



## Model Curriculum

**QP Name: Production Machine Operator- Sterile Formulations**  
**Electives: Preparation / Filling/ Cleaning and disinfection**

**QP Code: LFS/Q1203**

**QP Version: 3.0**

**NSQF Level: 4.5**

**Model Curriculum Version: 1.0**

## Table of Contents

Compulsory Modules .....	4
Elective Modules .....	6
Program Overview .....	8
Training Outcomes .....	8
Module Details .....	9
Module 1: Introduction to Life Sciences industry and the individual in Production. ....	9
Module 2: Fundamentals of Manufacturing in Life Sciences Sector .....	10
Module 3: GMP compliance in production process.....	11
Module 4: GMP compliance in waste management.....	12
Module 5: GMP compliance in machine maintenance.....	13
Module 6: GMP compliance in documentation.....	14
Module 7: Managing environmental sustainability .....	15
Module 8: Cleaning and Sanitization at workplace .....	16
Module 9: Comply with EHS rules in production and GMP controlled area .....	17
Module 10: Reporting and Documentation for sterile formulations manufacturing.....	18
Module 11: Coordination with Supervisor, teammates and Auditors.....	19
Module 12: Display sensitivity towards all genders and people with disability .....	20
Module 13: Employability Skills (60 Hours) .....	21
Module 14: Pre checks for preparation area .....	23
Module 15: Operations at the preparation area of sterile manufacturing unit .....	24
Module 16: Post preparation critical activities for sterile formulation manufacturing .....	26
Module 17: Pre-checks for Filling Area .....	27
Module 18: Operations at the filling area of sterile manufacturing unit .....	28
Module 19: Post filling critical activities for sterile formulation manufacturing .....	30
Module 20: Operations at the cleaning area of sterile manufacturing unit.....	31
Module 21: Post cleaning critical activities for sterile formulation manufacturing .....	33
Annexure.....	36
Trainer Requirements .....	36
Assessor Requirements.....	37
References .....	41
Glossary.....	41
Acronyms and Abbreviations .....	42

## Training Parameters

<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceuticals
<b>Occupation</b>	Pharma Manufacturing
<b>Country</b>	India
<b>NSQF Level</b>	4.5
<b>Aligned to NCO/ISCO/ISIC Code</b>	NCO-2015/ 8131.7200
<b>Minimum Educational Qualification and Experience</b>	Completed 1st year of UG / UG Certificate in Chemistry, biochemistry, biotechnology, microbiology, biomedical sciences and relevant field OR Completed Diploma in Pharmacy OR Completed 2nd year of 3- year Engineering diploma after 10th OR 12th Grade Pass with minimum 2 Years relevant Experience OR 10 <sup>th</sup> class pass + 2 year NTC/NAC (Engineering Trade) Pass with minimum 2 Years relevant Experience OR Certificate NSQF Level 3 (Assistant- Manufacturing and Packaging (Pharma, Biologics and Medical device) with minimum 4.5 Years of relevant experience OR Certificate NSQF Level 4 (Production Machine Operator- Non Sterile Formulation OR Production Machine Operator- API/Bulk Drug) with minimum 1.5 Years of relevant experience
<b>Pre-Requisite License or Training</b>	NA
<b>Minimum Job Entry Age</b>	18 Years
<b>Last Reviewed On</b>	17 December 2024
<b>Next Review Date</b>	17 December 2027
<b>NSQC Approval Date</b>	17 December 2024
<b>QP Version</b>	3.0
<b>Model Curriculum Creation Date</b>	17 December 2024

