is to create a tower out of the newspapers.
- The group which will create the highest tower standing on its own will be considered the winning group.
- Groups can use as many newspapers as they want to and in any way they want.

Ask 

- What did the winning group do differently?
- If you were given a chance, how would you have made the tower differently?
- How did you feel while making the tower?
- Did you feel motivated?

Say 

- Discuss the concept of achievement motivation and characteristics of entrepreneurs with achievement motivation as discussed in the Participant Handbook.

Ask 

- Is your attitude positive or negative?

Say 

- Let me tell you a story :

It's Little Things that Make a Big Difference.

There was a man taking a morning walk at the beach. He saw that along with the morning tide came hundreds of starfish and when the tide receded, they were left behind and with the morning sun rays, they would die. The tide was fresh and the starfish were alive. The man took a few steps, picked one and threw it into the water. He did that repeatedly. Right behind him there was another person who couldn't understand what this man was doing. He caught up with him and asked, "What are you doing? There are hundreds of starfish. How many can you help? What difference does it make?" This man did not reply, took two more steps, picked up another one, threw it into the water, and said, "It makes a difference to this one." What difference are we making? Big or small, it does not matter. If everyone made a small difference, we'd end up with a big difference, wouldn't we?

Ask 

- What did you learn from this story?

Activity **What Motivates You?**

- This is an individual activity.
- It is an exercise given in the Participant Handbook.

Do 

- Ask the class to open their Participant Handbook and complete the exercise given in the section What Motivates You?
- Ensure that the participants have opened the correct page for the activity.
- Give the class 5 minutes to complete the activity.

Say

- Discuss the concept of attitude and how to cultivate a positive attitude as discussed in the Participant Handbook.

Summarize

- Close the discussion by summarizing how self-analysis, knowledge about what motivates you and your positive attitude can help in your business as well in life.

UNIT 9.1.4: Honesty & Work Ethics

Unit Objectives

At the end of this unit, participants will be able to:

- Discuss the qualities of honest people
- Describe the importance of honesty in entrepreneurs
- Discuss the elements of a strong work ethic
- Discuss how to foster a good work ethic

Resources to be Used

- Participant Handbook

Ask

- What do you understand by honesty?
- Why is it important for entrepreneurs to be honest?
- Do you remember any incident where your honesty helped you in gaining confidence?
- Do you remember any incident where someone lost business due to dishonesty?

Say

- Talk about honesty, qualities of an honest person, and the importance of honesty in entrepreneurs as discussed in the Participant Handbook.
- “Let's understand it better with the help of some case scenarios. You will be given some cases within your groups. You have to analyse the case scenario that has been given to you and then find an appropriate solution to the problem.
- Keep your discussion focussed around the following:
 - What went wrong?
 - Who was at fault?
 - Whom did it impact- the customer or the businessman?
 - How would it impact the business immediately? What would be the long term impact?
 - What could be done?
 - What did you learn from the exercise?

Do

- Divide the class into four groups of maximum six participants depending on the batch size.
- Give one case study to each group.
- Instruct them to read the case carefully.
- Put down the de-brief questions on the board and ask the groups to focus their discussion around these questions.
- The group is expected to analyse and discuss the case amongst them and find a solution to the given problem. Give the class 5-10 minutes to discuss the case and note down their solutions.
- At the end of 10 minutes the team should present their case solution to the class. The presentation can be a narration or a role play.
- Ask the group to select a group leader for their group. The group leader to discuss and assign roles to the group members for the presentation.

Team Activity

Case Study Analysis

Scenario 1

Aakash has a small mobile retail sales and repair shop in Allahabad. He has one of the most popular outlets and has great rapport with his customers.

It's around 11 AM when a customer barges in to the shop and starts shouting at Aakash for giving her a faulty instrument. The screen of her mobile is cracked from one side. Aakash remembered thoroughly checking the handset before handing it over to the customer. The customer threatens to sue him and to go to Consumer Court for cheating her. Now, the problem occurred somewhere outside the shop but as other customers were listening to the conversation, it might impact his business. The situation needs to be managed very sensitively. What would you do if you were in Aakash's place?

Scenario 2

Rajni does beautiful Phulkari embroidery on suits and sarees. She has a small home-based business. She has a huge list of customers on Facebook and WhatsApp who give her orders regularly. Smita is one of her old and regular customers. As her sister-in-law's wedding was around the corner, Smita wanted to buy few handcrafted Phulkari duppatta. She placed an order for three duppattas via WhatsApp and requested Rajni to send them as soon as possible. When the parcel reached Smita through courier she found that out of the three duppattas, only one was hand embroidered and the other two had machine embroidery on them. Even the length and the quality of the material was not as desired. Smita was heartbroken. It was a complete waste of money and moreover she couldn't wear what she had planned to during the wedding functions. She sent a message to Rajni on WhatsApp, expressing her anger and disappointment.

Smita has also sent a feedback and expressed her disappointment on the social media... this will directly affect Rajni's business. What would you do if you were in Rajni's place?

Scenario 3

Shankar is a tattoo artist who has a small tattoo showroom in a big, reputed mall in New Delhi. Mr Saksham had an appointment for today, at 11:00 am but he reached at 11:50 am. Meanwhile, Shankar had to reschedule his next appointment. After availing Shankar's services, Mr Saksham started yelling in an abusive language, refusing to pay the requisite amount, and finding faults in the services provided by him. Who was at fault in this case? What should Shankar do? Should he confront Saksham or give in to the demands of the client?

Scenario 4

Shailender is an online cloth reseller who does business through social networking sites such as Facebook and WhatsApp. Priyanka made online payment for a dress to Shailender. But she did not receive the dress for a month. When she asked for a cancellation, Shailender started misleading her. For almost 45 days, he kept promising her that he will pay the amount today, tomorrow, day after etc. Even after repeated calls and messages when she did not receive the payment or the dress, she decided to write a post against him on a popular social media platform. As a result, Shailender lost lots of customers and his flourishing business faced a major crisis. How could this situation have been managed?

Say

- Now, let's discuss the problem and solution with the larger group.
- The group will first briefly describe the case to the class.
- Then discuss the issue identified and the proposed solution.
- Once the presentation is over, the class can ask their questions.

Do 

- Congratulate each group for the group presentation.
- Ask the audience to applaud for them.
- Ask de-brief questions to cull out the information from each group.
- Keep a check on time. Tell the group to wind up the discussion quickly if they go beyond the given time limit.

Summarize 

- Ask the participants what they have learnt from the exercise/ activity.
- Ask if they have any questions related to what they have talked about so far.
- Close the discussion by summarizing the importance of honesty and work ethics for entrepreneurs.

UNIT 9.1.5: Creativity and Innovation

Unit Objectives

At the end of this unit, participants will be able to:

- List the characteristics of highly creative people
- List the characteristics of highly innovative people

Resources to be Used

- Participant Handbook
- Chart papers
- Marker pens

Ask

- You must be aware of the term 'Rags to riches' and heard stories related to the term.
- What do these stories tell us?
- What was so special about these people?

Say

- Let's have a look at these stories.
- There are some inspiring stories about people which I would like to share with you.
- Narrate these stories to the class.

A.P.J. Abdul Kalam

Who has not heard of A.P.J. Abdul Kalam: Avul Pakir Jainulabdeen Abdul Kalam hailed from a very humble background. His father was a boat owner. To help his family, Kalam would work as a newspaper vendor. With limited resources, he graduated in Physics and studied aerospace engineering. He was instrumental in India's step towards nuclear energy. In 2002, he became the 11th President of India.

Water filter/purifier at source

Two young boys studying in classes 4 and 5, from Lingzya Junior High School, Sikkim designed a simple innovative low cost water purifier.

Inspiration behind the idea: Most people today prefer to use a water filter/purifier at their home.

Both the children have given idea to have filter/purifier at the source of water so that everyone has access to clean water without having to make an investment in purchasing a filter/purifier.

Spring's idea is to have a centralised purification system at the point of distribution like water tank while Subash's idea is to have such purifiers attached to public taps.

Source: <http://www.rediff.com/getahead/report/achievers-top-31-amazing-innovations-from-young-indians/20151208.htm>

Solar seeder

This is a story of a innovative solar seeder and developed by Subash Chandra Bose, a class 8, student from St Sebasthiyar Matriculation School, Pudukkottai, Tamil Nadu. Subash has developed a solar powered seed drill, which can undertake plantation for different size of seeds at variable depth and space between two seeds.

Source: <http://www.rediff.com/getahead/report/achievers-top-31-amazing-innovations-from-young-indians/20151208.htm>

Looms for physically challenged

Now this is really inspiring of two sisters, Elakkiya a Class 6 student and Pavithra a Class 9 student of SRC Memorial Matriculation, Erode, Tamil Nadu.

The two sisters have come up with loom for lower limbed physically challenged. In their loom they have replaced the pedal operated system with a motor and a gearbox attached to a pulley mechanism.

Source: <http://www.rediff.com/getahead/report/achievers-top-31-amazing-innovations-from-young-indians/20151208.htm>

Ask 

- If they can, why can't you?
- Discuss concepts related to 'Creativity and Innovation' with the participants as given in the Participant Handbook.

Say 

- Recall the stories on motivation.
- What is the inner drive that motivates people to succeed?
- Let's learn more about such creative and innovative entrepreneurs with the help of an activity.

Team Activity 

- This is a group activity.

- Think of any one famous entrepreneur and write a few lines about him or her.

Activity De-brief

- Why did you choose this particular entrepreneur?
- What is his/her brand name?
- What creativity does he/she possess?
- What was innovative about their ideas?

Do 

- Instruct the participants that this is group work.
- Divide the class into small groups of 4 or 6 depending on the batch size.
- Give each group a chart paper.
- Tell the participants they have to write a few lines about any one famous entrepreneur.
- Give the participants 10 minutes to discuss and write.
- Keep a check on time. Tell the group to wind up quickly if they go beyond the given time limit.
- Ask each group to read out what they have written.
- Ask the de-brief questions.

Summarize

- Summarize the unit by asking participants if they know of some people who are highly creative and innovative in their approach.
- Ask them to share some experiences about these people with the class.

Notes for Facilitation

- Source for stories on innovations:

<http://www.rediff.com/getahead/report/achievers-top-31-amazing-innovations-from-young-indians/20151208.htm>

UNIT 9.1.6: Time Management

Unit Objectives

At the end of this unit, participants will be able to:

- Discuss the benefits of time management
- List the traits of effective time managers
- Describe effective time management techniques

Resources to be Used

- Participant Handbook

Ask

Does this sound like you?

- I can never get enough time to finish what I am doing in a day.
- I have so many things to do that I get confused.
- I want to go for a walk and exercise, but I just do not have the time.
- I had so much to do, so I could not deliver that order on time.
- I would love to start my dream business; but, I just do not have the time.

Example

- Let's look at these two examples:

Example 1:

Ankita works from home as a freelance writer. She says she can easily put in 8 hours of dedicated work in a day. Because she works from home, she saves money on travel and has a comfortable work routine. But there is a challenge and it is distraction. As she works from home, she can easily just get up and sit down on the sofa to watch TV, wasting valuable time. She may have chores to do, errands to run and bills to pay. She ends up working only two to three hours a day and the result is, her work gets piled up. She is unable to take on more work due to this. Even though her quality of work is appreciated her clients are not very happy about the delay in submission.

Example 2:

Javed has started a successful online selling company from home and makes a good living from his sales. He has set up a small office space in his living room. As both his parents are working full-time, he also has the role of taking care of his two younger siblings. He almost spends half of his day with the younger kids. He does not mind it but it means taking time away from the work. He is still able to manage his online business with these commitments. He wants to spend some more dedicated hours so as to increase his profits. He also wants to look into new business avenues. What should he be doing.

Ask

- Does this happen with you too?
- Do you find it difficult to prioritize your work?
- Are you able to manage your time effectively?

Activity

- Conduct a group discussion based on the above examples.
- Direct the discussion on how to prioritize work and manage time effectively.

Say

- Time management is not only about how hard you work but also about how smart you work.
- Discuss “What is Time Management” with the participants as given in the Participant Handbook.

Ask

- Why is it important to manage time? How does it help?
- What happens when you don't manage your time effectively?
- Do you find it difficult to prioritize your work?

Say

- Discuss the benefits of time management given in the Participant Handbook.
- Let's learn effective time management with the help of an activity.

Activity

Effective Time Management

- This activity has two parts:

PART 1 TO-DO LIST

- You have to make a to-do list.
- List all of the activities/ tasks that you have to do.
- Try to include everything that takes up your time, however unimportant it may be.
- If they are large tasks, break them into action steps, and write this down with the larger task.
- You can make one list for all your tasks or have separate to-do lists for personal and professional tasks.

PART 2 URGENT-IMPORTANT GRID

- You have to make a grid as shown on the board here. .
- This grid has four boxes. As you can see, each box has a different heading.
- At the heart of the urgent-important grid, are these two questions:
 - ♦ Is this task important?
 - ♦ Is this task urgent?
- Now, you have to think about each activity that you have written in your to-do list and put it into one of the four categories.
- **What do these categories depict?**
- **Category 1: Urgent/Important**
 - ♦ This category is for the highest priority tasks. They need to get done now.

- **Category 2: Not Urgent/Important**
 - This is where you want to spend most of your time.
 - This category allows you to work on something important and have the time to do it properly.
 - This will help you produce high quality work in an efficient manner.
 - The tasks in this category are probably the most neglected ones, but also the most crucial ones for success.
 - The tasks in this category can include strategic thinking, deciding on goals or general direction and planning – all vital parts of running a successful business.
- **Category 3: Urgent/Not Important**
 - This is where you are busy but not productive. These tasks are often mistaken to be important, when they're most often busywork.
 - Urgent but not important tasks are things that prevent you from achieving your goals.
 - However, some may be activities that other people want you to do.
- **Category 4: Not Important and Not Urgent**
 - This category doesn't really include tasks, but rather habits that provide comfort, and a refuge from being disciplined and rigorous with your time management.
 - Some may be activities that other people want you to do.
 - These might include unplanned leisure activities as well.

TO- DO list format

1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
11.	
12.	
13.	
14.	
15.	

URGENT-IMPORTANT GRID

URGENT/ IMPORTANT

- Meetings
- Last minute demands
- Project deadlines
- Crisis

NOT URGENT/ IMPORTANT

- Planning
- Working towards goals
- Building relationship
- Personal commitments

1

2

3

4

- Interruptions
- Phone calls/ E-mails
- Other people's minor demands

URGENT/ NOT IMPORTANT

- Internet surfing
- Social media
- Watching TV

NOT URGENT/ NOT IMPORTANT

URGENT/ IMPORTANT GRID format

URGENT/ IMPORTANT

NOT URGENT/ IMPORTANT

1

2

3

4

URGENT/ NOT IMPORTANT

NOT URGENT/ NOT IMPORTANT

Do

- Put down the formats for the to-do list and the urgent/important grid on the board.
- Instruct the participants to prepare their to-do list first.
- Give the participants 10 minutes to prepare the list.
- Once done, instruct them to divide the tasks in to-do list into the four categories.
- Explain the four categories to the participants giving examples specific to their context.
- As you explain the categories fill the grid with the type of tasks.
- Give the participants 40 minutes to fill the grid.
- Then explain how to balance the tasks between the four categories.
- Keep a check on time. Tell the group to wind up quickly if they go beyond the given time limit.

Say

Activity De-brief:

How can we balance tasks between the four categories?

How to manage time through this grid?

- **Category 1: Urgent/Important**
 - ♦ Try to keep as few tasks as possible here, with the aim to eliminate.
 - ♦ If you spend too much of your time in this category, you are working solely as a trouble shooter, and never finding time to work on longer-term plans.
- **Category 2: Not Urgent/Important**
 - ♦ Plan these tasks carefully and efficiently as they are most crucial ones for success.
 - ♦ If necessary, also plan where you will do these tasks, so that you're free from interruptions.
 - ♦ Include strategic thinking, deciding on goals or general direction and planning in your planning process.
- **Category 3: Urgent/Not Important**
 - ♦ Ask yourself whether you can reschedule or delegate them.
 - ♦ A common source of such activities is other people. Sometimes it's appropriate to say "no" to people politely, or to encourage them to solve the problem themselves.
- **Category 4: Not Important and Not Urgent**
 - ♦ You also want to minimize the tasks that you have in this category.
 - ♦ These activities are just a distraction – avoid them if possible.
 - ♦ You can simply ignore or cancel many of them.
 - ♦ Politely say "no" to work assigned by others, if you can, and explain why you cannot do it.
 - ♦ Schedule your leisure activities carefully so that they don't have an impact on other important tasks.
- Discuss the traits of effective time managers and effective time management techniques as given in the Participant Handbook.

Summarize

- Discuss the traits of effective time managers and effective time management techniques as given in the Participant Handbook.

Notes for Facilitation



- Here is a short story. You can conclude the session narrating the story. To make it more interesting you can perform the demonstration described and discuss the short story.
 - ♦ One day an expert in time management was speaking to a group of students. As he stood in front of the group, he pulled out a large wide-mouthed glass jar and set it on the table in front of him. Then he took out a bag of about a dozen rocks and placed them, one at a time, into the jar. When the jar was filled to the top and no more rocks would fit inside, he asked, "Is this jar full?" Everyone in the class said, "Yes." Then he said, "Really?"
 - ♦ He reached under the table and pulled out a bucket of gravel (small stones). He dumped some gravel in and shook the jar causing pieces of gravel to work themselves down into the space between the rocks. Then he asked the group once more, "Is the jar full?" By this time, the class began to understand. "Probably not," one of them answered. "Good!" he replied.
 - ♦ He reached under the table and brought out a bucket of sand. He started dumping the sand in the jar and it went into all of the spaces left between the rocks and the gravel. Once more he asked the question, "Is this jar full?" "No!" the class shouted. Once again he said, "Good." Then he grabbed a jug of water and began to pour it in until the jar was filled to the brim. Then he looked at the class and asked, "What is the point of this illustration?" "One student raised his hand and said, "No matter how full your schedule is, if you try really hard you can always fit some more things in it!" "No," the speaker replied, "that's not the point. The truth this illustration teaches us is: If you don't put the big rocks in first, you'll never get them in at all." What are the 'big rocks' in your life? Your children; your loved ones; your education; your dreams; a worthy cause; teaching or mentoring others; doing things that you love; time for yourself; your health; your mate (or significant other). Remember to put these BIG ROCKS in first or you'll never get them in at all. If you sweat about the little stuff (the gravel, sand, and water) then you'll fill your life with little things you worry about that don't really matter, and you'll never have the time you need to spend on the big, important stuff (the big rocks).
- End the story with these lines...

So, tonight, or in the morning tomorrow, when you are reflecting on this short story, ask yourself this question: What are the 'big rocks' in my life? Then, put those in your jar first

UNIT 9.1.7: Anger Management

Unit Objectives

At the end of this unit, participants will be able to:

- Discuss the importance of anger management
- Describe anger management strategies
- Discuss tips for anger management

Resources to be Used

- Participant Handbook

Ask

- What is anger? Is anger good or bad?
- Is anger normal or an abnormal behaviour? How can anger harm you?
- Why is it important for entrepreneurs to manage their anger?

Say

- Talk about anger and the importance of anger management in entrepreneurs as discussed in the Participant Handbook.
- Let us do a small activity. This is an individual activity.
- Think of the incidents and situations that angered you and hurt you.

Do

- Instruct them to note down these situations under different categories (as given in the Activity).
- Give the class 3-5 minutes to think and note down their answers.
- At the end of 5 minutes, ask some participants to volunteer and present their answers.
- They can also share these situations with their fellow participants if they do not wish to share it with the entire class.

Activity

- Do you remember any incident which has hurt
 - ♦ you physically
 - ♦ you mentally
 - ♦ your career
 - ♦ your relationships.

Ask

- Do you ever get angry?
- What are the things that make you angry?
- Do you remember any incident where your anger management helped you in maintaining healthy relationship?
- Do you remember any incident where someone lost business/ friend/ relationship due to temper (anger)?

Say

- There are a few strategies which can help in controlling your anger. Let's do an activity to understand the anger management process better.
- This is an individual activity.
- Think of the incidents/ situations which trigger your anger (the cause).
- Then think what happened as a result of your anger (the effect).
- You need to come up with some techniques to manage your anger.

Do

- Give the class the anger triggers (the cause) as listed in the activity.
- Put down the activity format (Anger Triggers, Result of your Anger, Anger Management Techniques) on the board and instruct the class to write the answers under different categories.
- Give the class 3-5 minutes to think and note down their answers.
- At the end of 5 minutes, ask the participants who wish to volunteer and present their answers.

Activity

Trigger points and Anger Management Techniques Activity

Anger Triggers

List of triggers that make you angry:
Someone says you did something wrong.
You want something you can't have now.
You get caught doing something you shouldn't have been doing.
You are accused of doing something you didn't do.
You are told that you can't do something.
Someone doesn't agree with you.
Someone doesn't do what you tell him to do.
Someone unexpected happens that messes up your schedule.

Result of your anger:

--

Write the techniques that you use to manage your anger:

Anger Management Techniques

Say

- Now, let's discuss the problems and solution with all.
- The individual will first briefly describe trigger points to the class.
- Then discuss the result of the anger. Other participants are requested to remain quiet while one is making the presentation.
- Post presentation, other participants may ask questions.

Do

- Congratulate each individual for sharing their points.
- Ask the audience to applaud for them.
- Ask de-brief questions after the presentation to the class.
- Keep a check on the time. Ask the participants to wind up the activity quickly if they go beyond the given time limit.