<b>Model Curriculum Valid Up to Date</b>	17 December 2027
<b>Model Curriculum Version</b>	1.0
<b>Minimum Duration of the Course</b>	<p>Compulsory Notional Hours Theory=120 Hours Practical= 180 Hours Employability Skills= 60 Hours Total Compulsory Notional Hours=360 Hours</p> <p>3 Electives = 90 Hours each Theory= 30 Hours Practical= 60 Hours Total Notional Hours with one elective=450 Hours Total Notional Hours with maximum 2 elective=540 Hours</p> <p>Min Notional Hours : 450 Hours Max Notional Hours with 3 elective : 630 Hours</p>
<b>Maximum Duration of the Course</b>	<p>Compulsory Notional Hours Theory=120 Hours Practical= 180 Hours Employability Skills= 60 Hours Total Compulsory Notional Hours=360 Hours</p> <p>3 Electives = 90 Hours each Theory= 30 Hours Practical= 60 Hours Total Notional Hours with one elective=450 Hours Total Notional Hours with maximum 2 elective=540 Hours</p> <p>Min Notional Hours : 450 Hours Max Notional Hours with 3 elective : 630 Hours</p>

## Compulsory Modules

The table lists the modules and their duration corresponding to the Compulsory NOS of the QP.

NOS and Module Details	Theory Duration	Practical Duration	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration
<b>LFS/N1224: Introduction to Life Sciences Industry and sterile Manufacturing NOS Version No. 1 NSQF Level-4.5</b>	<b>30:00</b>	<b>30:00</b>	<b>00:00</b>	<b>00:00</b>	<b>60:00</b>
Module 1: Introduction to life sciences industry and sterile manufacturing Operations	10:00	00:00	00:00	00:00	10:00
Module 2: Fundamentals of sterile manufacturing in life sciences sector	20:00	30:00	00:00	00:00	50:00
<b>LFS/N0265: Maintain compliance with current Good Manufacturing Practices (cGMP) and other regulations NOS Version No. 3 NSQF Level-4</b>	<b>30:00</b>	<b>90:00</b>	<b>00:00</b>	<b>00:00</b>	<b>120:00</b>
Module 3: GMP compliance in production Process	08:00	24:00	00:00	00:00	32:00
Module 4: GMP compliance in waste management	03:00	12:00	00:00	00:00	15:00
Module 5: GMP compliance in machine maintenance	08:00	24:00	00:00	00:00	32:00
Module 6: GMP compliance in documentation	08:00	24:00	00:00	00:00	32:00
Module 7: Managing Environment Sustainability	03:00	06:00	00:00	00:00	09:00
<b>LFS/N0113: Ensure hygienic and clean work area to avoid contamination</b>	<b>15:00</b>	<b>15:00</b>	<b>00:00</b>	<b>00:00</b>	<b>30:00</b>

<b>NOS Version No. 3 NSQF Level-4</b>					
Module 8 : Cleaning and Sanitisation at workplace	15:00	15:00	00:00	00:00	30:00
<b>LFS/N0112: Adhere to Environment, health and safety guidelines in a production facility and GMP controlled areas</b> <b>NOS Version No. 4 NSQF Level-4</b>	<b>15:00</b>	<b>15:00</b>	<b>00:00</b>	<b>00:00</b>	<b>30:00</b>
Module 9: Comply EHS rules in production and GMP controlled area	15:00	15:00	00:00	00:00	30:00
<b>LFS/N0268: Perform Reporting and documentation with Data Integrity</b> <b>NOS Version No. 3 NSQF Level-4</b>	<b>10:00</b>	<b>20:00</b>	<b>00:00</b>	<b>00:00</b>	<b>30:00</b>
Module 10: Reporting and documentation for sterile formulation	15:00	15:00	00:00	00:00	30:00
<b>LFS/N0104: Coordinate and communicate with Supervisor/ production chemist, teams and auditors</b> <b>NOS Version No. 3 NSQF Level-4</b>	<b>15:00</b>	<b>15:00</b>	<b>00:00</b>	<b>00:00</b>	<b>30:00</b>
Module 11: Coordination with Supervisor, teammates and Auditors	10:00	10:00	00:00	00:00	20:00
Module 12: Display Sensitivity towards genders and people with disability	05:00	05:00	00:00	00:00	10:00
<b>DGT/VSQ/N0102 : Employability Skills (60 Hours)</b> <b>NOS Version No. 1</b>					
Module 13: Employability Skills					
Introduction to Employability Skills	01:00	00:30	00:00	00:00	01:30
Constitutional values - Citizenship	01:00	00:30	00:00	00:00	01:30
Becoming a Professional in the 21st Century	01:30	01:00	00:00	00:00	02:30

Basic English Skills	05:00	05:00	00:00	00:00	10:00
Career Development & Goal Setting	01:00	01:00	00:00	00:00	02:00
Communication Skills	02:30	02:30	00:00	00:00	05:00
Diversity and Inclusion	01:00	01:30	00:00	00:00	02:30
Financial and Legal Literacy	02:30	02:30	00:00	00:00	05:00
Essential Digital Skills	05:00	05:00	00:00	00:00	10:00
Entrepreneurship	03:00	04:00	00:00	00:00	07:00
Customer Service	02:30	02:30	00:00	00:00	05:00
Getting ready for apprenticeship & Jobs	04:00	04:00	00:00	00:00	08:00
<b>Apprenticeship Training</b>	<b>00:00</b>	<b>00:00</b>	<b>00:00</b>	<b>2010:00</b>	<b>2010:00</b>
<b>Total Duration</b>	<b>150:00</b>	<b>210:00</b>	<b>00:00</b>	<b>2010:00</b>	<b>2370:00</b>

## Elective Modules

The table lists the modules and their duration corresponding to the Elective NOS of the QP.

### Elective 1: Preparation

NOS and Module Details	Theory Duration	Practical Duration	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration
<b>LFS/N1212: Prepare machines and perform pre-preparation check and operation activities at preparation area of sterile dosage manufacturing NOS Version No. 3.0 NSQF Level-4.5</b>	<b>30:00</b>	<b>60:00</b>	<b>00:00</b>	<b>00:00</b>	<b>90:00</b>
Module 14: Pre checks for preparation area	05:00	15:00	00:00	00:00	20:00
Module 15: Operations at the preparation area of sterile manufacturing unit	20:00	30:00	00:00	00:00	50:00
Module 16: Post preparation critical activities for sterile formulation manufacturing	05:00	15:00	00:00	00:00	20:00
<b>Total Duration</b>	<b>30:00</b>	<b>60:00</b>	<b>00:00</b>	<b>00:00</b>	<b>90:00</b>

### Elective 2: Filling

NOS and Module Details	Theory Duration	Practical Duration	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration
<b>LFS/N1213: Prepare machines and perform Pre-Filling check and operation activities at filling area of sterile dosage manufacturing</b> NOS Version No. 3.0 NSQF Level-4.5	30:00	60:00	00:00	00:00	90:00
Module 17: Pre-checks for Filling Area	05:00	15:00	00:00	00:00	20:00
Module 18: Operations at the filling area of sterile manufacturing unit	20:00	30:00	00:00	00:00	50:00
Module 19: Post filling critical activities for sterile formulation manufacturing	05:00	15:00	00:00	00:00	20:00
<b>Total Duration</b>	<b>30:00</b>	<b>60:00</b>	<b>00:00</b>	<b>00:00</b>	<b>90:00</b>

### Elective 3: Cleaning

NOS and Module Details	Theory Duration	Practical Duration	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration
<b>LFS/N01215: Perform cleaning &amp; disinfection operations at cleaning area of sterile dosage manufacturing</b> NOS Version No. 3.0 NSQF Level-4.5	30:00	60:00	00:00	00:00	90:00
Module 20: Operations at the cleaning area of sterile manufacturing unit	25:00	40:00	00:00	00:00	65:00
Module 21: Post cleaning critical activities for sterile formulation manufacturing	05:00	20:00	00:00	00:00	25:00
<b>Total Duration</b>	<b>30:00</b>	<b>60:00</b>	<b>00:00</b>	<b>00:00</b>	<b>90:00</b>

## Program Overview

This section summarizes the end objectives of the program along with its duration.

### Training Outcomes

At the end of the program, the learner should have acquired the listed knowledge and skills.