Ask

De-brief questions:

- In the situation described by the presenter, who was at fault?
- How could you have handled this situation alternatively?

Summarize

- Close the discussion by summarizing the strategies and tips of anger management for entrepreneurs.
- Ask the participants what have they learnt from this exercise/ activity.
- Ask if they have any questions related to what they have talked about so far.

Notes for Facilitation

- Encourage the participants to share information about them while presenting the situations to the class.
- Keep the format of the Activity prepared in a chart paper so that it can be displayed during the session.

UNIT 9.1.8: Stress Management: What is stress?

Unit Objectives

At the end of this unit, participants will be able to:

- Discuss the causes of stress
- Discuss the symptoms of stress
- Discuss tips for stress management

Resources to be Used

- Participant Handbook

Ask

- You are waiting in the reception for an interview or a very important meeting, suddenly your legs are shaky, your hands are cold, you are feeling nervous. Have you ever been in this kind of situation?
- Have you had days when you had trouble sleeping?
- Have you ever been so worried about something that you ended up with a terrible headache?

Say

- You've probably heard people say, "I'm really stressed out" or "This is making me totally stressed."

Ask

- What do you understand by stress?
- What gives you stress?
- How do you feel when you are stressed or what are the symptoms of stress?
- How can stress harm you?
- Why is it important for entrepreneurs to manage stress?

Say

- When we feel overloaded or unsure of our ability to deal with certain challenges, we feel stressed.
- Discuss about stress, causes of stress, and symptoms of stress as discussed in the Participant Handbook.
- Let's understand the causes of stress and how to deal with them with the help of some case scenarios.
- You will be given some cases.
- You have to analyse the case scenario and then find an appropriate solution to the problem.
- This will be a group activity.

Do

- Divide the class into four groups of 5-6 participants (depending on the batch size).
- Assign one case scenario to each group.
- Instruct them to read the case carefully.
- The group is expected to analyse and discuss the case amongst them and find a solution to the given problem.
- Explain their discussion should result in getting answers for the following questions:

- ♦ What was/ were the cause(s) of stress?
- ♦ Was the stress avoidable or manageable under the given circumstances?
- ♦ If yes, how do you think that the stress could be avoided (managed)?
- ♦ If no, then why not?
- Give the class 10-12 minutes to discuss the case and note down their solutions.
- At the end of 12 minutes, the team should present their case solution to the larger group.
- Ask the group to select a group leader for their group.
- The group leader to discuss and assign roles to the group members for the presentation.

Team Activity

Case Study Analysis

Scenario 1

Akash's alarm doesn't go off and he gets late getting out of the house. He hits traffic and ends up 15 minutes late to work, which his boss notices. He gets to his desk and finds he has to complete 2 reports in next one hour. Just when he is about to begin work, a message pops up "Telecon with the client begins in 10 minutes. Please be in the conference room in 5 minutes."

His is not prepared for the call. He is stressed. He does not want to speak to his boss about this. He is stressed, feeling uncomfortable and sick. Not in a position to attend the call or finish the reports on time.

Scenario 2

While paying his overdue bills, Rahul realised that it's the middle of the month and he has only Rs 500 left in his account. He has already asked all of his friends, and family for loans, which he hasn't paid back yet. He is still contemplating over the issue when his phone rings. His sister's birthday is due next week and she has seen a beautiful dress which she wants to buy but cannot tell the parents as it is a bit expensive. She wishes if Rahul could buy the dress for her. Rahul has promised to buy her the dress for her birthday.

Rahul is stressed, does not understand what to do. He is unable to concentrate on his work and unable to complete the tasks assigned. His team leader has already warned him of the delay.

Scenario 3

Sheela calls the cable company as she has unknown charges on her bill. She has to go through the automated voice mail menu three times and still can't get through to a customer care executive. After 15 minutes of repeated efforts, her call is answered. She explains the entire issue to the customer care executive but before the person could suggest a way out, the call drops.

Now Sheela has to call back and repeat the whole process all over again with a new customer care executive. She is very angry and calls again but cannot connect this time.

She has to leave to office so she decides to call from office and check. When she connects this time she is angry and argues with the executive on the call. All her co-workers around are looking at her as her volume has suddenly increased. She bangs the phone and ends the call.

Her co-worker Neelam enquires what has happened to her. She ignores her and just walks off. She has become irritable and her behaviour and tone with other co-workers is not acceptable.

Scenario 4

Arpit is a young entrepreneur who started doing business through Facebook few weeks back. He had always been into a job. Although Arpit has very few financial liabilities, it wasn't an easy decision to leave a comfortable job at once and look for newer pastures. Arpit's boss warned him of the consequences and the challenges of starting a business when nobody ever in his family had been in business.

He has not been able to get a good deal till now. This is an important life shift for him which comes with unknown variables. Arpit is nervous and is wondering if he has what it takes to fulfill the requirement of his new role, or the new experiences he's likely to face.

Ask**De-brief questions:**

- What was/ were the cause(s) of stress?
- Was the stress avoidable or manageable under the given circumstances?
- If yes, how do you think that the stress could be avoided (managed)?
- If no, then why not?

Say

- Now, let's discuss the problem and solution with the larger group.
- The group will first briefly describe the case to the class.
- Then discuss the issue identified and the proposed solution.
- Post presentation, the other groups may ask questions to the group that has presented.

Do

- Congratulate each group for sharing their points.
- Ask the audience to applaud for them.
- Ask de-brief questions to cull out the information from each group.
- Keep a check on time. Tell participants to wind up the discussion quickly if they go beyond the given time limit.

Say

- While it is common and normal to feel some tension. This feeling nervous and tensed can interfere with your thinking process and can have a negative impact on your performance.
- Stress can deplete the most vibrant of souls. It can have a negative effect on every aspect of a person's life including their health, emotional well-being, relationships, and career. However, one needs to understand the causes and types of stress before looking for ways to manage it.

De-brief:**Scenario 1**

The cause of stress was lack of time management and the habit of procrastinating. If Akash would have managed his time well, planned alternate ways to get up on time, finished prior tasks on time and planned for client meetings in advance then he wouldn't have faced stress.

Scenario 2

The cause of stress was lack of financial planning. Rahul should have planned his financial resources well in advance and saved some money for the rainy day. Also, differentiating between needs and wants and keeping a check on non-essential expenditure would have saved Rahul from this situation.

Scenario 3

Sometimes, stress is caused due to external factors instead of internal ones. In this case, the stress was unavoidable because we have no control over this customer care system. Every time, you will get in touch with a new executive and will have to explain all over again. This might cause stress but despite being frustrated and angry there is little that we can do about it. All Sheela could do was to find ways to calm herself down through some breathing exercises and meditation, reading some good book or listening to music and then start afresh.

Scenario 4

A positive, major life change can be a source of good stress. Regardless of how good the change is, it can be stressful. Stress caused by a positive and major life change can be beneficial because it causes a person to step out of their comfort zone and learn new skills. Here, Arpit may become a successful entrepreneur or learn new ways to do things differently.

Now let us see this scenario, can I have a volunteer to read out this case to the class.

Do 

- Ask one of the participant who can volunteer and read out this scenario to the class.

Scenario 5

Rakesh lives in Kathmandu with his wife and two beautiful daughters Sarah and Sanya. Nepal was hit by a massive earthquake and Rakesh's building collapsed during the earthquake. During evacuation, Rakesh realised that though his wife and Sarah were fine and suffered only minor bruises, Sanya was nowhere in the scene. Panic stricken, he started calling her name and searching her frantically. A little later, he heard a meek voice from beneath the debris. He quickly removed the rubble to find a huge bed. Rakesh was pretty sure that Sanya was trapped underneath. Though he was badly bruised, he gathered all his courage and with all his might, he lifted the several-ton bed to save Sanya's life. Everyone was relieved to see Sanya alive and also extremely surprised to see this father's ability to access superhuman strength.

- Ask the audience to applaud for the participant after the scenario is read completely.
- Discuss the scenario, ask de-brief questions:
 - ♦ What kind of stress was Rakesh undergoing in this case?
 - ♦ Was the stress avoidable or manageable under the given circumstances?
 - ♦ What was the result of the stress?

Say **De-brief:**

- Not all stress is harmful; good stress is actually energizing. This was a case of lifesaving stress, or hero stress, which is an important example of good stress. You may have heard stories in which a person performs an impossible feat of physical strength in order to save their life or the life of someone they love. This type of stress causing a surge of adrenaline is good for us.

Summarize

- Close the discussion by summarizing the tips to manage stress as given in the Participant Handbook.
- Ask the participants what they have learnt from this exercise/ activity.
- Ask if they have any questions related to what they have talked about so far.

Notes for Facilitation

- Keep printed copies of the activities/ scenarios ready for the session.
- Put down the de-brief questions on a flip chart so that it can be displayed in the class during the activity.
- Encourage participation and make the discussions interactive.

UNIT 9.2: Digital Literacy: A Recap

Key Learning Outcomes



At the end of this unit, participants will be able to:

1. Identify the basic parts of a computer
2. Identify the basic parts of a keyboard
3. Recall basic computer terminology
4. Recall the functions of basic computer keys
5. Discuss the main applications of MS Office
6. Discuss the benefits of Microsoft Outlook
7. Identify different types of e-commerce
8. List the benefits of e-commerce for retailers and customers
9. Discuss Digital India campaign will help boost e-commerce in India
10. Describe how you will sell a product or service on an e-commerce platform

UNIT 9.2.1: Computer and Internet Basics: Basic Parts of a Computer

Unit Objectives

At the end of this unit, participants will be able to:

- Identify the basic parts of a computer
- Identify the basic parts of a keyboard
- Recall basic computer terminology
- Recall the functions of basic computer keys

Resources to be Used

- Participant Handbook
- Computer Systems with the required applications

Say

- Let's take a quick recap of the basic computer parts.
- Discuss 'Basic Parts of Computer' and 'Basic Parts of a Keyboard' with the class as given in the Participant Handbook.

Explain

- Explain all the parts of the computer and the keyboard by demonstrating on the real system.

Ask

- Do you know about internet?
- Have you ever used internet?
- Why do you think internet is useful?
- What was the last task you performed on internet?

Say

- Let's look at some basic internet terms.
- Discuss 'Basic Internet Terms' with the participants as given in the Participant Handbook.

Summarize

- Ask the participants what they have learnt from this exercise/ activity.
- Ask if they have any questions related to what they have talked about so far.
- Close the discussion by summarizing the importance of computer and internet for entrepreneurs.

Practical

- Conduct a practical session.
- Ask the participants to assemble in the computer lab.
- Give some hands on practice exercises.

Do

- Group the participants for the activity depending on the batch size and the number of computer systems available in the lab.
- Explain the purpose and duration of the activity.
- Ensure the participants complete the practical exercises assigned.

UNIT 9.2.2: MS Office and Email: About MS Office

Unit Objectives

At the end of this unit, participants will be able to:

- Discuss the main applications of MS Office
- Discuss the benefits of Microsoft Outlook

Resources to be Used

- Participant Handbook
- Computer Systems with MS Office

Ask

- What is the most frequent activity that you do on the computer?
- Do you know how to make presentations on the computer?

Say

- Give a brief introduction of MS Office as given in the Participant Handbook.
- Discuss the most popular office products. Explain in brief their application, benefits and working.
- **Microsoft Word** is a word processing program that allows for the creation of documents. The program is equipped with templates for quick formatting. There are also features that allow you to add graphics, tables, etc.
- **Microsoft Excel** is a tool for accounting and managing large sets of data. It can also simplify analysing data. It is also used to create charts based from data, and perform complex calculations. A Cell is an individual data box which will have a corresponding Column and Row heading. This gives the cell a name, referred to as the Cell Reference. There can be multiple pages in each workbook. Each page, or sheet, is called a Worksheet. When you open a new Excel file, it automatically starts you with three worksheets, but you can add more.

Explain

- Explain the working and frequently used features of Office on a real system.

Ask

- What do you know about e-mails?
- Do you have an email id?
- How often do you check your e-mails?

Say

- Communication is vital for every business. The fastest and the safest way to communicate these days are through emails. MS Outlook helps to manage your emails in a better way and also offers a host of other benefits.
- Discuss “Why Choose Microsoft Outlook?” with the participants as given in the Participant Handbook.

Do 

- Ask the participants to assemble in the computer lab.
- Explain the working of Outlook on a real system..

Demonstrate 

- Demonstrate how to create email id.
- Demonstrate how to write new mails, send mails.
- Demonstrate how to use MS Office application to create a letter and send it as attachment in an email.
- Demonstrate how to use other MS Office applications.

Practical 

- Give some hands on practice exercises
- Group the participants for the activity depending on the batch size and the number of computer systems available in the lab.
- Explain the purpose and duration of the activity.

Summarize 

- Ask the participants what they have learnt from this exercise/ activity.
- Ask if they have any questions related to what they have talked about so far.

UNIT 9.2.3: E-Commerce

Unit Objectives

At the end of this unit, participants will be able to:

- Identify different types of e-commerce
- List the benefits of e-commerce for retailers and customers
- Discuss Digital India campaign will help boost e-commerce in India
- Describe how you will sell a product or service on an e-commerce platform

Resources to be Used

- Computer System with internet connection
- Participant Handbook

Ask

- How many of you have done shopping online?
- Can you name at least five shopping websites?
- What is the product that you most frequently buy online?
- Why do you do shopping online instead of going to the market?

Say

- Give a brief introduction of “What is E-commerce”. Refer to the Participant Handbook.
- E-commerce emerged in the early 1990s, and its use has increased at a rapid rate. Today, many companies sell their products online. Everything from food, clothes, entertainment, furniture and many other items can be purchased online.

Ask

- What other types of transactions have you performed on the internet other than buying products?

Say

- Give examples of e-commerce activities from Participant Handbook.

Team Activity

E-commerce examples

- Instruct the participants to list some of the payment gateways that they have used for e-commerce activities.
- Give them 5 minutes to make this list.
- Discuss payment gateways and transaction through payment gateways.
- Conclude the discussion by mentioning how important e-commerce has become in our day to day transactions.

Say

- E-commerce activities can be classified based on the types of participants in the transaction.
- Discuss “Types of E-commerce” from the Participant Handbook.

Do

- Discuss all types of E-commerce by giving examples and names of some popular websites which use them.
- Make the discussion interactive by asking the class to share some popular e-commerce sites of each type.

Say

- E-commerce activities bring a host of benefits for both, retailers and customers.
- Discuss benefits of E-commerce from the Participant Handbook.

Explain

- The majority of the population that uses E-commerce activities lives in tier-1 and tier-2 cities. To encourage the use of digital money in tier-3 and 4 areas, PM Mr. Modi launched the “Digital India Campaign”.
- Discuss “Digital India Campaign” from the Participant Handbook.
- By Digital India project the government will deliver services via mobile connectivity and in doing so, is expected to bring the internet and broadband to remote corners of the country. This connectivity will in turn enhance e-commerce activities also. Furthermore, the Indian Government is also modernizing India Post and aims to develop it as a distribution channel for e-commerce related services.

Say

- Now let us discuss how to sell a product using E-commerce.
- Every product has to be sold on a platform on the internet. Think of it as a shop that you have to sell your product. Now this shop can be your own or shared or rented. If the shop is your own or rented there will be only your products in that shop. If the shop is shared, there will be products of multiple sellers in that shop. A common example is a departmental store which has products from multiple brands in the shop.
- Similarly, in E-commerce the shop is the website where your products are displayed. If it is your own website it will exclusively showcase your products. In this case the cost that you will incur will be:
 - Developing the website
 - Hosting the website
 - Maintenance of the website
- If you rent a website it will also showcase your own products but the development, hosting and maintenance parts goes to the owner. This saves time and the cost to manage these activities.
- Smaller companies usually go for renting a website and the bigger ones develop their own website.
- The concept of shared platforms has become very popular in recent times. In this platform the sellers have to register and then they can sell their goods on a common platform. Among the most popular of these are Amazon, Myntra, Flipkart, etc.

Role Play

- Tell the participants to choose a product or service that they want to sell online.
- Tell them to write a brief note explaining how they will use existing e-commerce platforms, or create a new e-commerce platform to sell their product or service.

Ask 

- How much money are you carrying in your wallet?
- Do you have a credit/debit card?
- How do you make payments while doing online shopping?

Say 

- Demonetization has made carrying cash in the wallet very difficult. People either shop through cards or some other form of digital money.
- So what do you think is digital money?
- In this form the money is both paid and received digitally. There is no hard cash involved. It is an instant and convenient way to make payments.
- There are various types of digital payments. Let us discuss some of them in brief here.
- The first one is the most commonly used system i.e. the cards. Debit card, credit card, prepaid card, all fall under this category.
- Then is the e-wallet or the mobile wallet. This has become the most used form of digital money after demonetization. Examples are Paytm, state bank buddy, Freecharge, etc.
- Many other forms of digital money are also coming up in market like mobile apps, Aadhar card based payment, etc.

Do 

- Demonstrate how to make and receive payments through digital models like Paytm and state bank buddy.

Ask 

- Why do you think people have started using digital money instead of hard cash? Is demonetization the only reason?

Say 

- Digital money gives a lot of advantages over the conventional hard cash. Some of them are:
 - ♦ Digital payments are easy and convenient. You do not need to take loads of cash with you, a mobile phone or a card will suffice.
 - ♦ With digital payment modes, you can pay from anywhere anytime.
 - ♦ Digital payments have less risk.

Summarize 

- Ask the participants what they have learnt from this exercise/ activity.
- Ask if they have any questions related to what they have talked about so far.
- Close the discussion by summarizing the importance of e-commerce and digital money.

UNIT 9.3: Money Matters

Key Learning Outcomes

At the end of this unit, participants will be able to:

1. Discuss the importance of saving money
2. Discuss the benefits of saving money
3. Discuss the main types of bank accounts
4. Describe the process of opening a bank account
5. Differentiate between fixed and variable costs
6. Describe the main types of investment options
7. Describe the different types of insurance products
8. Describe the different types of taxes
9. Discuss the uses of online banking
10. Discuss the main types of electronic funds transfer

UNIT 9.3.1: Personal Finance – Why to Save?

Unit Objectives

At the end of this unit, participants will be able to:

- Discuss the importance of saving money
- Discuss the benefits of saving money

Resources to be Used

- Participant Handbook

Ask

- How many of you save money?
- Why do you feel the need to save it?
- Do you plan your savings?
- Where do you keep the money you save?
- How do you use the money that you have saved?

Example

- Let's look at these two examples:

Example 1:

Suhani works in a good company and earns Rs.30,000 month. She always saves 5000 per month and keeps it aside as a personal saving. She keeps the money at home and has saved quite a lot. One day her mother has a medical emergency and has to be taken to the hospital. Her family is worried about the amount they have to spend for the treatment. It will cost them atleast 40,000.

Suhani says tells her family not to worry and that she has about 50,000, which she has saved over the months.

Example 2:

Jasmeet works in the same company and earns the same as Suhani. She is very fond of shopping and spends most of her money on buying new clothes. At the end of the month, she is always asking her father for money as her pay is finished.

Ask

- Who do you identify with –Suhani or Jasmeet ?
- How do you think Suhani manages to save money which Jasmeet is unable to do?

Say

- We should always set aside some and save some money from our monthly pay. The future is unpredictable. Saving money not only gives you a sense of financial security but it can be used in case of emergencies.
- Discuss “Importance of Saving” with the participants as given in the Participant Handbook.

Ask

- What are the benefits of saving money?
- What does being financially independent mean to you?

Say

- Discuss “Benefits of Saving” with the participants as given in the Participant Handbook.
- Now let us continue with Suhani's story. Suhani has told her family not to worry and that she has about 50,000, which she has saved over the months. The family is happy about Suhani's decision of saving money, which will be of great help for them now.

Suhani is going to the hospital today to pay the first instalment for the treatment. Suddenly finds only 35,000 in her cash box when she counts and does not remember using it. She has not kept any record and now she is upset.

Ask

- Was it a good decision by Suhani to save a part of her earnings every month?
- Was it a wise decision to keep all her savings as cash in a cash box?
- Could she have managed to save money in a better and more effective manner?
- Do you want to learn how to save money and use it effectively?

Say

- Let's learn personal saving with the help of a group activity.

Team Activity

Personal Finance- Why to save

- This activity has two parts:

PART 1

WAYS TO SAVE MONEY

- You are earning 30,000/- per month. You have recently changed your job and have to move to a metropolitan city. You are now living as a paying guest paying 10,000/- per month. Your other estimated expenditures like travel, food, recreation would be around Rs. 17, 000 per month.
- Make a list of different ways to save money.

PART 2

HOW WILL YOU USE THE MONEY

- After a year how much have you been able to save?
- How will you use the money that you have saved?

Do

- Divide the class into groups of four.
- Instruct the participants to think and prepare a list of the various ways they can save money.
- Give the participants 10 minutes to prepare the list.
- Once done, instruct them to think of how they could use the money they have saved.
- Give the participants 10 minutes to prepare the list.
- Keep a check on time. Tell the group to wind up quickly if they go beyond the given time limit.

Activity De-brief

- What were the different ways you could save money?
- How much money were you able to save?
- How will you use the money you have saved in one year?

Say



- Discuss the importance of personal finance and why it is important to save money.

Summarize



You can summarize the session by discussing:

- The importance of saving money.
- Ways to save money.
- How the money saved can be used for different purposes.