- Discuss performance of Machine Operator in compliance with current Good Manufacturing Practices (cGMP) and other environmental regulatory guidelines.
- Discuss the pre-production safety checks performed for sterile formulation production.
- Demonstrate the machine preparation operations for sterile formulation production.
- Demonstrate GMP compliance in production processes, waste management and machine maintenance.
- Discuss how to maintain a healthy, safe and secure working environment in the production and GMP controlled area.
- Demonstrate how to maintain a hygienic and clean work area to avoid contamination.
- Demonstrate how to coordinate with supervisor, colleagues and respond to audit queries during GMP/ regulatory audits.
- Demonstrate sensitivity towards genders, cultures and specially abled persons.
- Discuss the preparatory operations for sterile formulation manufacturing operation processes.
- Discuss the various post production critical activities performed for sterile formulation manufacturing process.

## Module Details

### Module 1: Introduction to Life Sciences industry and sterile manufacturing LFS/N1224

#### Terminal Outcomes:

- Explain the overview of the Life Sciences industry in regulation applicable to individual working in Production. Discuss the importance of a skilled Production in individual.

<b>Duration:</b> 10:00	<b>Duration:</b> 00:00
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Discuss the Life Sciences industry in Indian and global context.</li> <li>● Discuss the regulations, legislation, and good practices to be followed by individual working in sterile manufacturing in a life sciences manufacturing facility.</li> <li>● Explain the basic skills required to perform the job of individual working in sterile manufacturing plant.</li> <li>● Explain the importance of a individual working in sterile manufacturing plant.</li> </ul>	
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector/ screen, Scanner, Computer speakers, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
N/A	

## Module 2: Fundamentals of Manufacturing in Life Sciences Sector

### LFS/N1224

#### Terminal Outcomes:

- Discuss the fundamental concepts of sterile formulations production and its various process.

Duration: 20:00	Duration: 30:00
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Discuss the basic concepts of microbiology and route of contamination in sterile manufacturing process.</li> <li>● Explain the fundamental concepts of sterile formulations.</li> <li>● Explain the various component of manufacturing plant and their function in sterile manufacturing.</li> <li>● Discuss the sterile formulation manufacturing processes.</li> <li>● Describe various utility systems and their application for sterile formulation manufacturing.</li> <li>● Identify and communicate any allergies, illnesses, or breaches in the work environment to designated personnel.</li> </ul>	<ul style="list-style-type: none"> <li>● Execute handwashing procedures prior to entering the production area following standard operating procedures.</li> <li>● Demonstrate function of each component of sterile manufacturing</li> <li>● Demonstrate how to perform the sterile formulations manufacturing process in life sciences manufacturing facility.</li> <li>● Demonstrate various utility systems and their application for sterile formulation manufacturing</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector/ screen, Scanner, Computer speakers, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
N/A	

## Module 3: GMP compliance in production process

### Mapped to LFS/N0265, v3

#### Terminal Outcomes:

- Describe the WHO and GMP guidelines followed in production process.
- Demonstrate how to perform in-process production checks in compliance with GMP guidelines.

<b>Duration: 08:00</b>	<b>Duration: 24:00</b>
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Discuss the standard environmental conditions of the production area.</li> <li>● Discuss material handling and storage guidelines of WHO.</li> <li>● Explain USFDA and WHO regulations and current Good Manufacturing Practices (GMP) guidelines related to machine operations.</li> <li>● Discuss the Standard Operating Procedure (SOP) for entry and exit from the GMP area.</li> </ul>	<ul style="list-style-type: none"> <li>● Perform the cleaning of machine in compliance with WHO guidelines and ICH-cGMP rules.</li> <li>● Demonstrate how to monitor environmental conditions in production area in compliance with WHO guidelines and ICH-cGMP rules.</li> <li>● Perform the specific in-process production checks as directed in SOP in compliance with WHO guidelines and ICH-cGMP rules.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
Printouts of WHO guidelines and GMP guidelines, Sample SOP document, Cleaning agents	

## Module 4: GMP compliance in waste management

Mapped to LFS/N0265, v3

### Terminal Outcomes:

- Demonstrate how to perform waste management in compliance with GMP guidelines.

<b>Duration:</b> 03:00	<b>Duration:</b> 12:00
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Explain WHO regulations and current Good Manufacturing Practices (GMP) guidelines for waste management.</li> <li>● Explain the standard waste management procedures.</li> </ul>	<ul style="list-style-type: none"> <li>● Perform waste disposal under supervision in compliance with WHO guidelines and ICH-cGMP rules.</li> <li>● Demonstrate how to perform waste segregation.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
Printouts of WHO guidelines and GMP guidelines, Sample SOP document	

## Module 5: GMP compliance in machine maintenance

*Mapped to LFS/N0265, v3*

### Terminal Outcomes:

- Discuss how to perform machine maintenance in compliance with GMP guidelines.

<b>Duration:</b> 08:00	<b>Duration:</b> 24:00
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>• Explain WHO regulations and ICH- Good Manufacturing Practices (GMP) guidelines for machine maintenance.</li> <li>• Discuss the machine operations manual and troubleshooting of the machines available in assigned section.</li> </ul>	<ul style="list-style-type: none"> <li>• Perform the general routine maintenance of machine in compliance with WHO guidelines and ICH-cGMP rules.</li> <li>• Perform the calibration of machine in compliance with WHO guidelines and ICH-cGMP rules.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
Printouts of WHO guidelines and GMP guidelines, Sample SOP document	

## Module 6: GMP compliance in documentation

*Mapped to LFS/N0265, v3*

### Terminal Outcomes:

- Discuss how to perform documentation in compliance with Good Manufacturing Practices (GMP).

<b>Duration:</b> 08:00	<b>Duration:</b> 24:00
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Explain WHO regulations and ICH- Good Manufacturing Practices (GMP) guidelines for documentation.</li> <li>● Describe the Attributable, Legible, Contemporaneous, Original, and Accurate Plus Plus (ALCOA ++ ) principle and its importance.</li> <li>● Explain the method of reporting and documentation as per Good Documentation Practices and other regulatory guidelines.</li> </ul>	<ul style="list-style-type: none"> <li>● Demonstrate adherence to ALCOA++ principles during documentation of the activities performed.</li> <li>● Perform reporting and documentation for each stage in compliance with GMP guidelines.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
Printouts of WHO guidelines and GMP guidelines, Sample formats for BMR & BPR	

## Module 7: Managing environmental sustainability

### Mapped to LFS/N0265, v3

#### Terminal Outcomes:

- Discuss the importance of environmental sustainability.
- Demonstrate the adoption of environmental sustainability methods at work for minimizing pollution, water wastage, and maximizing energy conservation.

<b>Duration:</b> 03:00	<b>Duration:</b> 06:00
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Explain the concept and importance of energy conservation.</li> <li>● Describe the possible actions to optimize energy consumption and minimize energy wastage.</li> <li>● Explain the concept of environmental pollution and its impact on the health of self, community, and planet.</li> <li>● Describe the possible actions to be taken to minimize environmental pollution at work.</li> <li>● Explain various guidelines to be followed for hazardous waste management and disposal of waste.</li> </ul>	<ul style="list-style-type: none"> <li>● Create a checklist of energy conservation practices during and post-work.</li> <li>● Classify waste into recyclable, non-recyclable, and hazardous.</li> <li>● Demonstrate the sustainable waste disposal- process.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector/ screen, Computer speakers, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
color-coded waste bin bag, color-coded waste container	

## Module 8: Cleaning and Sanitization at workplace

Mapped to LFS/N0113, v3

### Terminal Outcomes:

- Demonstrate how to perform cleaning and sanitation activities before, during and after work.