UNIT 9.3.2: Types of Bank Accounts, Opening a Bank Account

Unit Objectives

At the end of this unit, participants will be able to:

- Discuss the main types of bank accounts
- Describe the process of opening a bank account

Resources to be Used

- Account opening sample forms
- Participant Handbook

Ask

- How many of you save money?
- Where do you keep the money you save?
- How many of you have a bank account?
- What type of account do you have?

Example

- Let's look at the given example:

Reena is in the third year of college but in the evening she gives tuitions for children living in her colony. She earns 15,000/- per month. As her students stay in different parts of the city, she has to walk a lot.

To save time, she decides to buy a second hand scooter for herself. But she has to save money for it. Her class mate advises her to open a recurring deposit account in the bank.

She goes to the bank close to her home. The personal manager gives her some forms to fill. She is confused as she has never done this before. Her elder sister has an account in the same bank. She asks for help from her sister. She goes to the bank the next day with her sister. The personal banker gives her a list of documents that she will need to submit with the form for opening an account. The banker advises her to open a 6 months recurring deposit.

Ask

- Do you try to save money monthly but have to spend it on unforeseen expenditure?
- Have you ever thought of depositing your savings in a bank?

Say

- Before opening a bank account, you need to know the types of accounts we have in India.
- Discuss “Types of Bank Accounts” with the participants as given in the Participant Handbook.

Ask

- Can someone say what are the different types of bank accounts?

Say

- Let's learn about the different types of bank accounts through an activity.

Team Activity

- Divide the class in four groups.
- Label the groups as savings account, current account, recurring account and fixed deposit.
- On a chart paper, ask them to write the key points of their account.

Activity De-brief

- Ask each group to present the key points of their account.

Say

- Now that you know about the four different types of accounts, let's learn how to open a bank account.
- Discuss "Opening a Bank Account" with the participants as given in the Participant Handbook.
- Discuss "Tips" that the participants should keep in mind while opening a bank account as given in the Participant Handbook.

Ask

- What are the main documents required for opening a bank account?
- What are some important points to ask the bank personnel while opening an account?

Say

- Mention officially valid KYC documents (refer to the Participant Handbook)
- Now, let's understand the procedure of opening a bank account through an activity.

Team Activity

Opening a Bank Account

- This activity is done in groups.
- Divide the class in groups of four or six.

PART 1

FILLING A BANK ACCOUNT OPENING FORM

- You have to fill a bank opening form.
- You can refer to the section "Opening a Bank Account" of your Handbook for reference.
- List all the steps that you will be required to fill in the form.
- List the documents that you needs for filling the form.
- Now fill in the form.

Activity De-brief

How did you design the form?

- What all details did you fill in the form?
- What were your KYC documents?
- How would this activity help you in future?

Do

- Instruct the participants to read the section "Opening a Bank Account" of the Participant Handbook.
- Give each group one sample account opening form.
- Give the participants 5 minutes to read the form.
- Give them 15 minutes to fill it.
- Assist them by explaining each category and how to fill it.
- Keep a check on time.
- Tell the group to wind up quickly if they go beyond the given time limit.

Summarize

Note:

- You can summarize the unit through a role play.
 - ♦ A person wanting to open an account in the bank.
 - ♦ What is the procedure that he will go through?
 - ♦ Discuss the key points of different types of bank accounts.
 - ♦ How to select the type of account
 - ♦ How to fill the account opening form.
- A sample account opening form is given in the following page for reference. Use it for the activity in the class.

Sample Bank Account Opening form.

Photograph	XXX Bank			
SAVING BANK ACCOUNT OPENING FORM				
Account No.: _____	Date: _____			
Name of the Branch				
Village/Town				
Sub District / Block Name				
District				
State				
SSA Code / Ward No.				
Village Code / Town Code	Name of Village / Town			
Applicant Details:				
Full Name	Mr./Mrs./Ms.	First	Middle	Last Name
Marital Status				
Name of Spouse/Father				
Name of Mother				
Address				
Pin Code				
Tel No. Mobile		Date of Birth		
Aadhaar No.		Pan No.		
MNREGA Job Card No.				
Occupation/Profession				
Annual Income				
No. of Dependents				

Detail of Assets	Owning House : Y/N	Owning Farm : Y/N
	No. of Animals :	Any other :
Existing Bank A/c. of family members / household	Y / N	If yes, No. of A/cs. _____
Kisan Credit Card	Whether Eligible	Y / N

I request you to issue me a **Rupay Card**.

I also understand that I am eligible for an Overdraft after satisfactory operation of my account after 6 months of opening my account for meeting my emergency/ family needs subject to the condition that only one member from the household will be eligible for overdraft facility. I shall abide by the terms and conditions stipulated by the Bank in this regard.

Declaration:

I hereby apply for opening of a Bank Account. I declare that the information provided by me in this application form is true and correct. The terms and conditions applicable have been read over and explained to me and have understood the same. I shall abide by all the terms and conditions as may be in force from time to time. I declare that I have not availed any Overdraft or Credit facility from any other bank.

Place:

Date:

Signature / LTI of Applicant

Nomination:

I want to nominate as under				
Name of Nominee	Relationship	Age	Date of Birth in case of minor	Person authorised in case to receive the amount of deposit on behalf of the nominee in the event of my /minor(s) death.

Place:

Date:

Signature / LTI of Applicant

Witness(es)*

1. _____

2. _____

*Witness is requires only for thumb impression and not for signature

UNIT 9.3.3: Costs: Fixed vs. Variables: What are Fixed and Variable Costs?

Unit Objectives

At the end of this unit, participants will be able to:

- Differentiate between fixed and variable costs

Resources to be Used

- Participant Handbook
- Blank sheets of paper
- Pens

Ask

- What is cost?
- Will a telephone bill fall under the category of a fixed or variable cost?

Say

- Discuss: Fixed and Variable cost with examples. Let us do a small activity.

Team Activity

Identify the type of cost

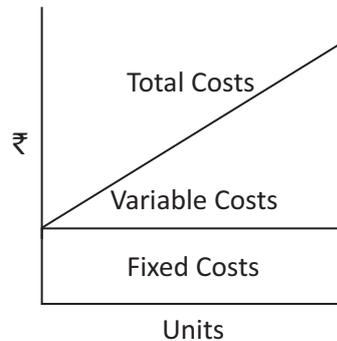
1. Rent
2. Telephone bill
3. Electricity bill
4. Machinery
5. Insurance
6. Office supplies/ Raw materials
7. Employee salaries
8. Commission percentage given to sales person for every unit sold
9. Credit card fees
10. Vendor bills

Do

- Divide the class into two groups. Read out the list of costs given in the activity.
- Read out each item from the cost list and ask the groups in turns to identify whether it is a fixed or variable cost.

Say

- We saw that your utility bills like rent, electricity, telephone etc. are all fixed costs because you have to pay it every month.
- Variable costs is an expense which varies with production output or volume. For example commission, raw material etc.
- Discuss “Cost: Fixed vs. variables” with the participants as given in the Participant Handbook.
- Illustrate the relation between the costs with a graph.



- Let's learn the difference between fixed and variable cost with the help of an activity.

Team Activity

Fixed vs. Variable Costs

- This is a group activity.

- You want to start your own entrepreneur business.
- State the type of business you want to start.
- List down all the cost or requirements for your business.
- How will you differentiate between the fixed and variable cost.

Activity De-brief

- What is the total cost of your business?
- What are the fixed costs?
- What are the variable costs?
- How did you differentiate between the fixed and variable costs?

Do

- Instruct the participants that this is group work.
- Divide the class into small groups of 4 or 6.
- Give each group a sheet of paper.
- Tell the participants that they have to start their own entrepreneur business.
- Ask them the type of business they want to start.
- Instruct them to differentiate between the fixed and the variable costs of the business they want to start.
- Give the participants 15 minutes to discuss and write.
- Keep a check on time. Tell the group to wind up quickly if they go beyond the given time limit.

Summarize

- Note: You can summarize the unit either by having a role play between a consultant and a budding entrepreneur explaining the differences between fixed and variable costs or by discussing the key points of the unit.

Notes for Facilitation

- Answers for the activity - Identify the type of cost

1. Rent	(Fixed)
2. Telephone bill	(Fixed)
3. Electricity bill	(Fixed)
4. Machinery	(Fixed)
5. Insurance	(Fixed)
6. Office supplies/Raw materials	(Variable)
7. Employee salaries	(Fixed)
8. Commission percentage given to sales person for every unit sold	(Variable)
9. Credit card fees	(Variable)
10. Vendor bills	(Variable)

UNIT 9.3.4: Investments, Insurance and Taxes

Unit Objectives

At the end of this unit, participants will be able to:

- Describe the main types of investment options
- Describe the different types of insurance products
- Describe the different types of taxes

Resources to be Used

- Participant Handbook

Ask

- Ask the participants- “What do you see first thing in when you get your mobile bill? Apart from the amount and due date do you have a look at the taxes you are being billed for?”
- Why do you think people get their cars insured or have a medical insurance?
- You have saved money and want to invest it, how would you decide what is the best investment for your money?

Example

- Let's have a look at a few scenarios.

Ranbir has sold his house and deposited the money in his bank. His Chartered Accountant tells him that he will have to re-invest the money otherwise he will have to pay capital tax. What is capital tax and how is it different from income tax?

Jasmeet and Anup are blessed with a baby girl. They decide to have an insurance policy that will mature when their daughter is ready to higher education.

Shivani is working in a corporate office and getting good pay. She will have to pay income tax so she decides to invest her money in tax saving schemes. She goes to the bank manager to discuss the best products in which she can invest.

Say

- Discuss the Investment, Insurance and Taxes as given in the Participant Handbook.

Ask

- How do investments, insurances and taxes differ from each other?

Say

- Let's learn the differences between the three by having an activity.

Say

- We will have a quiz today.

Team Activity

- The activity is a quiz.

Do

- Divide the class into groups of three and give a name to each group
- Explain the rules of the quiz. For each correct answer the group gets 1 mark. If the group is unable to answer the question is rolled over to the next group.
- Explain the purpose and duration of the activity.
- On the blackboard write the names of the groups.
- Ask the questions of the quiz.
- Keep a score for the groups.
- Set guidelines pertaining to discipline and expected tasks.

Summarize

- Summarize the unit by discussing the key points and answering question

Notes for Facilitation

Questions for the quiz

1. What are bonds?
Bonds are instruments used by public and private companies to raise large sums of money.
2. Who issues the bonds?
Private and public companies issue the bonds.
3. Why are bonds issued?
To raise large amount of money as it cannot be borrowed from the bank.
4. Who is the buyer of stocks and equities?
The general public is the buyer.
5. What types of scheme is the Sukanya Samriddhi Scheme?
Small Saving Scheme
6. What is the difference between mutual and hedge funds?
Mutual funds are professionally managed financial instruments that invest the money in different securities on behalf of investors. Hedge funds invest in both financial derivatives and/or publicly traded securities.
7. Why is a loan taken from the bank to purchase real estate?
To lease or sell to make profit on appreciated property price.
8. Name the two types of insurances?
Life Insurance and Non-life or general insurance
9. Which insurance product offers financial protection for 15-20 years?
Term Insurance
10. What is the benefit of taking an endowment policy?
It offers the dual benefit of investment and insurance.
11. Mr. Das gets monthly return on one of his insurance policies. Name the policy?
Money Back Life Insurance

12. What are the two benefits of a Whole Life Insurance?

It offers the dual benefit of investment and insurance

13. Which policy covers loss or damage of goods during transit?

Marine Insurance

14. After what duration is the income tax levied?

One financial year

15. What is long term capital gain tax?

It is the tax payable for investments held for more than 36 months.

16. Name the tax that is added while buying shares?

Securities Transaction Tax

17. What is the source of corporate tax?

The revenue earned by a company.

18. Name the tax whose amount is decided by the state?

VAT or Value Added Tax

19. You have bought a T.V. What tax will you pay?

Sales Tax

20. What is the difference between custom duty and OCTROI?

Custom duty is the charges payable when importing or purchasing goods from another country. OCTROI is levied on goods that cross borders within India.

UNIT 9.3.5: Online Banking, NEFT, RTGS, etc.

Unit Objectives

At the end of this unit, participants will be able to:

- Discuss the uses of online banking
- Discuss the main types of electronic funds transfer

Resources to be Used

- Participant Handbook
- Computer System with internet connection
- Debit card

Ask

- When was the last time you visited a bank?
- How do you pay your bill for electricity and telephone?
- Have you ever tried to transfer money from one bank account to another bank account using the online banking facility?

Say

- Most of us lead a busy life. Time has become more important than money. In this busy schedule no one has time to stand in bank queues. That's where Online Banking comes in. Online banking or internet banking means accessing your bank account and carrying out financial transactions through the internet.
- Discuss "What is online banking?" from the Participant Handbook.
- There are various advantages of online banking:
 - ♦ It saves time, as you need to visit the branch. .
 - ♦ You can conduct your banking transactions safely and securely without leaving the comfort of your home.
 - ♦ Online Banking also gives you round the clock access.
 - ♦ Online Banking makes it possible for you to pay your bills electronically.

Do

- Show them how they can use the internet banking.
- Use the computer system and show the demo videos on how to use internet banking provided on most banking sites. the computer system.
- Tell the class the various features of online banking:
 - ♦ Through their website set-up your online account.
 - ♦ Choose a secure username and password.
 - ♦ Set-up your contact information.
 - ♦ Once your information is verified, you are good to go.
 - ♦ Once you enter the portal explore all the features and learn your way through the portal.
- Discuss about maintaining the security of the online account.

Say

- One of the biggest advantage that online banking offers, as discussed earlier, is transferring money from one account to another. This transaction is called electronic funds transfer. Electronic transfers are processed immediately with the transferred amount being deducted from one account and credited to the other in real time, thus saving time and effort involved in physically transferring a sum of money.
- Discuss “Electronic Funds Transfer” from the Participant Handbook.

Do

- Discuss how to transfer money from one account to another using online banking (NEFT/ RTGS, etc.).
- Illustrate with an example.

Summarize

- Close the discussion by summarizing the about online banking.
- Ask the participants if they have any questions related to what they have talked about so far.

UNIT 9.4: Preparing for Employment & Self Employment

Key Learning Outcomes

At the end of this unit, participants will be able to:

1. Discuss the steps to follow to prepare for an interview
2. Discuss the steps to create an effective Resume
3. Discuss the most frequently asked interview questions
4. Discuss how to answer the most frequently asked interview questions
5. Identify basic workplace terminology

UNIT 9.4.1: Interview Preparation: How to Prepare for an Interview?

Unit Objectives

At the end of this unit, participants will be able to:

- Discuss the steps to follow to prepare for an interview

Resources to be Used

- Participant Handbook

Ask

- Have you ever attended an interview?
- How did you prepare before going for an interview?

Say

- An interview is a conversation between two or more people (the interviewer(s) and interviewee) where questions are asked by the interviewer to obtain information from the interviewee.
- It provides the employer with an opportunity to gather sufficient information about a candidate and help them select the ideal candidate.
- It also provides the interviewee with an opportunity to present their true potential to the employer, build confidence and help make a decision about the job by asking questions regarding designation, salary, perks, benefits, promotions, transfers, etc.
- Let's do an activity to understand how to prepare for interviews better.

Activity 1

- Introducing Yourself

Do

- Select a participant and ask him/her to answer the following questions: "What can you tell me about yourself?"
- Give the participant at least one minute to speak.
- Once he/she is done, ask the rest of the participant what they gathered about the participant who was providing information.
- Now repeat the exercise with five other participants.

Ask

- What information you should include when you are describing or introducing yourself in an interview?
- What information you should not include when you are describing or introducing yourself in an interview?

Say

- Tell the participants that when an interviewer asks you to say something about yourself, he/she is not asking you to present your life history.
- Introduction should be short and crisp, and should present you in a positive light. It should include the following points:
 - ♦ Any work experience that you might have
 - ♦ A brief summary of your educational qualifications
 - ♦ Your strengths and achievements
 - ♦ Any special projects that you might have been part of
- The following topics should be avoided during an introduction:
 - ♦ Detailed description of your family (unless you are specifically asked to do so)
 - ♦ Too much information about your weaknesses
 - ♦ Information that is not true

Do

- Congratulate each participant for sharing their points.
- Ask the audience to applaud for them.
- Ask de-brief questions to cull out the information from each group.
- Keep a check on time.

Activity 2

- Planning the right attire

Do

- Describe 2 individuals to the participants. One is wearing a casual t-shirt, jeans, and slippers. He has not combed his hair and neither has he trimmed or shaved his beard. The other individual is dressed formally with a shirt and pant, and is well-groomed. He has also worn formal shoes and a belt. Ask the participants which person would they prefer to hire in their organization and why?

Summarize

- Close the discussion by discussing 'how to prepare for an interview' as discussed in the Participant Handbook.
- You can add the following points to it:
 - ♦ Tell the participants to create a positive and good impression in an interview. It is important for them to prepare for an interview beforehand.
 - ♦ The interviewer analyses not only your technical knowledge in relation to the job, but also whether or not you are a fit for the organization.
 - ♦ Every employer looks at the whole package and not just one or two things in isolation. Therefore, the way you dress and the way you present yourself is also important along with your skills and talents.
 - ♦ The participants will get only one chance to create a good first impression.

UNIT 9.4.2: Preparing an Effective Resume: How to Create an Effective Resume?

Unit Objectives

At the end of this unit, participants will be able to:

- Discuss the steps to create an effective Resume

Resources to be Used

- Participant Handbook
- Blank papers
- Pens

Ask

- When preparing for an interview, what are the most important things that you need to do?
- What documents do you carry with you, when you go for an interview?
- What is a resume?
- Why do you need a resume?

Say

- Resume is not just a sheet of paper with your qualifications printed on it.
- It is a selling tool that will help the employer to see how and what you can contribute for company.
- Talk about the steps involved in creating an effective/attractive resumes discussed in the Participant Handbook.
- Now let's prepare a resume to understand the process in a better way.

Do

- This is an individual activity.
- Give the details of the activity.
- Instruct them to read the activity carefully.
- The participant is expected to make an attractive resume based on the information provided.
- Give the class 25-30 minutes to study the case and create a resume.
- At the end of 30 minutes, the participants should exchange the resume with the person sitting next to him or her.
- Every participant will evaluate the resume prepared with their fellow participants.

Say

- Do you think the candidate should apply for the job posting described in the advertisement?
- We have already discussed the steps involved in creating an effective/attractive resumes.
- Now let's prepare a resume for the candidate details given in the activity.

Activity

Case Study Analysis

- In the first section of the activity, you are being given the information about a candidate who is applying for a particular job.
- In the second section, you are being given the detailed description of the job posting. Create a resume for the candidate to apply for the job posting.
- Use the information that has been provided about the candidate to create this resume.

Candidate Details

Nipesh Singla was born on 20th April, 1988 in Chandigarh, India. He currently resides at 1XX7, Sector XX D, Chandigarh –160018. His mobile number is 988XXXXX01, and e-mail address is nxxxxxxxla@gmail.com. Nipesh attended middle and senior school at Government Boys Senior Secondary School, Sector 15, Chandigarh. He has been a very talented boy since school. He was fond of painting and watching old Hindi movies. As part of a school charity program, he volunteered at the children's hospital during his senior years.

In July 2007, he joined Westwood School of Hotel Management, Zirakpur to pursue a diploma course in Hotel Management and Catering. After completing this course, he joined XYZ Group of Hotels as a Housekeeping intern in June 2010 for six months. In this role, he was responsible for cleanliness and maintenance of one floor in the hotel. Taking advantage of his strong interpersonal skills, he also got opportunities to make housekeeping arrangements for corporate meetings. While pursuing education, he gained working knowledge of Microsoft Word, Excel, Access and PowerPoint.

Nipesh is detail-oriented, flexible and adaptable. He has successfully worked with a diverse work force. He gelled well with his peers, both in college and during his internship. After completing the internship, his objective has been to find a job opportunity where he can use his skills and experience. Backed by experience, he is confident about his skills as housekeeping assistant.

Job Posting

* Do you see yourself as a HOUSEKEEPING SUPERVISOR?

What's your passion? Whether you're into cricket, reading or hiking, at IHG we are interested in YOU. At IHG, we employ people who apply the same amount of care and passion to their jobs as they do in their hobbies - people who put our guests at the heart of everything they do. And we're looking for more people like this to join our friendly and professional team.

THE LOCATION:

At the moment, we are looking for HOUSEKEEPING SUPERVISOR to join our youthful and dynamic team at Holiday Inn Amritsar, Ranjit Avenue in Amritsar, Punjab (India). Holiday Inn Amritsar is ideally located in Amritsar's commercial district on Ranjit Avenue with the world famous Golden Temple located only a short distance away. Sparkling chandeliers mark an incomparable arrival experience as you escape to the welcoming environment that is, Holiday Inn Amritsar. The fresh international brand to celebrate and explore Amritsar.

Salary: Negotiable

Industry: Travel / Hotels / Restaurants / Airlines / Railways

Functional Area: Hotels, Restaurants

Role Category: Housekeeping

Role: Housekeeping Executive/Assistant.

Desired Candidate Profile

Friendly, pleasant personality, Service - oriented.

You should ideally be Graduate/ Diploma holder in HM and at least 2 years of experience as a supervisor in good brand with good communication skills, English is a must.

In return we'll give you a competitive financial and benefits package. Hotel discounts worldwide are available as well as access to wide variety of discount schemes and the chance to work with a great team of people. Most importantly, we'll give you the room to be yourself.

*Please get in touch and tell us how you could bring your individual skills to IHG.