Duration: 15:00	Duration: 15:00
<p><b>Theory – Key Learning Outcomes</b></p> <ul style="list-style-type: none"> <li>● Describe levels of hygiene standards required in the production area and the importance of maintaining the same.</li> <li>● Explain the methods, materials, and checks required for cleaning a variety of surfaces and equipment.</li> <li>● Explain the list of various equipment, machines, instruments, different materials, and chemicals used in cleaning and sanitation of production area.</li> <li>● Explain the essential Good Manufacturing Practices (GMP) and WHO guidelines and rules for cleaning, sanitation, and hygiene activity.</li> <li>● Explain waste disposal guidelines as per WHO and GLP/GMP and relevant organizational Standard Operating Procedures (SOPs).</li> <li>● Discuss the concept of cleaning validation and its importance.</li> </ul>	<p><b>Practical – Key Learning Outcomes</b></p> <ul style="list-style-type: none"> <li>● Prepare a check list of the hygiene standards required in the production area.</li> <li>● Demonstrate how to clean and check surfaces, equipment, and instruments by applying appropriate methods and materials.</li> <li>● Perform cleaning and sanitation of production area using various equipment and chemicals.</li> <li>● Demonstrate how to handle different types of hazards by applying critical thinking skills.</li> </ul>
<p><b>Classroom Aids:</b></p> <p>Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil</p>	
<p><b>Tools, Equipment and Other Requirements</b></p> <p>Cleaning agents (soap/alconox etc.), Glassware for cleaning ,Half Face Mask, Gloves(Nitrile, {Heat, acid, chemical} resistant, washing etc..), and PPE</p>	

## Module 9: Comply with EHS rules in production and GMP controlled area

### Mapped to LFS/N0112, v3

#### Terminal Outcomes:

- Explain the health and hygiene protocols to be followed in production and GMP controlled area.
- Describe safety, security and emergency procedures at the production and GMP controlled area.

Duration: 15:00	Duration: 15:00
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Explain relevant legislative requirements and company’s procedures for the environment, health and safety including an individual’s role and responsibilities.</li> <li>● Discuss workplace hazards in the manufacturing facility in the life sciences sector including how and when to report hazards.</li> <li>● Explain all the emergency procedures for different emergencies.</li> <li>● Explain the evacuation procedures for employees, contract staff and visitors</li> <li>● Discuss health, safety and accident reporting procedures.</li> <li>● Explain the importance of material segregation and the 5S system.</li> <li>● Discuss the type of safety gears and procedure to use them.</li> </ul>	<ul style="list-style-type: none"> <li>● Demonstrate how and when to report hazards at the workplace.</li> <li>● Demonstrate emergency procedures to be followed in different emergencies.</li> <li>● Demonstrate how to evacuate employees, contract staff and visitors as per procedures in case of emergency.</li> <li>● Demonstrate how to use different types of safety gears by following the procedures to use them.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
Printouts of WHO guidelines, Flashcards of signages, coding, and instructions, CO2 type Fire Extinguisher, ABC Type Fire Extinguisher, Personal Protective Equipments and gowning material	

## Module 10: Reporting and Documentation for sterile formulations manufacturing

*Mapped to LFS/N0268, v3*

### Terminal Outcomes:

- Explain the methods of reporting and documentation for sterile manufacturing operations.
- Awareness of data integrity importance

<b>Duration:</b> 15:00	<b>Duration:</b> 15:00
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Explain the procedures of reporting and documentation for sterile formulations manufacturing process.</li> <li>● Describe procedure of generating electronic records for sterile formulations manufacturing.</li> <li>● Explain data integrity and information security rules.</li> </ul>	<ul style="list-style-type: none"> <li>● Demonstrate how to maintain both electronic and manual records in the log books.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
Formats of Log books ,Sample reporting formats, GDP guidelines	

## Module 11: Coordination with Supervisor, teammates and Auditors

### Mapped to LFS/N0104, v3

#### Terminal Outcomes:

- Describe various scenarios at work that demand coordination and collaboration with the manager, team, and cross-functional stakeholders.
- Demonstrate the effective coordination and collaboration with manager, cross-functional teams.
- Demonstrate how to participate in audit interviews.