Education-

UG: Any Graduate/ Diploma holder

PG: Post Graduation Not Required

Say

- Now, let's share the resume with the fellow participant sitting next to you and evaluate each other's effort.

Do

- Congratulate each participant for making their first attempt towards creating an effective resume.
- As a follow up activity, you can suggest them to prepare their own resume and show it to you the next day.

Summarize

- Close the discussion by showing some effective resume samples to the candidates.
- Ask the participants what they have learnt from this activity.
- Ask if they have any questions related to what they have talked about so far.

Notes for Facilitation

- Keep printed copies of the activity ready for the session.
- Put down the suggested format of the resume on the board while explaining the steps in preparing a resume.
- Do check the participants' resume and suggest necessary changes.
- Suggested example for the case presented:

Nipesh Singla

#1XX7, Sector XX-D

Chandigarh-160018

Mobile No: 91-988XXXXX01

E-mail: nxxxxxxxxla@gmail.com

Objective: Seeking an opportunity to use my interpersonal skills and experience to contribute to your company's growth, profitability and objectives.

Professional strengths:

- Proficient in housekeeping
- Experienced in and capable of working with a diverse work force
- Team player and friendly in nature
- Successful working in a multi-cultural environment

- Detail oriented, flexible, and adaptable
- Knowledge of Microsoft Word, Excel, Access and PowerPoint

Educational background:

- Diploma in Hotel Management and Catering, Westwood School of Hotel Management, Zirakpur
- High School, Government Boys Senior Secondary School, Sector 15, Chandigarh

Professional internships:

- Housekeeping Intern, XYZ Group of Hotels, New Delhi (June 2010 – August 2010)
 - ♦ Responsible for cleanliness and maintenance of one floor in the hotel.
 - ♦ Got opportunities to make housekeeping arrangements for corporate meetings.

Volunteer Work:

- Student volunteer at children's hospital in Chandigarh.

Nipesh Singla

UNIT 9.4.3: Interview FAQs

Unit Objectives

At the end of this unit, participants will be able to:

- Discuss the most frequently asked interview questions
- Discuss how to answer the most frequently asked interview questions

Resources to be Used

- Participant Handbook

Say

- Tell the participants you will provide them with interview situation and questions and they have to try to answer them.
- Tell them you will also explain the different ways to approach these questions.

Do

- Divide the class in pairs and ask the participants to perform a role play.
- One partner will play the role of the interviewer while the other will play the role of the interviewee.
- Tell them the interviewer can start the interview by asking the interviewee to introduce himself/herself.
- Call all the pairs one by one in front of the class to enact the role play.
- Follow the same pattern for all other situations.
- Time allotted for each situation is 8-10 minutes.
- Congratulate each participant for giving their input.
- Ask the class to applaud each time a team has completed their role play.
- Keep a check on time.

Role Play

Conduct a role play for the situation given.

Situation 1

- The interviewer will start by asking the interviewee a few generic questions such as:
 - ♦ What is your name?
 - ♦ Tell me something about yourself?
 - ♦ Can you tell me something about your family?
- Then, the interviewer will bluntly ask the following questions:
 - ♦ How do you explain this huge time gap in your resume?
 - ♦ What is the reason for this?
 - ♦ Weren't you looking for a job or is it that no one selected you?

Say

De-brief:

- When you put information on your resume, you should be prepared to answer any questions about it.
- Be present and focused on the questions being asked to you.
- One way of tackling the blunt questions is to tell the interviewer you did not come across an opportunity where you were sufficiently satisfied with both the remuneration offered as well as the profile. Therefore, you waited for the right opportunity to come along while looking for an ideal job.

Role Play

Conduct a role play for the situation given.

Role Play – Situation 2

- The interviewer will start by asking the interviewee a few generic questions such as:
 - ♦ What is your name?
 - ♦ Tell me something about yourself?
 - ♦ Can you tell me something about your family?
- Then, at the end of the interview, ask the interviewee:
 - ♦ There are over 200 people who have applied for this job, some with excellent work experience. Why should I hire you?

Say

De-brief:

- There is nothing wrong with stating your strengths and achievements. However, do not come across as arrogant or too boastful.
- You need show the interviewee that you have unique skills or talents to contribute to the company. The interviewer needs to know how you stand apart from the rest of the crowd.
- Tell the interviewer you are looking forward to working with the company and that you are a hard-working individual.

Role Play

Conduct a role play for the situation given.

Role Play – Situation 3

- The interviewer will start by asking the interviewee a few generic questions such as:
 - ♦ What is your name?
 - ♦ Tell me something about yourself?
 - ♦ Can you tell me something about your family?
- Then, lean forward, clasp your hands on the table and in a soft voice ask the interviewee:
 - ♦ Did you ever experience any neglect or disregard from your previous office? In other words, did you ever suffer because your office or team displayed favouritism?

Say

De-brief:

- Keep this in mind: Do not criticize anyone during an interview.
- You are free to express your opinion, however, your language, answers, body language, and the tone of your voice should remain constructive and neutral.
- Since criticism will show you in negative light, you should keep your answers honest yet diplomatic.
- You can tackle such questions by saying, “I got along well with most of my faculty and peers.”

Role Play

Conduct a role play for the situation given.

Role Play – Situation 4

- The interviewer will start by asking the interviewee a few generic questions such as:
 - ♦ What is your name?
 - ♦ Tell me something about yourself?
 - ♦ Can you tell me something about your family?
- Then very bluntly ask the interviewee:
 - ♦ How long do you plan to stay with this company if you are selected?
- After the candidate responds, ask sarcastically:
 - ♦ Do you seriously mean that?

Say

De-brief:

- Don't provide unreal and idealistic answers.
- Your answers should be honest yet diplomatic. In a situation like this, the interviewer does not expect you to provide a specific timeline.
- You can say something like, “I would like to stay with the company as long as I can contribute constructively and develop as an employee, within the organization, professionally and financially.”

Role Play

Conduct a role play for the situation given.

Role Play – Situation 5

- The interviewer will start by asking the interviewee a few generic questions such as:
 - ♦ What is your name?
 - ♦ Tell me something about yourself?
 - ♦ Can you tell me something about your family?
- Ask him/her how important he/she thinks it is to be punctual in the corporate world.
- After he/she answers, look up sternly at the interviewee and in a crisp voice, say:
 - ♦ You were late for this interview by 10 minutes. That surely does not seem to be in line with what you just said?

Say

De-brief:

- Politely apologize for being late.
- You can add something such as, “I assure you this is not a habit”. All your future actions should be in line with this statement.
- Avoid giving any excuses.
- You might feel obligated to provide a justification for your tardiness, but the interviewer is not interested in that.
- Do not over apologize. Once this response is out of the way, turn your focus back to the interview.

Role Play

Conduct a role play for the situation given.

Role Play – Situation 6

- The interviewer will start by asking the interviewee a few generic questions such as:
 - ♦ What is your name?
 - ♦ Tell me something about yourself?
 - ♦ Can you tell me something about your family?
- After asking a few academic or job-related questions, ask the interviewee:
 - ♦ If you get this job, what salary package do you expect us to give you?

Say

De-brief:

- If there is no way for you to avoid this question, respond to the interviewer by providing a reasonable and well-thought out salary range.

Role Play

Conduct a role play for the situation given.

Role Play – Situation 7

- The interviewer will start by asking the interviewee a few generic questions such as:
 - ♦ What is your name?
 - ♦ Tell me something about yourself?
 - ♦ Can you tell me something about your family?
- Then, bringing the interview to a close, ask the interviewee:
 - ♦ Do you have any questions for me?

Say

De-brief:

- Ask relevant questions.
- Don't bombard the interviewer with questions.
- If you have questions about the result of the interview, you can limit your questions to 1 or 2. Keep them short and relevant like:
 - ♦ When will I be informed about the results of the interview?
 - ♦ What are the working hours?
 - ♦ Will the job require me to travel?

Explain

- Tell the participants to be prepared for answering different types of questions in an interview.
- Stay calm and focused, and take a moment to think about how you should respond. Always maintain a confident tone.
- Even if you don't intend to, your body language conveys your level of discomfort with a particular question. Try to keep your actions, tone, and gestures neutral.
- Maintain your composure while answering personal question.

Do

- Tell all the participants to form pairs again.
- Tell them to use the following list of frequently asked interview questions to conduct mock interviews.
- They will use all or some of these questions to conduct mock interviews with their partners.
- One partner will play the role of the interviewer while the other will play the role of the interviewee.
- After they are through asking and answering the questions, the roles will be reversed.
- The same list of questions will be used again.
- After each mock interview ask the interviewer to provide feedback and clear any doubts that may arise.
- Time allotted for each situation is 30-35 minutes.

Activity

Mock Interview Questions

Mock Interview Questions
Tell me something about your family.
What qualities would you look for in a Manager or a Supervisor?
Why did you apply for this job?
What do you know about this company?
How do you deal with criticism?
How do you plan to strike a good work-life balance?
Where do you see yourself five years from now?
Have you applied for jobs in other companies?
What kind of salary do you expect from this job?
Do you have any questions for me?

Summarize

- Close the discussion by discussing the questions in the both activities.
- Ask the participants what they have learned from this activity.
- Ask if they have any questions related to what they have talked about so far.

UNIT 9.4.4: Work Readiness – Terms and Terminology

Unit Objectives

At the end of this unit, participants will be able to:

- Identify basic workplace terminology

Resources to be Used

- Participant Handbook
- Chart papers
- Blank sheets of paper
- Pens

Ask

- What do you understand by workplace terminology?
- Are offer letter and contract of employment the same?

Say

- Let's start this unit with an activity.

Team Activity

Workplace terminology

- This is a group activity conducted in three parts.

Part 1

Sheila received a call from the recruiter of MND Company. Before she is recruited by the company, think of the recruitment process she will have to go through. Start from the telephone call to signing her letter of acceptance. Write down all the words that come to your mind.

Activity De-brief

- Have the participants read out the words they have written
- Encourage all the participants to participate in the activity

Do

- Divide the class into small groups of 4 or 6.
- Instruct the participants that they will be doing a brainstorming activity.
- Give them one chart paper each. Tell them to divide the chart in two parts.
- Instruct them that they have to use one half of the chart paper now. The other half will be used later.
- The participants have to write all the words that come to their mind related to the recruitment process.
- Give them 10 minutes to do the activity.
- Tell them that there are no right or wrong answers.
- Keep a track of the time.

Say 

- You all know quite a few words related to the terms used in the office.
- Let us talk about some new terms that have been missed out.
- Discuss “Work Readiness – Terms and Terminology” with the participants as given in the Participant Handbook.

Ask 

- Why is it important to know the workplace terms?
- How do they help?
- Can the words be categorised further?

Say 

- Let's now continue the activity.

Team Activity **Terms and Terminology**

- This is again a group activity. The members of the group remain the same as in Activity 1.

Part 2

With the help of the new terms you have learned, make a flow chart of the hiring process of MND Company.

Activity De-brief

- Ask the groups to share the flow charts and the new terms they added while preparing the flow chart.

Do 

- Instruct the participants that they have to use the 2nd half of the same chart they had used before.
- Using the new terminology and the terms they had previously written on the chart, they have to make a flow chart of the hiring process of the MND Company.
- Give them 10 minutes for this activity.
- Keep a check on time. Tell the group to wind up quickly if they go beyond the given time limit.

Say 

- Let's go ahead with the activity.

Team Activity **Terms and Terminology**

- The activity continues with the same group members.

Part 3

Sheila now works for the MND Company. She is not aware of the company culture and policies. She goes to the HR Department to get her doubts clarified. Can you think of the terms for which she wants clarity? Make a list of those words.

Activity De-brief

- Ask the groups to share their list of words. Some of the words are benefits, comp. time, deduction, employee training, holidays, lay-off, leave, maternity leave, mentor, notice, paternity leave, and time sheet.

Do 

- Instruct the participants to identify the key terms an employee of a company should know. They can use the same chart paper for this activity.
- Give them 5 minutes for this activity.
- Keep a check on time. Tell the group to wind up quickly if they go beyond the given time limit.

Summarize 

- Note: You can either summarize the key points of the unit or have a role play where an employee has just joined a company and the HR Manager explains the terms of employment.

UNIT 9.5: Understanding Entrepreneurship

Key Learning Outcomes



At the end of this unit, participants will be able to:

1. Discuss the concept of entrepreneurship
2. Discuss the importance of entrepreneurship
3. Describe the characteristics of an entrepreneur
4. Describe the different types of enterprises
5. List the qualities of an effective leader
6. Discuss the benefits of effective leadership
7. List the traits of an effective team
8. Discuss the importance of listening effectively
9. Discuss how to listen effectively
10. Discuss the importance of speaking effectively
11. Discuss how to speak effectively
12. Discuss how to solve problems
13. List important problem solving traits
14. Discuss ways to assess problem solving skills
15. Discuss the importance of negotiation
16. Discuss how to negotiate
17. Discuss how to identify new business opportunities
18. Discuss how to identify business opportunities within your business
19. Explain the meaning of entrepreneur
20. Describe the different types of entrepreneurs
21. List the characteristics of entrepreneurs
22. Recall entrepreneur success stories
23. Discuss the entrepreneurial process
24. Describe the entrepreneurship ecosystem
25. Discuss the purpose of the Make in India campaign
26. Discuss key schemes to promote entrepreneurs
27. Discuss the relationship between entrepreneurship and risk appetite
28. Discuss the relationship between entrepreneurship and resilience
29. Describe the characteristics of a resilient entrepreneur
30. Discuss how to deal with failure

UNIT 9.5.1: Concept Introduction (Characteristic of an Entrepreneur, types of firms/ types of enterprises)

Unit Objectives

At the end of this unit, participants will be able to:

- Discuss the concept of entrepreneurship
- Discuss the importance of entrepreneurship
- Discuss the characteristics of an entrepreneur
- Describe the different types of enterprises

Resources to be Used

- Participant Handbook

Say

- Let's start this session with some interesting questions about Indian entrepreneurs.

Team Activity

Quiz Questions

1. Who is the founder of Reliance Industries?
Dhirubhai Ambani
2. Who is the Chairman of Wipro Limited?
Azim Premji
3. Who launched e-commerce website Flipkart?
Sachin Bansal and Binny Bansal
4. Who is the founder of Paytm?
Vijay Shekhar Sharma
5. Who is CEO of OLA Cabs?
Bhavish Aggarwal
6. Who is the founder of Jugnoo?
Samar Singla (autorickshaw aggregator)
7. Who is the founder of OYO Rooms?
Bhavish Aggarwal

Do

- Tell them that you will ask them few questions about a few entrepreneurs.
- Divide the class in to two groups.
- In turns ask the quiz questions to the groups.
- If the answer is incorrect pass the question to the other group.
- Share the answer if the groups are not able to answer.
- Congratulate the participants who answered correctly.

Ask



- What do you understand by entrepreneurs?
- What is the importance of entrepreneurship in today's scenario?
- What do you think are the characteristics of successful entrepreneurs?
- What are different types of enterprises that an entrepreneur in India can own and run?

Say



- Talk about entrepreneurs, importance of entrepreneurship, characteristics of successful entrepreneurs, and different types of enterprises in India as discussed in the Participant Handbook.
- Tell the participants, stories of successful Indian entrepreneurs- their struggles, the moments of heartbreak, the perseverance and triumph.
- Ask them if they know of any such entrepreneur.

Summarize



- Close the discussion by summarizing about the opportunities for entrepreneurs in India.

Notes for Facilitation



- Check out different Government schemes for small entrepreneurs. Share the information with the participants.
- You can tell them about the government websites like Start Up India, mudra.org.in etc.
- Discuss about various schemes and policies by the Government of India for entrepreneurs.

UNIT 9.5.2: Leadership and Teamwork

Unit Objectives

At the end of this unit, participants will be able to:

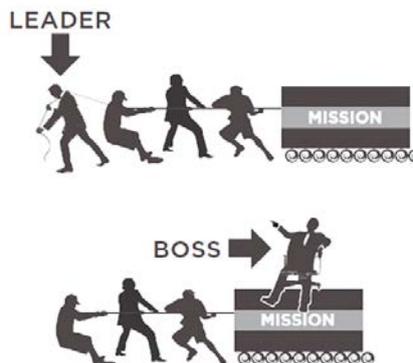
- List the qualities of an effective leader
- Discuss the benefits of effective leadership
- List the traits of an effective team

Resources to be Used

- Participant Handbook
- Blank sheets of paper
- Pens

Do

- Show the picture given below to the class.
- Ask them to quickly write on a piece of paper what comes to their mind after seeing the picture.
- Now ask them, “What do you understand from this picture?”
- Encourage participants to share their thoughts.



Say

- This picture depicts the qualities of a leader and the difference between a leader and a boss.
- A boss focuses on structure and inspires fear whereas a leader follows vision and generates enthusiasm.
- A boss blames employees for the breakdown whereas a leader fixes breakdowns.
- A boss depends on authority whereas a leader depends on goodwill.
- A boss says “I” and a leader says “We.”
- A boss drives employees whereas a leader coaches them.
- A boss takes credit whereas a leader gives credit.

Say

- Talk about leadership and leadership qualities for an entrepreneur as discussed in the Participant Handbook.

Ask

- Why is it important for a leader to be effective? How does it help the organization?

Say 

- Let us discuss benefits of effective leadership as discussed in the Participant Handbook.
- “Out-of-the-box thinking” is one of the new leadership styles. It means thinking differently and from a new perspective.

Ask 

- Do you consider yourself a team player?

Team Activity **Long Chain**

- This is a group activity.

Do 

- Divide the class into 2 teams.
- Ask each team to create a chain using materials they have in class such as shoe laces, belts, paper, handkerchief, ribbons, etc.
- The team that creates the longest chain wins the game.
- Observe if the participants are interacting with their team or working in isolation.
- Share your observations with the class.

Say **De-brief:**

- What did the winning team do differently?
- Who was responsible for the winning team's success?
- How does this activity explain the role of teamwork in entrepreneurial success?

Say 

- Tell the class that both the teams performed well.
- Discuss that the objective of this activity was to open communication channels and how this has been achieved.
- The participants should aim to keep the communication channels open when interacting with their peers and team members.
- It will set the pace and enthusiasm required for all the ensuing teamwork activities.
- Talk about teamwork and importance of teamwork in entrepreneurial success as discussed in the Participant Handbook.

Summarize 

- Close the discussion by summarizing about the importance of teamwork for employees.
 - Teamwork helps in reducing stress for the employees.
 - Teamwork helps employers in generating more number of solutions to a problem and developing improved communication amongst employees.
- Ask the participants what they have learned from these exercises.
- Ask if they have any questions related to what they have talked about so far.

UNIT 9.5.3: Communication Skills: Listening & Speaking: The Importance of Listening Effectively

Unit Objectives

At the end of this unit, participants will be able to:

- Discuss the importance of listening effectively
- Discuss how to listen effectively
- Discuss the importance of speaking effectively
- Discuss how to speak effectively

Resources to be Used

- Participant Handbook

Activity 1

Activity – Chinese Whisper

Step 1: Form a circle.

Step 2: Start a whisper chain. Any one participant will whisper a message into his/her neighbour's ear. No one else must hear the message. The message can be serious or downright silly.

Step 3: The next person who first heard the message should whisper the message very quickly to the person sitting next to them.

Step 4: The game goes on until the last person says whatever they heard out loud and the first person reveals the real message.

Compare them and have a great laugh!

Ask

De-brief questions:

- Was the original message the same as the message that is communicated at the end of the game?
- Why do you think there was a difference in the messages?

Say

- No, the original message was not same at the end of game.
- The barriers to communication like language, disturbance and noise, poor listening skills, boredom, poor speaking skills, etc. are the potential reasons this happens.
- There are various aspects to communication. Speaking skills and listening skills are two major components to any communication. There is always some room for improvement in the way we communicate.
- It is important to accept the reality of miscommunication and work to minimise its negative impacts.

Say

- Communication is a two-way process where people exchange information or express their thoughts and feelings
- It involves effective speaking and effective listening.
- If I go to the store to get bread, I exchange money for the bread. I give something and get something in return. Communication takes place in the same manner. You have to provide and receive information for communication to take place.

Ask

- How often do you hear these statements?
 - ♦ “You're not listening to me!”
 - ♦ “Why don't you let me finish what I'm saying?”
 - ♦ “You just don't understand!”
- What do you think the other person is trying to convey to you through these sentences?
- We will not talk about the importance of listening effectively as discussed in the Participant Handbook.

Say

- Let's play a game to understand effective listening process better.

Do

- This is a class activity.
- The participants need to answer the questions they hear.
- Instruct them to listen carefully.
- You will read it at a stretch and if need be repeat it once more.
- Tell the participants to raise their hand if they know the answer to the question asked.
- Keep a check on time.

Activity 2

Riddles:

Is there any law against a man marrying his widow's sister?

If you went to bed at eight o'clock at night and set the clock's alarm to ring at nine o'clock, how many hours of sleep would you get?

Do they have a 26th of January in England?

If you had only one match and entered a dark room that had a kerosene lamp, oil heater, and a wood stove, what would you light first?

The Delhi Daredevils and the Chennai Super Kings play five IPL matches. Each wins three matches. No match was a tie or dispute. How is this possible?

There was an airplane crash. Every single person died, but two people survived. How is this possible?

If an airplane crashes on the border of two countries, would unidentified survivors be buried in the country they were travelling to or the country they were travelling from?

A man builds an ordinary house with four sides except that each side has a southern exposure. A bear comes to the door and rings the doorbell. What is the colour of the bear?

Answers:

There's no law against a man marrying his widow's sister, but it would be the neatest trick in the book since to have a widow, the man would have to be dead.

You'd get one hour's sleep since alarm clocks do not know the difference between morning and night.

Oh, yes. They have a 26th of January in England. They also have a 27th, a 28th, and so on.

First of all, you would light the match.

Who said the Delhi Daredevils and the Chennai Super Kings were playing against each other in those games?

Every SINGLE person died, but those two were married.

You can't bury survivors under any law especially if they still have enough strength to object.

The bear that rang the doorbell would have to be a white bear. The only place you could build a house with four southern exposures is at the North Pole where every direction is in South.

Ask **De-brief question:**

- What were the barriers that came into your way of listening?
- How can you overcome barriers to listening?

Say 

- There is a difference between hearing and listening.
- If you don't listen properly, the message may be misunderstood.
- Be open-minded while listening to someone.
- It is important to listen effectively and carefully without making assumptions.

Activity 3 **Elevator Pitch:**

You are in the lift of a hotel and you bumped into your former client who is a famous businessman. He has financed a lot of small business ventures and can finance your new start-up too. After exchanging pleasantries, he asks you what your new company does. You open your mouth, and then pause. Where do you even begin?

Then, as you try to organize your thoughts, his meeting is called, and he is on his way. If you would have been better prepared, you're sure that he would have stayed long enough to schedule a meeting with you too.

If you were given another chance, what would you have said to this person?

Do 

- Start off the task by providing a beginning sentence to get the story started, and then go around the classroom getting each one to add a new sentence to keep the story going.
- This task should be done spontaneously allowing only a little time to think (30 seconds).
- For example: **There was once a student who was looking for a job after graduation.**

Notes for Facilitation

- Tell the participants to follow these steps to create a great pitch, but bear in mind that you'll need to vary your approach depending on what your pitch is about.
 1. **Identify Your Goal:** Start by thinking about the objective of your pitch. For instance, do you want to tell the potential clients about your organization? Do you have a great new product idea that you want to pitch to an executive or do you want a simple and engaging speech to explain what you do for a living?
 2. **Explain What You Do:** Start your pitch by describing what your organization does. Focus on the problems that you solve and how you help people. Ask yourself this question as you start writing: what do you want your audience to remember most about you? Keep in mind that your pitch should excite you first. After all, if you don't get excited about what you're saying neither will your audience. People may not remember everything that you say, but they will likely remember your enthusiasm.
 3. **Communicate Your USP:** Your elevator pitch also needs to communicate your unique selling proposition or USP. Identify what makes you, your organization or your idea unique. You'll want to communicate your USP after you've talked about what you do.
 4. **Engage with a Question:** After you communicate your USP, you need to engage your audience. To do this, prepare open-ended questions (questions that can't be answered with a "yes" or "no" answer) to involve them in the conversation. Make sure that you're able to answer any questions that he or she may have.
 5. **Put it all Together:** When you've completed each section of your pitch, put it all together. Then, read it aloud and use a stopwatch to time how long it takes. It should be no longer than 20-30 seconds. Remember, the shorter it is, the better!

Example:

Here's how your pitch could come together:

"My company deals with cloth retail online business and we use various e-commerce platforms to sell our products. This means that you can do shopping with ease and spend time on other important tasks. Unlike other similar companies, we have a strong feedback mechanism to find out exactly what people need. This means that, on average, 95 percent of our clients are happy with our products. So, how can you help us in creating our own web portal?"

6. **Practice:** Like anything else, practice makes perfect. Remember, how you say it is just as important as what you say. If you don't practice, it's likely that you'll talk too fast, sound unnatural or forget important elements of your pitch. Set a goal to practice your pitch regularly. The more you practice, the more natural your pitch will become. Practice in front of a mirror or in front of colleagues until the pitch feels natural.

Summarize

- Close the discussion by summarizing how to speak effectively as discussed in the Participant Handbook.

UNIT 9.5.4: Problem Solving & Negotiation Skills

Unit Objectives

At the end of this unit, participants will be able to:

- Discuss how to solve problems
- List the important problem solving traits
- Discuss ways to assess problem solving skills
- Discuss the importance of negotiation
- Discuss how to negotiate

Resources to be Used

- Participant Handbook

Ask

- What is a 'problem'?
- What do you think are the problems you may face in the process of becoming a successful entrepreneur?

Say

- Discuss the definition of problem as given in the Participant Handbook.
- In a hurdle race the hurdles are the obstacles on the way to reach your goal.
- Similarly, obstacles are the hurdles you may face while reaching your goal i.e. to set-up your own business. Your goal will be to reach the finishing line after crossing these hurdles.

Ask

- What do you do when you face a problem?
- How do you resolve it? You can pick examples from the question asked previously 'the problems they are likely to face in the process of becoming a successful entrepreneur'.

Say

- Discuss how to solve problems as given in the Participant Handbook.

Team Activity

- This is a group activity.
 - The groups will solve the problem and come up with the best solution in each case.
1. Unable to arrange for some extra finance for setting up a beauty parlour. The loan sanctioned and disbursed is not enough. You have tried all your contacts, friends and relatives. But unable to manage the extra amount. Bank will not sanction more amount as you have used up the complete sanction limit.
 2. You have rented a space for your business and all arrangements are done. You will be operating from the office space rented in two days. Now the owner comes up to you and says he wants to sell the place and wants you to vacate in 15 days.
 3. You have just set up your business and need extra human resource. You have tried inviting a few also tied up with an agency for getting the right candidate. But you are unable to get the right candidate. If the candidate is good, you cannot offer the salary demanded. If the candidate agrees to the salary, he/she has other demands like working hours to be reduced, leaves etc. which may not work for your set up.

Do 

- Divide the class into three groups. Give one scenario to each group.
- Explain the purpose and duration of the activity.
- Ask the groups to build on the scenario and present their solution as a role play.

Say **De-brief questions:**

1. What was the problem?
2. Is there any other alternative solution?
3. Is this the best solution presented?

Ask 

- Try to think of some people around you who are able to solve problems very easily. Even you or your friends might be approaching them when there is a problem. What qualities do they have? What personality traits do such people possess?

Say 

- Discuss the important traits for problem- solving as given in the Participant Handbook.

Ask 

- In order to build a successful organization, you need to hire people who possess good problem solving skills. How would you assess the level of problem solving skills of potential candidates before hiring them?

Say 

- Discuss how to assess for problem- solving skills as given in the Participant Handbook.

Summarize 

- Ask the participants the things that they have learnt so far.
- Ask if they have any questions related to what they have talked about so far.
- Summarize the discussion on problem solving.

Activity 

- The activity is to organise an election event. Select three volunteers from the group. They have to give a speech on their election manifesto to the class. They have to negotiate with the fellow participants and convince them to vote for them. The best negotiator will win the election.

Do 

- Ask three participants to volunteer for the activity.
- Explain the purpose and duration of the activity.
- Set guidelines pertaining to discipline and expected tasks.

Ask 

- Out of the three contestants, whom would you support? Why? What did they say or do which convinced you to make your decision?
- Have you ever tried to negotiate in your personal or professional life?
- Ask the class to share some of their experiences where they have been able to strike a deal by negotiating.

Say 

- Discuss “What is Negotiation?” as given in the Participant Handbook.

Ask 

- Why is it important to negotiate? As an entrepreneur, where do you think that negotiation skills will be needed?

Say 

- Discuss the importance of negotiation while starting a business as given in the Participant Handbook.

Say 

- Discuss the important steps to negotiate as given in the Participant Handbook.

Role Play 

- Conduct a role play activity.
- Ask the participants to assemble together.
- Explain the purpose and duration of the activity.
- Set guidelines pertaining to discipline and expected tasks.

Do 

- Divide them into groups of four (4) (depending on the batch size).
- Give them the hand-outs for role play scenarios.
- Two groups to be given scenarios on problem solving.
- Other two groups to be given scenarios on negotiation.
- The groups will build on the scenarios and prepare for the role play.
- Give the groups atleast 5 mins to discuss and be ready with the role play.
- Invite each group one by one to come and present their role play.

Problem solving Scenario 1

Avinash has a Mobile Repair Store in Allahabad. His outlet is one of the most popular one in the vicinity and he has great rapport with his customers. He is always well-dressed, jovial and full of energy.

It's around 11 AM, when a customer barges in to the shop and starts shouting at Avinash for giving her back the instrument which is still not working. The screen of her mobile is also cracked from one side. Avinash remembered thoroughly checking the handset before handing it over to the customer. The customer threatens to sue the company and to go to Consumer Court for cheating her.

Problem solving Scenario 2

You are running a successful small scale business, Shreeji Aggarbattis,. Your staff members do door to door selling and organise marketing campaigns in local markets. Your brand has established it's name in last few years.

Recently, lot of customers have been coming to you and lodging complaints that your staff members indulge in malpractices. Few of them informed you that a staff member engaged them in a friendly conversation. In the meanwhile, the other gave them lesser packets of aggarbattis than they paid for.

Another set of customers lodged complaint about the misconduct and rude behaviour of a particular staff member. You often hear from your customers that the orders don't get delivered on time or wrong products get delivered.

You have already been struggling with shortage of staff and such complaints are a serious concern as it is hampering your brand image. What strategies will you adopt to solve this problem?

Negotiation Scenario 1

You have interviewed a prospective new employee who could be a key member of your new entrepreneurial venture. The new person is demanding a salary that is 20% higher than you thought based on your business plan. Finances are tight, yet you believe this person could make a significant impact on future profits. If you paid the required salary for the new person, then you would have to restructure your entire business plan. You've been searching for an individual with this skill level for three months. to the candidate is waiting for your response. Now you have to call him in to make the final negotiations.

Negotiation Scenario 2

You are a young entrepreneur who has just registered his start up project and applied for a bank loan accordingly. You receive a letter saying that your loan application has been rejected as your start up idea did not appeal to the bank and they think that it is not a revenue generating model. You have taken an appointment to meet the manager and show your negotiation skills to get your loan approved.

Notes for Facilitation

Facilitating Role Plays**Preparing for the activity**

1. Carefully review the details of the scenario and the character descriptions.
2. Become familiar with the key issues being addressed in the scenario.
3. Study the provided material so that you are ready to address issues related to the situations depicted in the role-plays.
4. Anticipate and know how to address issues participants might raise during the activity.

Conducting the activity

1. Introduce the activity. Emphasize that role-playing provides participants with an opportunity to apply their new knowledge, skills, and tools in situations that simulate actual interactions with customers.
2. Ask participants to form pairs. Direct the members of each group to choose who will play the roles. Remind the groups that each participant should be given the opportunity to play/practice the different roles.
3. Conduct a demonstration so that participants become familiar with the expectations related to the roles and support materials.
4. Give the pairs/ groups 10 to 15 minutes to conduct the role-play (depending on the duration of the session).
5. After all the groups have finished with the role-play, conduct a debriefing session on each role-play.
6. Ask the groups to take five minutes to talk about what happened during the role-play. The groups should discuss the questions given in the debriefing for each role-play. Encourage participants to provide constructive criticism during their discussions.

Summarize

- Wrap the unit up after summarizing the key points and answering questions.

UNIT 9.5.5: Business Opportunity Identification: Entrepreneurs and Opportunities

Unit Objectives

At the end of this unit, participants will be able to:

- Discuss how to identify new business opportunities
- Discuss how to identify business opportunities within their business

Resources to be Used

- Participant Handbook
- Blank sheets of paper
- Pens

Ask

- How does an entrepreneur identify an opportunity?
- What do you think are the common queries or concerns faced by entrepreneurs?
- How can you identify new business opportunity?

Say

- Let's talk about opportunity, common queries or concerns faced by entrepreneurs, idea as an opportunity, factors to consider when looking for opportunities, ways to identify new business, and opportunity analysis as discussed in Participant Handbook.
- Let's do an activity to understand ways to identify business opportunities within your business.

Do

- Tell the class that this is an individual activity.
- Tell the participants to create a matrix on their notebooks.
- There will be four boxes in your matrix.
- Strength, Weakness, Opportunity and Threats will be the four headings of the matrix. This is called the SWOT matrix.
- Read out the questions to them and tell the participants they need to answer the questions asked in each matrix.
- Tell them they can also use their own understanding of themselves to fill the SWOT matrix.

Activity

Do your SWOT analysis

Strength

What are your strengths?
What unique capabilities do you possess?
What do you do better than others?
What do others perceive as your strengths?

Weakness

What are your weaknesses?
What do your competitors do better than you?

Opportunity

What trends may positively impact you?
What opportunities are available to you?

Threat

Do you have solid financial support?
What trends may negatively impact you?

Do



- Congratulate everyone for the class activity.
- Ask the audience to applaud for themselves.
- Allot the participants sufficient time to complete this activity, but do keep a check on time.
- Ask de-brief questions to cull out information from the participants.

Ask



De-brief questions:

- What are your weaknesses according to your SWOT analysis?
- Do you think you can change your weakness into strength? How?
- Do you think you can work on your threats? How?

Summarize



- Close the discussion by summarizing ways to identify business opportunities within your business.
- Ask the participants what they have learned from this exercise.
- Ask if they have any questions related to what they have talked about so far.

UNIT 9.5.6: Entrepreneurship Support Eco-System

Unit Objectives

At the end of this unit, participants will be able to:

- Explain the meaning of entrepreneur
- Describe the different types of entrepreneurs
- List the characteristics of entrepreneurs
- Recall entrepreneur success stories
- Discuss the entrepreneurial process
- Describe the entrepreneurship ecosystem
- Discuss the purpose of the 'Make in India' campaign
- Discuss the key schemes to promote entrepreneurs

Resources to be Used

- Participant Handbook
- Chart papers
- Marker pens
- Pencils
- Colour pencils
- Scale
- Eraser
- Other requisite stationery material

Ask

- Do you think that entrepreneurs need support?
- What do you think is an eco-system?
- What do you think 'entrepreneurship support eco-system' means?

Say

- Let's learn what entrepreneurship support eco-system means.
- Discuss 'Entrepreneurship Support Eco-System' as given in the Participant Handbook.

Ask

- Can you define entrepreneurship support eco-system?
- What are the key domains of the support eco-system?

Say

- Let's learn more about these domains by conducting an activity.
- You have to make a poster showing the components of the six main domains of entrepreneurship support eco-system.

Team Activity

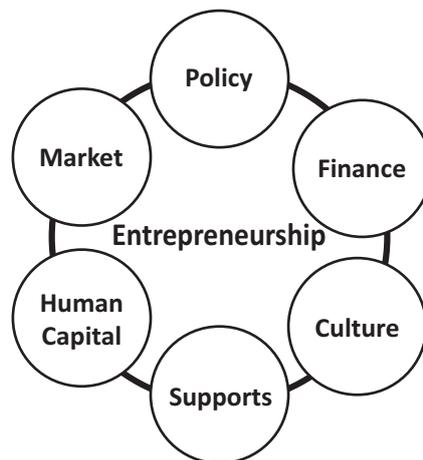
- Making a poster showing the entrepreneurship support eco-system.

Do

- Divide the class into groups of four or six.
- Hand out chart paper and coloured pens.
- Explain the purpose and duration of the activity.
- Go around checking the progress of each group.
- Set guidelines pertaining to discipline and expected tasks.

Activity De-brief

Ask each group to display their poster and explain the key domains of entrepreneurship support eco-system.



Ask

- What kind of government support eco-system is available for entrepreneurs in India?

Say

- Discuss 'Make in India' campaign as given in the Participant Handbook.

Team Activity

- Presentation on key schemes to promote entrepreneurs

Do

- Divide the class into pairs.
- Number each pair from 1-15.
- Assign a scheme, same as their group number, to each group.
- Ask them to read the scheme carefully and present it to the class.
- Explain the purpose and duration of the activity.
- Go around checking the progress of each group.
- Set guidelines pertaining to discipline and expected tasks.

Activity De-brief

- Ask each group to explain the scheme offered by government to promote entrepreneurs.

Summarize

- Summarize the unit by discussing the key points and answering questions the participants may have.

UNIT 9.5.7: Risk Appetite & Resilience

Unit Objectives

At the end of this unit, participants will be able to:

- Discuss the relationship between entrepreneurship and risk appetite
- Discuss the relationship between entrepreneurship and resilience
- Describe the characteristics of a resilient entrepreneur

Resources to be Used

- Participant Handbook
- Chart papers
- Blank sheets of paper
- Pens
- Marker pens

Ask

- Can you define risk or explain what constitutes a risk?
- What do you people mean when they say, “This may be a risky proposition”?
- What risks are they talking about?

Example

- Let's have a look at these two examples:

Rohit and his family were travelling by car from Delhi to Nainital. It was their second trip there. Rohit was familiar with the road. His friends told him that the highway after Rampur was in a bad condition. They advised him to take a shortcut and turn left from Moradabad and take the Kaladhungi road. This road is in a better condition.

Since he was going with his family, and did not want to take the risk of getting lost, he left early. He took the Kaladhungi road and reached Nainital well in time.

Suresh and his family too were travelling by car from Delhi to Nainital. It was their second trip there. His friends too advised him to take a shortcut and turn left from Moradabad and take the Kaladhungi road as this road was in a better condition.

Suresh too decided to take the Kaladhungi road but he left Delhi in the afternoon. It was dark by the time he reached Kaladhungi, and he was sure that he was taking the correct turn. As it was late, he could not find anyone to give him directions. He ended up being in an unknown place that was scarcely inhabited.

Say

- Let's see what type of risks Rohit and Suresh took.
- Discuss 'Risk Appetite and Resilience' with the participants as given in the Participant Handbook.

Say

- Let's learn more about risk appetite and resilience with the help of an activity.

Team Activity

Risk Appetite

- This is a group activity.

- In the previous unit, you read success stories of Mr Dhirubhai Ambani and Dr Karsanbhai Patel.
- Mr Ambani left his job and started his company Reliance with just Rs. 50,000/-.
- Dr Patel kept his job, went door-to-door to sell Nirma, and only when the brand started gaining popularity did he start his own company.
- What types of risk did both of them take?
- What risk factors, do you think, did they keep in mind before launching their company?
- Write the Risk Appetite Statement of both the companies.

Activity De-brief

- Who took a greater risk?
- What are the differences between the Risk Appetite Statement of both the companies?

Do

- Instruct the participants that this is group work.
- Divide the class into small groups of 4.
- Give each group a chart paper.
- Tell the participants that they have to evaluate the risks taken by Mr Dhirubhai Ambani and Dr Karsanbhai Patel.
- Give the participants 15 minutes to discuss and write.
- Keep a check on time. Tell the group to wind up quickly if they go beyond the given time limit.

Ask

- Do you think all entrepreneurial ventures are successful?
- What happens if the first venture is not successful?
- Should the entrepreneur stop when faced with challenges or face them?

Example

- Let's have a look at the following example:

Vijay Shekhar Sharma is the founder of Paytm, which is a giant Indian e-commerce. He was born in a middle-class family in Uttar Pradesh. He started his first job at an MNC. He quit after six months and built a company One97 with his friends. As One97 grew bigger, it needed more money because it was running more servers, bigger teams, and had to pay royalty. At that time, the tech bubble popped and technology companies were running in losses. Finally, money ran out. So One97 took loans and then more loans at higher rates of interest, as high as 24 per cent, and became caught in a vicious cycle.

In 2014, Paytm was launched with online wallet services after which, the company enabled online payment transactions. The company got licenses from RBI in 2016 to launch India's first ever payment bank. Moreover, the main motive of Paytm was to transform India into a cashless economy.

After demonetization came into effect, Vijay Shekhar Sharma started promoting online and digital transactions to deal with the cash crunch. In fact, the service of the company's mobile wallet is accepted across India. The logo of Paytm is now popular almost everywhere from tea stalls to major companies.

Say

- Let's see what qualities made Vijay Shekhar Sharma a resilient entrepreneur.
- Discuss Entrepreneurship and Resilience with the participants as given in the Participant Handbook.

Say

- Let's learn more about entrepreneurship and resilience with the help of an activity.

Team Activity

Entrepreneurship and Resilience

- This is a group activity.
- Think of some entrepreneurship ventures that faced challenging times, but later resulted in success stories.
 - Who is the founder of that company?
 - What challenging times did it face?
 - How did it overcome those challenges?
 - List the resilient characteristics of the entrepreneur.

Activity De-brief

- Each group to give their presentation.
- Why did you choose this company?
- What is the success story of the company?

Do

- Instruct the participants that this is group work.
- Divide the class into small groups of 4.
- Give each group a chart paper.
- Tell the participants that they have to think of an entrepreneur who faced challenging times, but eventually succeeded.
- Give the participants 15 minutes to discuss and write.
- Keep a check on time. Tell the group to wind up quickly if they go beyond the given time limit.

Summarize

- You can summarize the key points of the unit.
- Ask the participants what they learned from the activities.
- Clarify any questions or doubts they might have.

UNIT 9.5.8: Success and Failures

Unit Objectives

At the end of this unit, participants will be able to:

- Discuss how to deal with failure

Resources to be Used

- Participant Handbook

Ask

- Have you heard the quote 'nothing is impossible'?
- What do you think it means?
- Do you think that all successful entrepreneurs became famous overnight or did they have to struggle or face failure before succeeding?

Example

- Let's have a look at this example.

Shah Rukh Khan, also known as, SRK or King Khan is a force to reckon with. Did he achieve stardom overnight? Shah Rukh Khan, who has seen many struggles in his life – he has slept on streets, struggled to support himself and his sister at a very young age, and lost his parents very early in life, which led to his sister seeking mental health support. Amidst all the chaos and challenges, he kept pushing himself, and today he stands tall as the 'Badshah of Bollywood'. Certainly those years were not easy for him.

When he was young, he stood at Marine Drive and said, "I will rule this city one day". Failure was not just his companion during or before his stardom, it is still a substantial part of his life. Success does not come easy. What made him a star was his acceptance of failure and the urge to improve.

Say

- How do you define success and failure?
- What is fear?
- Discuss "success and failure" with the participants as given in the Participant Handbook.

Ask

- Have you felt or experienced fear?
- What led you to feel that emotion?
- How did you handle it?

Say

- Let's learn the about success and failure with the help of an activity.

Team Activity

- Divide the class into groups of four.
- Instruct them to think of one scenario where they have to interview a successful entrepreneur.
- Explain the purpose and duration of the activity.
- Set guidelines pertaining to discipline and expected tasks.
- They have to choose one person from the group as the interviewee and one as the interviewer.
- Go around and make sure they have understood what is to be done and are discussing the roles properly.
- Check that everyone understands their role. Give clarifications if needed. Give the participants about 5 minutes to discuss and decide their roles.
- Ask the groups to stop the discussion as soon as the time is over.
- Invite each group one by one to come and present their interview as a role play.

Notes for Facilitation

Facilitating Role Plays

Preparing for the activity

1. Carefully review the details of the scenario and the character descriptions.
2. Become familiar with the key issues being addressed in the scenario.
3. Study the provided material so that you are ready to address issues related to the situations depicted in the role plays.
4. Anticipate potential questions that might be raised by the participants and be ready to address them.

Conducting the activity

1. Introduce the activity. Emphasize that role playing provides participants with an opportunity to apply their new knowledge, skills, and tools in situations that simulate actual interactions with customers.
2. Ask participants to form pairs. Direct the members of each group to choose who will play the roles. Remind the groups that each participant should be given the opportunity to play/practice the different roles.
3. Conduct a demonstration so that participants become familiar with the expectations related to the roles and support materials.
4. To maintain spontaneity of the interactions during the role play, ask the participants not to discuss the details of their roles prior to the role play.
5. Give the pairs 15-20 minutes to conduct the role play.
6. Circulate among the groups to answer any questions that may arise and provide guidance as needed.
7. After all the pairs have finished with the role play, conduct a de-briefing session on each role play.
8. Ask the groups to take five minutes to talk about what happened during the role play. The groups should discuss the questions given in the de-briefing for each role play. Encourage participants to provide constructive criticism during their discussions.
9. Conclude the activity by asking participants to think about whether and how they might use scripted role plays in their real life.

Summarize

- Wrap the unit up after summarizing the key points and answering questions.

UNIT 9.6: Preparing to be an Entrepreneur

Key Learning Outcomes



At the end of this unit, participants will be able to:

1. Discuss how market research is carried out
2. Describe the 4 Ps of marketing
3. Discuss the importance of idea generation
4. Recall basic business terminology
5. Discuss the need for CRM
6. Discuss the benefits of CRM
7. Discuss the need for networking
8. Discuss the benefits of networking
9. Discuss the importance of setting goals
10. Differentiate between short-term, medium-term and long-term goals
11. Discuss how to write a business plan
12. Explain the financial planning process
13. Discuss ways to manage your risk
14. Describe the procedure and formalities for applying for bank finance
15. Discuss how to manage their own enterprise
16. List the important questions that every entrepreneur should ask before starting an enterprise

UNIT 9.6.1: Market Study/ The 4Ps of Marketing/ Importance of an IDEA: Understanding Market Research

Unit Objectives

At the end of this unit, participants will be able to:

- Discuss how market research is carried out
- Describe the 4 Ps of marketing
- Discuss the importance of idea generation

Resources to be Used

- Participant Handbook
- Chart papers
- Markers pens
- Blank sheets of paper

Ask

- Suppose, you want to open a restaurant, what are the factors you will consider?
- How will you promote your restaurant?

Example

- Let's have a look at this example.

Arjun was an MBA working in a company. But he wanted to start a low cost budget hostel for foreign tourists coming to India. He did a lot of market research before starting the project. Based on the information he gathered, he made his business plan. His hostel is now flourishing and he is thinking of expanding to other tourist destinations.

Say

- Discuss “Market Study” with the participants. Refer to the Participant Handbook.
- Let's learn about market study and research with the help of an activity.

Team Activity

Market Study

- This is a group activity.
- You want to start your own tuition centre.
- What type of research will you do?

Activity De-brief

- Ask each group to come forward and give a brief presentation.
- Encourage other groups to be interactive and ask questions.
- What factors did you keep in mind while doing your research?
- Based on our research would you go ahead and open a tuition centre?

Do 

- Instruct the participants that this is group work.
- Divide the class into small groups of 4 or 6.
- Give each group a chart paper.
- Tell the participants that they have to start their own tuition centre.
- Give the participants 10 minutes to discuss and write the research work they need to do.
- Keep a check on time. Tell the group to wind up quickly if they go beyond the given time limit.

Say 

- By opening a tuition centre you are offering a service.

Ask 

- What factors will you keep in mind before opening it?

Say 

- Discuss “The 4Ps of Marketing” with the participants as given in the Participant Handbook.

Say 

- Let's learn about the 4Ps of Marketing with the help of an activity.

Team Activity **4 Ps of Marketing**

- This is a group activity.
- You have to sell a pen to four different segments:
 1. Rural villagers
 2. Rural middle class
 3. Urban middle class
 4. Upper end rich people (Niche market)

Keeping the 4Ps of Marketing in mind, what marketing strategy will you design to sell the pen?

Activity De-brief

- Ask Each group to present their strategy.
- Encourage other groups to be interactive and ask questions.

Do 

- Instruct the participants that this is group work.
- Divide the class into four groups.
- Give each group a chart paper.
- Assign each group a target audience for selling the pens:
 1. Rural villagers
 2. Rural middle class
 3. Urban middle class

4. Upper end rich people

- Tell the participants that they have to design a marketing strategy keeping the 4Ps of Marketing in mind.
- Give the participants 20 minutes to discuss and come up with their strategy.
- Keep a check on time. Tell the group to wind up quickly if they go beyond the given time limit

Activity De-brief

- Ask each group to come forward and give a brief presentation.
- Ask each group what they kept in mind while designing their marketing strategy.
- Encourage other groups to be interactive and ask questions.

Say

- Each entrepreneur has an idea of wants he wants to sell. It may be a service or a product.
- Discuss “Importance of an IDEA” as given in the Participant Handbook.

Summarize

- Summarize the key points of the unit.
- Ask the participants what they learnt from the activities.
- Encourage them to ask if they have any doubts.

UNIT 9.6.2: Business Entity Concepts

Unit Objectives

At the end of this unit, participants will be able to:

- Recall basic business terminology

Resources to be Used

- Participant Handbook

Say

- Let's recall some basic business terminology.
- Discuss the Business Entity Concepts as given in the Participant Handbook.
- Let's learn some basic business terminology by having an activity.
- We will have a quiz today.

Activity

- The activity is a quiz.

Do

- Divide the class in two groups and give a name to each group.
- Explain the rules of the quiz. For each correct answer the group gets 1 mark.
- If the group is unable to answer the question is passed to the next group.
- Explain the purpose and duration of the activity.
- Ask the questions of the quiz.
- Keep a score of the groups.
- Set guidelines pertaining to discipline and expected tasks.

Summarize

- Summarize the unit by discussing the key points.

Notes for Facilitation

QUESTIONS FOR THE QUIZ

1. What does B2B mean?
Business to business
2. What is a financial report?
A comprehensive account of a business' transactions and expenses
3. Who is a sales prospect?
A potential customer
4. How is working capital calculated?
Current assets minus current liabilities

5. What is an estimation of the overall worth of a business called?
Valuation
6. You are buying a house. What type of transaction is it?
Complex transaction
7. How will you calculate the net income?
Revenue minus expenses
8. How is Return on Investment expressed?
As percentage
9. How will you calculate the cost of goods sold?
Cost of materials minus cost of outputs
10. What is revenue?
Total amount of income before expenses are subtracted.
11. What is a Break-Even Point?
This is the point at which the company will not make a profit or a loss. The total cost and total revenues are equal.
12. What is the formula used to calculate simple interest?
 $A = P(1 + rt); R = r * 100$
13. What are the three types of business transactions?
Simple, Complex and Ongoing Transactions
14. The degrading value of an asset over time is known as
Depreciation
15. What are the two main types of capital?
Debt and Equity

UNIT 9.6.3: CRM & Networking

Unit Objectives

At the end of this unit, participants will be able to:

- Discuss the need for CRM
- Discuss the benefits of CRM
- Discuss the need for networking
- Discuss the benefits of networking

Resources to be Used

- Participant Handbook

Ask

- Can your business run without customers/buyers?
- Who is the most important entity in any business?

Say

- The key to every success business lies on understanding the customer's expectations and providing excellent customer service.
- Discuss about CRM and its benefits. Refer to the Participant Handbook.
- Providing excellent customer service entails:
 - ♦ Treating your customers with respect.
 - ♦ Be available as per their need/ schedule.
 - ♦ Handling complaints effectively.
 - ♦ Building long lasting relationships.
 - ♦ Collecting regular feedback.
- Handle customer complaints proactively. Ask “what happened”, “why it happened”, “how can it be avoided next time”, etc.
- Collecting feedback from the customers regularly will enable you to improve your good/service.
- “Let's understand it better with the help of some case scenarios. You will be given some cases within your groups. You have to analyse the case scenario that has been given to you and then find an appropriate solution to the problem.”

Do

- Divide the class into four groups of maximum six participants depending on the batch size.
- Give one case study to each group.
- Instruct them to read the case carefully.
- The group is expected to analyse and discuss the case amongst them and find a solution to the given problem.
- Put down the discussion points (de-brief questions) on the board. Give the class 5-10 minutes to discuss the case and note down their solutions.
- At the end of 10 minutes, the team should present their case solution to the class.

Team Activity

Case Study Analysis

Raju runs a business of wooden furniture. He has a huge list of customers on Facebook and WhatsApp who give him orders regularly. Ankita is one of his old and regular customers. She placed an order for a new chester and TV cabinet via WhatsApp and requested Raju to send them as soon as possible. When the parcel reached Ankita through courier she found that chester was broken and the TV unit was chipped from the bottom. Ankita was heartbroken. It was a complete waste of money. She sent a message to Raju on WhatsApp, expressing her anger and disappointment. Raju might lose an old customer forever if he doesn't satisfy the customer. What should Raju do to retain his customer?

Scenario 2

Rajni runs a boutique shop. She sells suits and sarees. She is one of the most successful designer in her city. Rajni swears that all the clothes in her boutique have unique designs. Smita has to attend her cousin's wedding; she goes to Rajni's boutique to buy a saree. Smita wanted a unique designer saree. Rajni customized a saree for her and sent it over the courier. When Smita had a look at the saree she realised her two friends had the same design sarees. She sent a message to Rajni on WhatsApp, expressing her anger and disappointment. Did Rajni make a false promise? Were her designs copied? What could happen to Rajni's image after this incident? What would you do if you were in Rajni's place?

Scenario 3

Shama is a beautician who offers parlour services to ladies by making home visits. Recently, Shama got her name registered on an e-commerce website. Two days earlier, she got a message from Mrs Sushma. The appointment was fixed for next day, 11:00 am and the remuneration for the services was decided beforehand. When Shama reached there at 10:50 am, Mrs Sushma was not at home. When Shama called her, she asked her to wait for a while. Mrs Sushma reached home at 11:45 am. Meanwhile, Shama had to reschedule her next appointment. After availing Shama's services, Mrs Sushma refused to pay the requisite amount and started finding faults in the services provided by her. Who was at fault in this scenario? What should you do in case the customer behaves unreasonably? What would you do if you were in Shama's place?

Scenario 4

Shailender is the manager of a car showroom. He proactively takes part in all the transactions that happen in his showroom. Vinita wants to buy a new car. She has chosen a car from Shailender's showroom. The salesperson has given her a very good discount and has also promised free service for one year. Vinita goes to the showroom and asks to complete all the formalities to purchase the car. When she sees the final bill she realize that she has not received the promised discount neither was there any mention of the free services. She immediately demands to see the Shailender. When Shailender's head asks how much discount Vinita was promised, he realised the discount will make the sale in loss. The car showroom owner might lose a customer and deal due to false commitments made by his manager. Besides, the customer might tell this to other people, creating a bad name and image for the showroom. If you owned that showroom, how would you have convinced your customer?

Say

- Now, let's discuss the problem and solution with the class.
- The group will first briefly describe the case to the class.
- Then discuss the issue identified and the proposed solution.
- Present the solution as a role play.
- Post presentation, the other groups may ask questions from the group that has presented.

Do 

- Congratulate each group for the presentation/ role play.
- Ask the audience to applaud for them.
- Keep a check on time. Tell the group to wind up the discussion quickly if they go beyond the given time limit.

Say 

- If your customers are happy with you they will give referrals which will help to grow your business.
- One more way of growing business is 'Networking'.
- Discuss Networking and its benefits. Refer to the Participant Handbook.

Activity **Group Discussion**

- Conduct a group discussion in the class on how they can do networking for their business.

Summarize 

- Ask the participants what they have learnt from this exercise/ activity.
- Ask if they have any questions related to what they have talked about so far.
- Close the discussion by summarizing the importance of CRM and Networking for entrepreneurs.
- Close the discussion by summarizing the importance of CRM and Networking for entrepreneurs.

UNIT 9.6.4: Business Plan: Why Set Goals?

Unit Objectives

At the end of this unit, participants will be able to:

- Discuss the importance of setting goals
- Differentiate between short-term, medium-term and long-term goals
- Discuss how to write a business plan
- Explain the financial planning process
- Discuss ways to manage your risk

Resources to be Used

- Participant Handbook
- Chart papers
- Blank papers
- Marker pens
- Ruler

Ask

- Remember we had written SMART Goals in a previous session? Let's try and recall why it is important to set goals?
- While framing SMART goals, we talked about 'T' in SMART, which was 'Time Bound'? What do we mean by time bound goals?
- What time limit did you set for your goal- 3 weeks, 3 years, 10 years?

Say

- Talk about short term, long term and medium term goals, as discussed in the Participant Handbook.

Ask

- As you are planning to become an entrepreneur, you must have thought of an idea for a start-up. What is your business idea?

Do

- Ask few participants to share their business ideas.

Ask

- Have you created a business plan for your business idea?
- Do you think it is important to have a business plan in place? Why/ why not?

Say

- Talk about 'Why Create a Business Plan' as discussed in the Participant Handbook.
- Let's understand it better with the help of an activity.

Team Activity

Writing a business Plan

- This is a group activity.
- Give the groups the required resources such as chart paper and markers.
- This activity is divided into two parts:
 1. Create a business idea
 2. Develop a business plan
- The group will discuss and come up with a new business idea and present their idea to the class.
- In the second part of the activity the group will develop a business plan for the business idea.
- The business plan prepared will be presented by the groups to the class.

MY BUSINESS PLAN
Executive Summary: What is your Mission Statement?
Business Description: What is the nature of your business?
Market Analysis: What is your target market?
Organization and Management: What is your company's organizational structure?
Service or Product Line: What is the lifecycle of your product/ service?
Marketing and Sales: How will you advertise and sell your products?
Funding Request: How much fund is required and from where?

Say

- Teams will need to brainstorm for this part of the activity.
- Use the blank papers for the second part of this activity
- Make your business plan on a chart paper based on the following parameters:
 1. Executive Summary
 2. Business Description
 3. Market Analysis
 4. Organization and Management
 5. Service or Product Line
 6. Marketing and Sales
- Explain each parameter in detail as done in the Participant Handbook.
- Discuss each parameter with the business idea examples of the groups.
- Groups will discuss and develop the business plan for their business idea.

Say 

- Now, let's share our plan with the class.
- Each group will briefly describe the plan to the class.
- Post presentation, the other groups may ask questions to the group who have presented their plan.

Do 

- Congratulate each group for sharing their points.
- Ask the audience to applaud for them.
- Keep a check on time. Tell group to wind up the discussion quickly if they go beyond the given time limit.

Say 

- Along with a business plan, you need to create a financial plan and evaluate the risk involved with your start up.
- Discuss 'Financial Planning' and 'Risk Management' in detail as given in the Participant Handbook.

Summarize 

- Ask the participants what they have learnt from this exercise/ activity.
- Ask if they have any questions related to what they have talked about so far.

Notes for Facilitation 

- Keep the business plan format ready in a flipchart to display it during the activity.

UNIT 9.6.5: Procedures and Formalities for Bank Finance

Unit Objectives

At the end of this unit, participants will be able to:

- Describe the procedure and formalities for applying for bank finance

Resources to be Used

- Participant Handbook
- Bank loan/finance form sample

Ask

- While preparing a business plan in the last session, we discussed financial planning to arrange financial resources for your start-up. Therefore, how will you collect funds to start your business?

Say

- While most entrepreneurs think 'product' is the most difficult thing to decide for a business, start-up capital poses an even a bigger obstacle. Though there are various ways of funding the business, to convince investors to invest money is the most challenging.
- Some of the funding options available in India are:
 - ♦ **Bootstrapping:** Also called self-financing is the easiest way of financing
 - ♦ **Crowd funding:** Funds are collected by consumers pre-ordering or donating for starting the business.
 - ♦ **Angel investors:** Individual or group of investors investing in the company
 - ♦ **Venture capitalists:** Venture capitals are professionally managed funds who invest in companies that have huge potential. They usually invest in a business against equity.
 - ♦ **Bank loans:** The most popular method in India.
 - ♦ **Microfinance Providers or NBFCs**
 - ♦ **Government programmes**
- Let us know discuss the most popular method i.e. bank finance in detail here.

Do

- Discuss the list of documents that are required to apply for a loan like letter of introduction, business brochure, references of other banks, and financial statements.
- Explain the details to be filled in a loan application form.
- Divide the class into groups. Give each group a loan application form.
- Ask the groups to discuss and fill the form.

Summarize

- Close the discussion by summarizing the important documents needed for bank loan.
- Ask the participants if they have any questions related to what they have talked about so far.

Notes for Facilitation

- Checklist of documents is provided as resources for the session.
- You can make some copies and distribute it during the group activity.
- Download sample loan application forms from any nationalised bank's website. Print sufficient copies to circulate it amongst the groups.

CHECKLIST OF DOCUMENTS TO BE SUBMITTED ALONG WITH LOAN APPLICATION (Common for all banks)
1. Audited financial statements of the business concern for the last three years
2. Provisional financial statements for the half – year ended on _____
3. Audited financial statements of associate concern/s for the last three years
4. Copy of QIS II for the previous quarter ended on _____
5. Operational details in Annexure I
6. CMA data for the last three years, estimates for current year and projection for the next year
7. Term loan/DPG requirements in Annexure II
8. List of machinery in respect of machinery offered as security in Annexure III
9. Additional details for export advances furnished in Annexure IV
10. Property statements of all directors/partners/proprietor/guarantors
11. Copies of ITAO of the company for the last three years
12. Copies of ITAOs/WTAOs of the directors/partners/proprietor and guarantors
13. Copies of certificate from banks and financial institutions certifying the latest liability with them
14. Copy of board resolution authorizing the company to apply to your bank for the credit facilities mentioned in application
15. Copy of memorandum and article of association (in case of limited company)/partnership deed (in case of partnership firm)
16. Cash budget for the current year and next year in case of contractors and seasonal industries

UNIT 9.6.6: Enterprise Management – An Overview: How to Manage Your Enterprise?

Unit Objectives

At the end of this unit, participants will be able to:

- Discuss how to manage their own enterprise

Resources to be Used

- Participant Handbook

Ask

- Having set-up a business, do you think it is possible to do everything on your own?
- Does one require trained persons for help?
- What does management mean?

Say

- Let's have a look at this example:

Kapil had a small business that was beginning to pick up pace. He wanted to expand his business, and therefore employed few more people. One day, as he was walking past Ramesh, one of his new employees, he overheard Ramesh talking rudely to a customer on the phone. This set him thinking. Kapil realised that he should have regular team meetings to motivate his employees and speak with them about any problems they might be facing during work. He should also conduct training sessions on new practices, soft skills, and technology, and develop work ethics manual for managing his enterprise.

Say

- Was Kapil correct in his approach or he should have scolded Ramesh instantly in front of his other employees?
- Discuss “Enterprise Management – An Overview” with the participants as given in the Participant Handbook.

Say

- Let's learn how to effectively manage an enterprise or business through an activity.

Team Activity

Enterprise Management

- This is a group activity.
- Design a matrix listing the topics and key words that are needed to run an enterprise effectively and smoothly.

Activity De-brief

- Have each group present their matrix.
- Encourage participants of the other groups to ask question about each other's presentation.

Do

- Instruct the participants that this is group work.
- Divide the class into small groups of 4.
- Give each group a chart paper and coloured pen.
- Tell the participants that they have to make a matrix they need to fill.
- They have to write the main topics and key words that will help them effectively manage their enterprise.
- Give the participants 15 minutes to discuss and write.
- Keep a check on time. Tell the group to wind up quickly if they go beyond the given time limit.

Summarize

- Ask the participants what they have learned from this exercise/activity.
- Ask if they have any questions related to what they have talked about so far.
- Close the discussion by summarizing the importance of effective management to run an enterprise as given in the Participant Handbook.

UNIT 9.6.7: 20 Questions to Ask Yourself before Considering Entrepreneurship

Unit Objectives

At the end of this unit, participants will be able to:

- List the important questions that every entrepreneur should ask before starting an enterprise

Resources to be Used

- Participant Handbook
- Blank sheets of paper
- Pens

Ask

- Why do you want to become an entrepreneur?

Say

- It is very important to know why you want to become an entrepreneur. Your personal goals for becoming an entrepreneur play a key role in the success of your business. Your goals should be clear well before you start your business.
- Apart from the goals, the other aspects of business that you need to bear in mind are the potential problems that you may face to set-up, your areas of interest, and all the other dimensions of the business.
- Let's understand it better with the help of some questions that every entrepreneur should ask before starting their own business.
- Open the Participant Handbook section named '20 Questions to Ask Yourself Before Considering Entrepreneurship'. You have to answer the questions individually.
- Then, we will have a class discussion on all the questions.

Do

- Read out the questions one by one in front of all the participants.
- Participants have to answer all the one by one questions.
- Give the class 10-15 minutes to note down their answers.
- At the end of 15 minutes, open the discussion for all the questions.
- Moderate the discussion by focusing on the relevant points.
- Keep a check on time and don't let the discussion get sabotaged or lose track of time. Ensure all the questions are covered and discussed.

Summarize

- Ask the participants what they have learned from this exercise/activity.
- Ask if they have any questions related to what they have talked about so far.

Annexure I

Training Delivery Plan

Training Delivery Plan			
Program Name:	Production/Machine Operator		
Qualification Pack Name & Ref. ID	LFS/Q0207		
Version No.	1.0	Version Update Date	As per QP
Pre-requisites to Training	On the job training for GMP and EHS		
Training Outcomes	<p>By the end of this program, the participants will be able to:</p> <ol style="list-style-type: none"> 1. Prepare machines and accessories for the manufacturing process 2. Perform manufacturing operations 3. Ensure cleanliness in the work area 4. Carry out reporting and documentation 5. Carry out broad level quality checks before, in-process and post manufacturing 6. Maintain a healthy, safe and secure working environment in the life sciences facility 		

Sl. No.	Module Name	Session Name	Session Objectives	NOS Reference	Methodology	Training Tools/Aids	Duration
1.	Orientation Module	Life Sciences Industry and its Sub-Sectors	<p>Theory:</p> <ol style="list-style-type: none"> 1. Familiarise with general instructions for the participant 2. Familiarise with Indian Life Sciences Industry 3. Learn about Sub-sectors in Life Sciences Industry 4. Learn Organization structure 	Bridge Module	<ul style="list-style-type: none"> • Facilitator-led – Discussion • Demonstration 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	3:00 hrs.
		Drug Regulatory Agencies	<p>Theory:</p> <ol style="list-style-type: none"> 1. Familiarise with Drug Regulatory Agencies 	Bridge Module	<ul style="list-style-type: none"> • Facilitator-led – Discussion • Demonstration 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	1:00 hrs.
		Impact of Rules and Regulations	<p>Theory:</p> <ol style="list-style-type: none"> 1. Discuss ten Principles of Good manufacturing practices 2. Discuss WHO GMP Protocols 3. Discuss Schedule M Compliance 4. Learn about Pharmacopoeia 	Bridge Module	<ul style="list-style-type: none"> • Facilitator-led – Discussion • Demonstration 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	4:00 hrs.
		Role of Machine Operator	<p>Theory:</p> <ol style="list-style-type: none"> 1. Learn different role of machine operator 	Bridge Module	<ul style="list-style-type: none"> • Facilitator-led – Discussion • Demonstration 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	2:00 hrs.
2.	Fundamentals of Life Sciences Manufacturing	IUPAC Rules for Naming of Organic Compounds	<p>Theory:</p> <ol style="list-style-type: none"> 1. Gain knowledge about basics of Pharmaceutical Science 2. Learn about Alkanes 3. Learn about Alkenes and Alkynes 4. Learn about Alkyl Halides 5. Discuss Alcohols 6. Discuss Ethers 7. Discuss Aldehydes 8. Discuss Ketones 9. Discuss Carboxylic Acid 	LFS/N0213, 0214	<ul style="list-style-type: none"> • Power-point presentation • Facilitator- led - discussion • Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	8:00 hrs.
			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> • Explain the IUPAC Rules for naming of organic compounds 	LFS/N0213, 0214	<ul style="list-style-type: none"> • Practical Lab 	Note Pad, Pen, charts	3:00 hrs.
		Organic Reactions Mechanism	<p>Theory:</p> <ol style="list-style-type: none"> 1. Discuss different types of Organic Reactions 2. Discuss Mechanism of Organic Reactions 	LFS/N0213, 0214	<ul style="list-style-type: none"> • Power-point presentation • Facilitator- led - discussion • Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	8:00 hrs.
			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> • Demonstrate Organic reactions • Demonstrate mechanism of organic reactions 	LFS/N0213, 0214	<ul style="list-style-type: none"> • Practical Lab 	Note Pad, Pen, charts	3:00 hrs.
		Quality Management System	<p>Theory:</p> <ol style="list-style-type: none"> 1. Discuss quality management system 2. Learn about development of QMS 	LFS/N0213, 0214	<ul style="list-style-type: none"> • Power-point presentation • Facilitator- led - discussion • Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	2:00 hrs.

		Productivity Concepts	<p>Theory:</p> <ol style="list-style-type: none"> Learn about Productivity Discuss prime causes of production losses Learn to capture production data Learn about Overall Equipment Effectiveness (OEE) 	LFS/N0213, 0214	<ul style="list-style-type: none"> Power-point presentation Facilitator- led - discussion Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	3:00 hrs.
		Techniques of Improving Productivity	<p>Theory:</p> <ol style="list-style-type: none"> Discuss about Six Sigma Discuss about Lean Learn Quality control and Quality assurance Learn Quality Risk Management List the tips to reduce defects and improve quality in Pharmaceutical manufacturing 	LFS/N0213, 0214	<ul style="list-style-type: none"> Power-point presentation Facilitator- led - discussion Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	5:00 hrs.
		Good Manufacturing Practices	<p>Theory:</p> <ol style="list-style-type: none"> Discuss CGMP Enforcement and list guidelines Discuss Data Integrity Learn documentation practices required by CGMP 	LFS/N0213, 0214	<ul style="list-style-type: none"> Power-point presentation Facilitator- led - discussion Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	4:00 hrs.
3.	Prepare for and Perform Manufacturing Operations of API	Orientation with Machines and Manufacturing Concepts for API Manufacturing	<p>Theory:</p> <ol style="list-style-type: none"> Discuss Leading API Manufacturers Learn about API Outsourcing Discuss Size separation 	LFS/N0213, 0214	<ul style="list-style-type: none"> Power-point presentation Facilitator- led - discussion Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	7:00 hrs.
			<p>Theory:</p> <ol style="list-style-type: none"> Discuss Size Reduction 	LFS/N0213, 0214	<ul style="list-style-type: none"> Power-point presentation Facilitator- led - discussion Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	3:00 hrs.
			<p>Theory:</p> <ol style="list-style-type: none"> Learn mixing and Homogenization process Gain knowledge of fluid flow 	LFS/N0213, 0214	<ul style="list-style-type: none"> Power-point presentation Facilitator- led - discussion Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	3:00 hrs.
			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> Demonstrate Size separation Demonstrate Size reduction 	LFS/N0213, 0214	<ul style="list-style-type: none"> Practical Lab 	Note Pad, Pen, charts	6:00 hrs.
			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> Demonstrate Mixing and Homogenization process 	LFS/N0213, 0214 Practical Lab	<ul style="list-style-type: none"> Practical Lab 	Note Pad, Pen, charts	4:00 hrs.
		Perform Chemical Reactions and Manufacturing Operations for API	<p>Theory:</p> <ol style="list-style-type: none"> Discuss Unit process 	LFS/N0213, 0214	<ul style="list-style-type: none"> Power-point presentation Facilitator- led - discussion Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	6:00 hrs.
			<p>Theory:</p> <ol style="list-style-type: none"> Discuss Bulk Organic Chemicals 	LFS/N0213, 0214	<ul style="list-style-type: none"> Power-point presentation Facilitator- led - discussion Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	5:00 hrs.
			<p>Theory:</p> <ol style="list-style-type: none"> Discuss catalysis and biocatalysis in Industrial Production Discuss Chemical technologies for selected drugs 	LFS/N0213, 0214	<ul style="list-style-type: none"> Power-point presentation Facilitator- led - discussion Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	6:00 hrs.

			Practical: Demonstrate <ul style="list-style-type: none"> Demonstrate Unit process Explain Bulk organic chemicals 	LFS/ N0213,0214	<ul style="list-style-type: none"> Practical Lab 	Note Pad, Pen, charts	8:00 hrs.
			<ul style="list-style-type: none"> Practical: Demonstrate Demonstrate chemical technologies for selected drugs 	LFS/ N0213,0214	<ul style="list-style-type: none"> Practical Lab 	Note Pad, Pen, charts	6:00 hrs.
4.	Prepare for and Perform Manufacturing Operations of Formulations	Routes of Drug Administration	Theory: <ol style="list-style-type: none"> Discuss Dosage form Explain classification of Dosage forms (Physical form) Discuss about Pharmaceutical manufacturing equipment 	LFS/ N0213,0214	<ul style="list-style-type: none"> Power-point presentation Facilitator- led - discussion Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	6:00 hrs.
			Practical: Demonstrate <ul style="list-style-type: none"> Explain pharmaceutical manufacturing equipment 	LFS/ N0213,0214	<ul style="list-style-type: none"> Power-point presentation Facilitator- led - discussion Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	6:00 hrs.
		Prepare for and Perform Manufacturing Operations of Oral Solid Dosage	Theory: <ol style="list-style-type: none"> Discuss about Tablets Discuss about Granulation Learn primary unit operation: Drying, Milling and Screening, Blending. Discuss Tablet Compression Discuss about granule properties influencing compression Demonstrate steps involved in compression Learn Tablet Coating Discuss about Coating Equipment Discuss composition of coating dispersion Discuss the factors affecting film coating Discuss Capsules filing Discuss tablet defects and remedies List types of Capsules Discuss Capsule filling operation Explain Capsule Defects 	LFS/ N0213,0214	<ul style="list-style-type: none"> Power-point presentation Facilitator- led - discussion Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	7:00 hrs.
			Practical: Demonstrate <ul style="list-style-type: none"> Demonstrate Granulation Demonstrate primary unit operation: Drying, Milling and Screening, Blending Demonstrate steps involved in compression Perform capsule filling operation 	LFS/ N0213,0214	<ul style="list-style-type: none"> Practical Lab 	Note Pad, Pen, charts	7:00 hrs.

		Prepare for and Perform Manufacturing Operations of Liquid Oral Dosage	<p>Theory:</p> <ol style="list-style-type: none"> 1. Discuss types of Oral Liquids 2. Discuss types of Monophasic liquid dosage forms 3. Explain manufacturing considerations 4. Discuss Operation, Cleaning and maintenance of filter press 5. Discuss mixing processes 6. Discuss Biphasic Dosage Forms: Suspensions 7. Explain types of Suspension 8. Discuss preparation of suspensions 9. Discuss Biphasic Dosage Forms: Emulsions 10. Explain types of Emulsions 11. Explain uses of Emulsions 12. Discuss Emulsifying agents 13. Explain preservation Emulsions 14. Discuss Chemical Parameters for Formation of Emulsion 15. Discuss HLB Method for Selection of Emulsifying Agent 16. Discuss machineries required for Preparation of Emulsions 17. Discuss parameters for Assessing the Emulsion Stability 18. Explain Gels 	LFS/ N0213,0214	<ul style="list-style-type: none"> • Power-point presentation • Facilitator- led - discussion • Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	7:00 hrs.
			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> • Perform operation, cleaning and maintenance of filter press • Demonstrate mixing processes • Demonstrate preparation of suspensions 	LFS/ N0213,0214	<ul style="list-style-type: none"> • Practical Lab 	Note Pad, Pen, charts	7:00 hrs.
		Prepare for and Perform Manufacturing Operations of Sterile Dosage	<p>Theory:</p> <ol style="list-style-type: none"> 1. Discuss Terminal sterilization 2. Discuss Aseptic processing 3. Explain Water for Injection (WFI) 4. Discuss Gowning Procedures 5. Explain Good Aseptic Technique 6. Discuss HVAC Design and Construction 7. Discuss basic Microbiology and Environmental Monitoring 8. Explain preparation and filtration of solutions 9. Discuss Filter Integrity 10. Discuss Filter Integrity Testing 11. Discuss Equipment/Container Preparation and Sterilization 12. Explain operation and cleaning of autoclave 13. Explain CIP and SIP Process 14. Discuss operation and maintenance of Isolators 15. Discuss filling of Ampoules, Vials, Prefilled Syringes, Bags Facility Design and HEPA System 16. Explain Environmental Monitoring 17. Explain SMED Concept 18. Discuss Good Documentation Practices 19. Learn Handling of Equipment by Personnel 	LFS/ N0213,0214	<ul style="list-style-type: none"> • Power-point presentation • Facilitator- led - discussion • Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	6:00 hrs.

			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> • Demonstrate terminal sterilization • Preparation and filtration of solutions • Filter integrity testing • Demonstrate equipment/container preparation and sterilization • Demonstrate operation and cleaning of autoclave • Perform CIP and SIP process • Demonstrate operation and maintenance of isolators • Demonstrate Filling of Ampoules, Vials, Prefilled Syringes, Bags • Facility Design and HEPA System • Demonstrate environmental manufacturing 	LFS/ N0213,0214	<ul style="list-style-type: none"> • Practical Lab 	Note Pad, Pen, charts	6:00 hrs.
		Prepare for and Perform Manufacturing Operations of Dermatological Formulation	<p>Theory:</p> <ol style="list-style-type: none"> 1. Discuss classification and types of Dermatological products 2. Explain types of Ointment bases 3. Discuss Dermatological Product Formulations 4. Discuss In-Process Testing for Dermatological 5. Explain Common Manufacturing and Filling Defects and Trouble Shooting 6. Discuss Equipment and Production Control 7. Explain Critical Process Parameters (CPPs) and Critical Quality attributes (CQAs) 	LFS/ N0213,0214	<ul style="list-style-type: none"> • Power-point presentation • Facilitator- led - discussion • Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	4:00 hrs.
			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> • Demonstrate dermatological product formulations • Demonstrate In-process testing for dermatological 	LFS/ N0213,0214	<ul style="list-style-type: none"> • Practical Lab 	Note Pad, Pen, charts	4:00 hrs.
5.	Carry out Broad Level Checks Before, In-process and Post Manufacturing	Deviations and Incidents	<p>Theory:</p> <ol style="list-style-type: none"> 1. Learn Deviation handling 2. Explain Quality risk management and deviation 	LFS/N0215	<ul style="list-style-type: none"> • Power-point presentation • Facilitator- led - discussion • Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	5:00 hrs.
			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> • Explain Deviation Handling 	LFS/N0215	<ul style="list-style-type: none"> • Practical Lab 	Note Pad, Pen, charts	3:00 hrs.
		Quality Checks in Pharma/ Bio Pharma Manufacturing Operations	<p>Theory:</p> <ol style="list-style-type: none"> 1. Explain In-Process quality check 2. Discuss Quality control 3. Explain Sampling, Testing 4. Explain documentation of In Process Checks and Evaluation of data/information 5. Discuss Post manufacturing checks 	LFS/N0215	<ul style="list-style-type: none"> • Power-point presentation • Facilitator- led - discussion • Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	5:00 hrs.
			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> • Explain In-Process quality check • Explain Quality control • Perform Sampling • Perform Testing 	LFS/N0215	<ul style="list-style-type: none"> • Practical Lab 	Note Pad, Pen, charts	2:00 hrs.
6.	Carryout Reporting and Documentation	Documentation and Reporting for Machine Operator	<p>Theory:</p> <ol style="list-style-type: none"> 1. Learn to read and interpret the graphs/ images of product and instructions given in tool/ equipment manual. 2. Describe basic understanding of machines control panel, material labels & safety signage. 3. Identify various coding system of the company. 4. Select documentation. 5. Record and communicate details of work done. 6. Follow daily report format and submission as per the instructions. 	LFS/N0102	<ul style="list-style-type: none"> • Power-point presentation • Facilitator- led - discussion • Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	3:00 hrs.

			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> • Demonstrate the types of communication • Discuss the control panel 	LFS/N0102	<ul style="list-style-type: none"> • Practical Lab 	Note Pad, Pen, charts	6:00 hrs.
			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> • Demonstrate SOP guidelines • Role Play on Incident • Steps of decision making 	LFS/N0102	<ul style="list-style-type: none"> • Practical Lab 	Note Pad, Pen, charts	2:00 hrs.
		Introduction to Computer	<p>Theory:</p> <ol style="list-style-type: none"> 1. Define the computer. 2. Recognise its various parts. 3. Differentiate the advantages and disadvantages of computer. 	LFS/N0102	<ul style="list-style-type: none"> • Power-point presentation • Facilitator- led – discussion • Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	0.5:00 hrs.
		Basic Computer Knowledge	<p>Theory:</p> <ol style="list-style-type: none"> 1. Use computer. 2. Explain the web, email services. 	LFS/N0102	<ul style="list-style-type: none"> • Power-point presentation • Facilitator- led – discussion • Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	0.5:00 hrs.
		Components of Computer	<p>Theory:</p> <ol style="list-style-type: none"> 1. Know the different parts and components of computer. 	LFS/N0102	<ul style="list-style-type: none"> • Power-point presentation • Facilitator- led – discussion • Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	0.5:00 hrs.
		Concept of Operating System	<p>Theory:</p> <ol style="list-style-type: none"> 1. Familiarise with the concept of operating system. 2. Work on Windows 8 and 8.1. 3. Add or Remove desktop icons, make or delete a folder etc. 	LFS/N0102	<ul style="list-style-type: none"> • Power-point presentation • Facilitator- led – discussion • Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	1.5:00 hrs.
			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> • Demonstrate the tools and parts of an OS • Create a folder and use add or remove command • Demonstrate common window commands 	LFS/N0102	<ul style="list-style-type: none"> • Practical Lab 	Note Pad, Pen, charts	2:00 hrs.
		MS Word	<p>Theory:</p> <ol style="list-style-type: none"> 1. Learn the concept of and practice MS-Word. 2. Format a document. 3. Print a document etc. 	LFS/N0102	<ul style="list-style-type: none"> • Power-point presentation • Facilitator- led – discussion • Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	2:00 hrs.
			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> • Gain practical knowledge of MS-Word 	LFS/N0102	<ul style="list-style-type: none"> • Practical Lab 	Note Pad, Pen, charts	2:00 hrs.
		MS PowerPoint	<p>Theory:</p> <ol style="list-style-type: none"> 1. Practice MS – Power point. 2. Make a new presentation. 3. Format a slide as well 	LFS/N0102	<ul style="list-style-type: none"> • Power-point presentation • Facilitator- led – discussion • Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	2:00 hrs.
			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> • Gain practical knowledge of MS- Power point 	LFS/N0102	<ul style="list-style-type: none"> • Practical Lab 	Note Pad, Pen, charts	2:00 hrs.
		MS Excel	<p>Theory:</p> <ol style="list-style-type: none"> 1. Work on MS-Excel 2. Format cells and cell content 3. Use formulas 4. Make Charts and Pivot Table 	LFS/N0102	<ul style="list-style-type: none"> • Power-point presentation • Facilitator- led – discussion • Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	2:00 hrs.

			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> Gain practical knowledge of MS-Excel 	LFS/N0102	<ul style="list-style-type: none"> Practical Lab 	Practical Lab	2:00 hrs.
		Internet Concepts	<p>Theory:</p> <ol style="list-style-type: none"> Understand internet concepts Recognise the different types of URLs Use MS-Outlook 	LFS/N0102	<ul style="list-style-type: none"> Power-point presentation Facilitator- led – discussion Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	1:00 hrs.
		Introduction to LMIS	<p>Theory:</p> <ol style="list-style-type: none"> Discuss components and interfaces of a LMIS Explain LMIS workflow Explain LMIS screens Discuss working on LMIS Explain advantages of LMIS 	LFS/N0102	<ul style="list-style-type: none"> Power-point presentation Facilitator- led - discussion Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	2:00 hrs.
			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> Work on LMIS 	LFS/N0102	<ul style="list-style-type: none"> Practical Lab 	Note Pad, Pen, charts	6:00 hrs.
7	Maintain a Healthy, Safe and Secure Working Environment	Safety including Hazards, Accidents, Safety Signs and Signals and Heinrich Pyramid	<p>Theory:</p> <ol style="list-style-type: none"> Gain knowledge about safety including hazards, accidents, safety signs and signals. Understand the Heinrich Pyramid. Orient with Water Systems at Plant, Engineering related tools and techniques to operate the machine safely. Understand the clean room classifications and requirements. Relate with the clean room behaviour practices. Use Material Data Safety Sheet and Process of Safety Analysis. Orient with Fire Safety concepts, PPEs action to be taken in case of fire emergency at shop floor. Perform Job Safety Analysis for various production machines/ equipment and provide the critical information to concerned team members. Manage emergency procedures and apply first aid. Learn about basic professional and communication skills necessary to perform work successfully. 	LFS/N0101	<ul style="list-style-type: none"> Power-point presentation Facilitator- led - discussion Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	4:00 hrs.
			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> Demonstrate the relation b/w unsafe act, unsafe condition and hazard Discuss about the safety signs, prohibition sign, Warning Sign and Mandatory signs 	LFS/N0101	<ul style="list-style-type: none"> Practical Lab 	Note Pad, Pen, charts	3:00 hrs.
		Water Systems at Plant	<p>Theory:</p> <ol style="list-style-type: none"> Explain the water system at plant. 	LFS/N0101	<ul style="list-style-type: none"> Power-point presentation Facilitator- led - discussion Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	2:00 hrs.
			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> Discuss the types of water used in Pharmaceutical Processes 	LFS/N0101	<ul style="list-style-type: none"> Practical Lab 	Note Pad, Pen, charts	2:00 hrs.
		Clean Room: Classifications, Requirements and Behaviour Practices	<p>Theory:</p> <ol style="list-style-type: none"> Explain the clean room and its classification. Identify the personal behaviour of persons working in clean room. 	LFS/N0101	<ul style="list-style-type: none"> Power-point presentation Facilitator- led - discussion Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	1:00 hrs.

			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> Discuss the personal behavior of persons working in a Clean Room 	LFS/N0101	<ul style="list-style-type: none"> Practical Lab 	Note Pad, Pen, charts	1:00 hrs.
		Process of Safety Analysis	<p>Theory:</p> <ol style="list-style-type: none"> Describe the process of safety analysis. Prepare material safety data sheet. 	LFS/N0101	<ul style="list-style-type: none"> Power-point presentation Facilitator- led - discussion Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	4:00 hrs.
			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> Demonstrate Material Safety Data Sheet Role Play – Fire safety and Emergency Preparedness Demonstrate the classes of fire Discuss the fire-fighting rules Demonstrate PPEs 	LFS/N0101	<ul style="list-style-type: none"> Practical Lab 	Note Pad, Pen, charts	3:00 hrs.
		Job Safety Analysis (JSA)	<p>Theory:</p> <ol style="list-style-type: none"> Describe the job safety analysis. 	LFS/N0101	<ul style="list-style-type: none"> Power-point presentation Facilitator- led - discussion Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	1:00 hrs.
		Managing Emergency Procedures and First Aid	<p>Theory:</p> <ol style="list-style-type: none"> Identify different types emergencies. Follow the emergency procedures and perform first aid. 	LFS/N0101	<ul style="list-style-type: none"> Power-point presentation Facilitator- led - discussion Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	3:00 hrs.
			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> Role Play – Response in case of fire and Chemical Spill 	LFS/N0101	<ul style="list-style-type: none"> Practical Lab 	Note Pad, Pen, charts	1:00 hrs.
8.	Ensure Cleanliness at workplace	Material, Chemicals and Equipment and Cleaning Procedures	<p>Theory:</p> <ol style="list-style-type: none"> Identify different Material, chemicals and equipment and their cleaning procedure. 	LFS/N0103	<ul style="list-style-type: none"> Power-point presentation Facilitator- led – discussion Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	5:00 hrs.
			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> Perform housekeeping activities Demonstrate different materials and chemicals 	LFS/N0103	<ul style="list-style-type: none"> Practical Lab 	Note Pad, Pen, charts	3:00 hrs.
			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> Demonstrate the process of equipment maintenance and their cleaning Practice 5S System 	LFS/N0103	<ul style="list-style-type: none"> Practical Lab 	Note Pad, Pen, charts	3:00 hrs.
		Methodology for Storage Area Inspection	<p>Theory:</p> <ol style="list-style-type: none"> Explain methodology for storage area inspection. 	LFS/N0103	<ul style="list-style-type: none"> Power-point presentation Facilitator- led - discussion Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	4:00 hrs.
			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> Demonstrate the storage area guidelines Discuss about the validation of cleaning 	LFS/N0103	<ul style="list-style-type: none"> Practical Lab 	Note Pad, Pen, charts	2:00 hrs.

		Core Skills and Professional Skills	<p>Theory:</p> <ol style="list-style-type: none"> 1. Explain core skills and professional skills required for a machine operator in life science 	LFS/N0103	<ul style="list-style-type: none"> • Power-point presentation • Facilitator- led - discussion • Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	3:00 hrs.
			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> • Explain Case Study 	LFS/N0103	<ul style="list-style-type: none"> • Practical Lab 	Note Pad, Pen, charts	2:00 hrs.
		Waste Disposal and Scrap Management	<p>Theory:</p> <ol style="list-style-type: none"> 1. Identify where disposal take place and what procedure is to be followed for safety purpose 2. Discuss methods of disposal of waste material 3. Identify hazardous waste material 4. Learn proper handling, storage, transportation of all hazardous material 5. Identify chemical symbols and their meaning 6. Identify damaged and expired labels 7. Discuss waste management, reusing of non-confirming products 8. Discuss disposal of garnered waste 9. Discuss dispose of chemical and explain their reaction 	LFS/N0103	<ul style="list-style-type: none"> • Power-point presentation • Facilitator- led - discussion • Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	3:00 hrs.
			<p>Practical: Demonstrate</p> <ul style="list-style-type: none"> • Demonstrate pharmaceutical waste management • Perform pharmaceutical waste treatment and disposal 	LFS/N0103	<ul style="list-style-type: none"> • Practical Lab 	Note Pad, Pen, charts	3:00 hrs.

9.	Employability and Entrepreneurship skills	Personal Strengths & Value Systems	<p style="text-align: center;">Theory:</p> <ol style="list-style-type: none"> 1. Explain the meaning of health 2. List common health issues 3. Discuss tips to prevent common health issues 4. Explain the meaning of hygiene 5. Understand the purpose of Swacch Bharat Abhiyan 6. Explain the meaning of habit 7. Discuss ways to set up a safe work environment 8. Discuss critical safety habits to be followed by employees 9. Explain the importance of self-analysis 10. Understand motivation with the help of Maslow's Hierarchy of Needs 11. Discuss the meaning of achievement motivation 12. List the characteristics of entrepreneurs with achievement motivation 13. List the different factors that motivate you 14. Discuss how to maintain a positive attitude 15. Discuss the role of attitude in self-analysis 16. List your strengths and weaknesses 17. Discuss the qualities of honest people 18. Describe the importance of honesty in entrepreneurs 19. Discuss the elements of a strong work ethic 20. Discuss how to foster a good work ethic 21. List the characteristics of highly creative people 22. List the characteristics of highly innovative people 23. Discuss the benefits of time management 24. List the traits of effective time managers 25. Describe effective time management technique 26. Discuss the importance of anger management 27. Describe anger management strategies 28. Discuss tips for anger management 29. Discuss the causes of stress 30. Discuss the symptoms of stress 31. Discuss tips for stress management 	Bridge Module	<ul style="list-style-type: none"> • Power-point presentation • Facilitator- led - discussion • Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.
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	Digital Literacy: A Recap	<p>Theory:</p> <ol style="list-style-type: none"> 1. Identify the basic parts of a computer 2. Identify the basic parts of a keyboard 3. Recall basic computer terminology 4. Recall basic computer terminology 5. Recall the functions of basic computer keys 6. Discuss the main applications of MS Office 7. Discuss the benefits of Microsoft Outlook 8. Discuss the different types of e-commerce 9. List the benefits of e-commerce for retailers and customers 10. Discuss how the Digital India campaign will help boost e-commerce in India 11. Describe how you will sell a product or service on an e-commerce platform 	Bridge Module	<ul style="list-style-type: none"> • Power-point presentation • Facilitator- led - discussion • Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	
	Money Matters	<p>Theory:</p> <ol style="list-style-type: none"> 1. Discuss the importance of saving money 2. Discuss the benefits of saving money 3. Discuss the main types of bank accounts 4. Describe the process of opening a bank account 5. Differentiate between fixed and variable costs 6. Describe the main types of investment options 7. Describe the different types of insurance products 8. Describe the different types of taxes 9. Discuss the uses of online banking 10. Discuss the main types of electronic funds transfers 	Bridge Module	<ul style="list-style-type: none"> • Power-point presentation • Facilitator- led - discussion • Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	
	Preparing for Employment and Self Employment	<p>Theory:</p> <ol style="list-style-type: none"> 1. Discuss the steps to prepare for an interview 2. Discuss the steps to create an effective Resume 3. Discuss the most frequently asked interview questions 4. Discuss how to answer the most frequently asked interview questions 5. Discuss basic workplace terminology 	Bridge Module	<ul style="list-style-type: none"> • Power-point presentation • Facilitator- led - discussion • Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	

		Understanding Entrepreneurship	<p style="text-align: center;">Theory:</p> <ol style="list-style-type: none"> 1. Discuss the concept of entrepreneurship 2. Discuss the importance of entrepreneurship 3. Describe the characteristics of an entrepreneur 4. Describe the different types of enterprises 5. List the qualities of an effective leader 6. Discuss the benefits of effective leadership 7. List the traits of an effective team 8. Discuss the importance of listening effectively 9. Discuss how to listen effectively 10. Discuss the importance of speaking effectively 11. Discuss how to speak effectively 12. Discuss how to solve problems 13. List important problem solving traits 14. Discuss ways to assess problem solving skills 15. Discuss the importance of negotiation 16. Discuss how to negotiate 17. Discuss how to identify new business opportunities 18. Discuss how to identify business opportunities within your business 19. Understand the meaning of entrepreneur 20. Describe the different types of entrepreneurs 21. List the characteristics of entrepreneurs 22. Recall entrepreneur success stories 23. Discuss the entrepreneurial process 24. Describe the entrepreneurship ecosystem 25. Discuss the government's role in the entrepreneurship ecosystem 26. Discuss the current entrepreneurship ecosystem in India 27. Understand the purpose of the Make in India campaign 28. Discuss the relationship between entrepreneurship and risk appetite 29. Discuss the relationship between entrepreneurship and resilience 30. Describe the characteristics of a resilient entrepreneur 31. Discuss how to deal with failure 	Bridge Module	<ul style="list-style-type: none"> • Power-point presentation • Facilitator- led - discussion • Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	
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		Preparing to be an Entrepreneur	<p>Theory:</p> <ol style="list-style-type: none"> 1. Discuss how market research is carried out 2. Describe the 4 Ps of marketing 3. Discuss the importance of idea generation 4. Recall basic business terminology 5. Discuss the need for CRM 6. Discuss the benefits of CRM 7. Discuss the need for networking 8. Discuss the benefits of networking 9. Understand the importance of setting goals 10. Differentiate between short-term, medium-term and long-term goals 11. Discuss how to write a business plan 12. Explain the financial planning process 13. Discuss ways to manage your risk 14. Describe the procedure and formalities for applying for bank finance 15. Discuss how to manage your own enterprise 16. List important questions that every entrepreneur should ask before starting an enterprise 	Bridge Module	<ul style="list-style-type: none"> • Power-point presentation • Facilitator- led - discussion • Audio- visuals Images 	Available Objects such as a book, pen, duster, white board, marker, Computer, Projector etc.	
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Total Training hour	200 Hour
Theory	60 Hour
Practical	140 Hour

Annexure II

Assessment Criteria

CRITERIA FOR ASSESSMENT OF TRAINEES

Assessment Criteria for Production/Machine Operator – Life Sciences	
Job Role	Production/Machine Operator – Life Sciences
Qualification Pack	LFS/Q0207
Sector Skill Council	Life Sciences Sector Skill Development Council
Sr. No.	Guidelines for Assessment
1	Criteria for assessment for each Qualification Pack will be created by the Sector Skill Council. Each Performance Criteria (PC) will be assigned marks proportional to its importance in NOS. SSC will also lay down proportion of marks for Theory and Skills Practical for each PC.
2	The assessment for the theory part will be based on knowledge bank of questions created by the SSC.
3	Individual assessment agencies will create unique question papers for theory part for each candidate at each examination/training center (as per assessment criteria below)
4	Individual assessment agencies will create unique evaluations for skill practical for every student at each examination/training center based on this criteria
5	To pass the Qualification Pack , every trainee should score a minimum of 70% in every NOS
6	In case of successfully passing only certain number of NOS's, the trainee is eligible to take subsequent assessment on the balance NOS's to pass the Qualification Pack.

Assessment Outcome	Assessment Criteria of Outcomes	Total Marks (600)	Out Of	Marks Allocation	
				Theory	Skills Practical
LFS/N0213 (Prepare machines and accessories for the manufacturing process)	PC1. Take handover from the colleague in previous shift and ensure that the machine, surrounding areas and classified areas are clean, dry, sterilised (wherever required) and fit for use as per the SOP to avoid contamination and highlight the risk if any	100	4	2	2
	PC2. set up machines at the beginning of the batch processing to ensure proper working order and refer to the machine history received from the supervisor/colleague at the time of handover		4	2	2
	PC3. perform testing procedures to ensure that machines work optimally to carry out production activities		4	2	2
	PC4. ensure that the approach path from the input storage area to storage area for output is free		4	2	2

	of obstructions to transportation			
	PC5. select the correct material to be loaded	4	2	2
	PC6. ensure that the material is from a respective batch and is checked by the concerned supervisor and approved by the QA team	4	2	2
	PC7. assemble the machinery properly	4	2	2
	PC8. set critical parameters for the machinery (cycle time, temperature, pressure, ampere load, spray rate, etc.) as per the company's SOP	4	2	2
	PC9. keep all the accessories like cleaning brush, levers, release agent, etc. ready	4	2	2
	PC10. monitor machines during every procedure to ensure optimum performance	4	2	2
	PC11. perform random tests to ensure accuracy and maintain online documentation for the same along with justifications for any wrong entries, if any	4	2	2
	PC12. coordinate with maintenance teams for preventive maintenance	4	2	2
	PC13. ensure stocks of required materials are ready and available at all times	4	2	2
	PC14. ensure that the compound/material to be fed is approved by the laboratory as per SOP and record the receipt details like product name, batch name and operator name	4	2	2
	PC15. match the batch code/item code , authorized return (AR) No. of each compound/material with the batch code on the job schedule given by the planning department, ensuring FIFO and further record the name, shelf	4	2	2

	life and quantities during documentation				
	PC16. measure/weigh the raw material/compound as per the desired specifications (shape, size and weight) and return the unused material to warehouse with the appropriate label		4	2	2
	PC17. ensure, by visual inspection, that the compound is of desired quality (free of contamination/bloom), and reach out to the supervisor for rejection control if disparities exist		4	3	3
	PC18. ensure housekeeping/safety in the manufacturing area as per the SOP		4	2	2
	PC19. maintain and clean the machines before and after batch processing		4	2	2
	PC20. use lifting equipment such as forklift/trolleys while lifting heavy materials to avoid physical injury		4	2	2
	PC21. ensure that the lift/ejection/slide/pneumatic valve mechanism of the machinery is properly functioning		4	2	2
	PC22. ensure that signs indicating hot surfaces are put up wherever necessary		4	2	2
	PC23. adhere to all safety norms (like wearing protective gloves, shoes)		4	2	2
	PC24. comply with health, safety, environment guidelines, regulations in accordance with international/national standards or organizational SOP		4	3	3
	Total		100	50	50
LFS/N0214 (Perform manufacturing operations)	PC1. handle the chemicals, materials and compounds appropriately to avoid contamination	100	8	4	4
	PC2. conduct pre-start checks		12	6	6

PC3. start the equipment safely and perform 'dry runs' to warm hydraulics and components to operating temperature before production, as required	10	5	5
PC4. load the identified material in the correct pattern as per the SOP to minimize material overflow/wastage/excess flash	8	4	4
PC5. ensure smooth running of machines and the pressure and temperature is maintained in the machines as per the specifications and adhere to the production timelines	8	4	4
PC6. adhere to the SOPs and guidelines for maintaining quality	6	3	3
PC7. maintain both online and offline records in the log books and other documentation required as per GMP and GDP like – breakdown time, daily manufacturing record, yield report, etc	6	3	3
PC8. take appropriate safety steps while carrying out manufacturing operations	5	2	3
PC9. carry out status labelling and segregation of material/ intermediate/ finished goods as per SOPs	4	2	2
PC10. provide support for line clearance before the next batch is produced and handover the work / equipment to colleague in next shift in adherence of the shift schedule	4	2	2
PC 11. perform broad level in-process checks and report results to supervisor	4	2	2
PC 12. ensure and confirm correctness of online process parameters	6	3	3
PC 13. minimize waste during entire production operations	4	2	2

	PC14. coordinate and work with supervisor, team members in own department and cross functions to achieve the production targets and to ensure efficient workflow		6	2	4
	PC15. take necessary steps as per SOP and escalation matrix in case of any disagreement with colleagues or in other conflict		5	2	3
	PC16. discuss with supervisor on own performance and receive support and feedback from supervisor or any other appropriate authority		4	2	2
	Total		100	48	52
LFS/N0103 (Ensure cleanliness in the work area)	PC1.inspect the area while taking into account various surfaces	100	4	2	2
	PC2.identify the material requirements for cleaning the areas inspected, by considering risk, time, efficiency and type of stain		5	2	3
	PC3.ensure that the cleaning equipment is in proper working condition		5	2	3
	PC4.select the suitable alternatives for cleaning the areas in case the appropriate equipment and materials are not available and inform the appropriate person		4	2	2
	PC5.plan the sequence for cleaning the area to avoid re-soiling clean areas and surfaces		4	2	2
	PC6.inform the affected people about the cleaning activity		4	2	2
	PC7.display the appropriate signage for the work being conducted		4	2	2
	PC8.ensure that there is adequate ventilation for the work being carried out		5	2	3
	PC9.wear the personal protective equipment required for the cleaning method and materials being used		4	2	2

PC10.use the correct cleaning method for the work area, type of soiling and surface		4	2	2
PC11.deal with accidental damage, if any, caused while carrying out the work		4	2	2
PC12.report to the appropriate person any difficulties in carrying out work		4	2	2
PC13.identify and report to the appropriate person any additional cleaning required that is outside one's responsibility or skill		4	2	2
PC14.ensure that there is no oily substance on the floor to avoid slippage		4	2	2
PC15.ensure that no scrap material is lying around		4	2	2
PC16.maintain and store housekeeping equipment and supplies		4	2	2
PC17.follow workplace procedures to deal with any accidental damage caused during the cleaning process		4	2	2
PC18.ensure that, on completion of the work, the area is left clean and dry and meets requirements		4	2	2
PC19.return the equipment, materials and personal protective equipment that were used to the right places making sure they are clean, safe and securely stored		5	2	3
PC20.dispose the waste garnered from the activity in an appropriate manner		5	2	3
PC21.dispose of used and un-used solutions according to manufacturer's instructions, and clean the equipment thoroughly		5	2	3
PC22.maintain schedules and records for housekeeping duty		5	2	3

	PC23.replenish any necessary supplies or consumables		5	2	3
	Total		100	46	54
LFS/N0102 (Carry out reporting and documentation)	PC1.report data/problems/incidents as applicable in a timely manner	100	10	5	5
	PC2.report to the appropriate authority as laid down by the company		10	5	5
	PC3.follow reporting procedures as prescribed by the company		10	5	5
	PC4.identify documentation to be completed relating to one's role		10	5	5
	PC5.record details accurately in an appropriate format		10	5	5
	PC6.complete all documentation within stipulated time according to company procedure		10	5	5
	PC7.ensure that the final document meets regulatory and compliance requirements		10	5	5
	PC8.make sure documents are available to all appropriate authorities to inspect		10	5	5
	PC9.respond to requests for information in an appropriate manner whilst following organizational procedures		10	5	5
	PC10.inform the appropriate authority of requests for information received		10	4	6
	Total		100	49	51
LFS/N0215 (Carry out broad level quality checks before, in-process and post manufacturing)	PC1.ensure that total range of checks are regularly and consistently performed	100	10	5	5
	PC2.check that the products, materials and equipment meet the requirements for production		10	5	5
	PC3.use appropriate measuring instruments, equipment, tools, accessories etc. as required		10	5	5
	PC4.identify non-conformities to quality assurance standards		10	5	5

	PC5.identify potential causes of non-conformities to quality assurance standards		10	5	5
	PC6.identify impact on final product due to non-conformance to company standards		15	7	8
	PC7.evaluate the need for action to ensure that problems do not recur		10	5	5
	PC8.suggest corrective action to address problems		12	6	6
	PC9.review effectiveness of corrective action		13	6	7
	Total		100	49	51
LFS/N0101 (Maintain a healthy, safe and secure working environment in the life sciences facility)	PC1.observe and comply with the company's current health, safety and security policies and procedures	100	10	5	5
	PC2.while carrying out work, use appropriate safety gears like head gear, masks, gloves and other accessories as mentioned in the guidelines		10	5	5
	PC3.report any identified breaches in health, safety, and security policies and procedures to the designated person		10	5	5
	PC4. responsible for maintaining discipline at the shop-floor/ production area		10	5	5
	PC5. identify and correct any hazards that the individual can deal with safely, competently and within the limits of their authority		10	5	5
	PC6.adhere and comply to storage and handling guidelines for hazardous material		10	5	5
	PC7.identify and recommend opportunities for improving health, safety, and security to the designated person		10	5	5
	PC8. complete any health, safety and security activities like safety drills and prepare records legibly and accurately		10	4	6

	PC9. report any hazards that the individual is not competent to deal with to the relevant person in line with organizational procedures and warn other people who may be affected		10	4	6
	PC10. follow the company's emergency procedures promptly, calmly, and efficiently		10	5	5
	Total		100	48	52

Do

- Explain each Guideline for Assessment in detail
- Explain the score that each trainee needs to obtain
- Recapitulate each NOS one-by-one and take participants through the allocation of marks for Theory and Skills Practical.
- Explain the Allocation of Marks. Explain that they will be assessed on Theory and Skills Practical.



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