Duration: 06:00	Duration: 12:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<ul style="list-style-type: none"> <li>● List the functional and cross-functional stakeholders for Production Machine Operator-Sterile Formulations.</li> <li>● Explain efficient and clear communication methods for reporting incidents/ deviations.</li> <li>● Explain the techniques for gaining emotional stability.</li> <li>● Discuss various ways for conflict resolution.</li> <li>● Explain the best strategies of collaborating with others.</li> <li>● Describe the problem-solving techniques for routine work-related issues.</li> <li>● Explain the types of audits in the life sciences sector for the manufacturing operations.</li> </ul>	<ul style="list-style-type: none"> <li>● Demonstrate how to effectively communicate and collaborate with various stakeholders (e.g. manager, groups etc.) in a simulated environment for multiple scenarios.</li> <li>● Respond to regulatory audit questions in a mock audit situation.</li> <li>● Demonstrate how to resolve conflict in multiple scenarios.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
N/A	

## Module 12: Display sensitivity towards all genders and people with disability

*Mapped to LFS/N0104, v3*

### Terminal Outcomes:

- Discuss the Prevention of Sexual Harassment (POSH) rules at the workplace.
- Demonstrate how to respect all genders and cultures at the workplace.
- Explain the importance of sensitivity towards people with disability.

Duration: 04:00	Duration: 08:00
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Discuss the rules laid by the Sexual Harassment of Women at Workplace (Prevention, Prohibition, and Redressal) Act and the provided penalties for violation.</li> <li>● Explain the importance of gender sensitive behaviour.</li> <li>● Explain the procedure to report inappropriate behaviour e.g. sexual harassment.</li> <li>● Describe the importance of an equal opportunity work culture.</li> <li>● Discuss the importance of respecting other's cultures, religion, and caste.</li> <li>● Explain the need for sensitivity towards people with disabilities.</li> <li>● Explain the correct ways of communication and collaboration with people with disabilities in compliance with the legal framework.</li> <li>● Identify stereotypes and prejudices associated with people with disabilities and the negative consequences of prejudice and stereotypes.</li> </ul>	<ul style="list-style-type: none"> <li>● Demonstrate appropriate verbal and nonverbal communication that is respectful of gender, religion, disability, etc.</li> <li>● Prepare a list of gender-neutral communication terms.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speakers, flip charts	
<b>Tools, Equipment and Other Requirements</b>	
N/A	

## Module 13: Employability Skills (60 Hours)

Mapped to DGT/VSQ/N0102 - v1.0

### Introduction to Employability Skills (Duration: 1.5 Hours )

After completing this programme, participants will be able to:

1. Discuss the Employability Skills required for jobs in various industries
2. List different learning and employability related GOI and private portals and their usage

### Constitutional values - Citizenship (Duration: 1.5 Hours )

3. Explain the constitutional values, including civic rights and duties, citizenship, responsibility towards society and personal values and ethics such as honesty, integrity, caring and respecting others that are required to become a responsible citizen
4. Show how to practice different environmentally sustainable practices.

### Becoming a Professional in the 21st Century (Duration: 2.5 Hours )

5. Discuss importance of relevant 21st century skills.
6. Exhibit 21st century skills like Self-Awareness, Behavior Skills, time management, critical and adaptive thinking, problem-solving, creative thinking, social and cultural awareness, emotional awareness, learning to learn etc. in personal or professional life.
7. Describe the benefits of continuous learning.

### Basic English Skills (Duration: 10 Hours )

8. Show how to use basic English sentences for everyday conversation in different contexts, in person and over the telephone
9. Read and interpret text written in basic English
10. Write a short note/paragraph / letter/e-mail using basic English

### Career Development & Goal Setting (Duration: 2 Hours)

11. Create a career development plan with well-defined short- and long-term goals

### Communication Skills (Duration: 5 Hours)

12. Demonstrate how to communicate effectively using verbal and nonverbal communication etiquette.
13. Explain the importance of active listening for effective communication
14. Discuss the significance of working collaboratively with others in a team

### Diversity & Inclusion (Duration: 2.5 Hours )

15. Demonstrate how to behave, communicate, and conduct oneself appropriately with all genders and PwD
16. Discuss the significance of escalating sexual harassment issues as per POSH act.

### Financial and Legal Literacy Duration:5 Hours

17. Outline the importance of selecting the right financial institution, product, and service
18. Demonstrate how to carry out offline and online financial transactions, safely and securely
19. List the common components of salary and compute income, expenditure, taxes, investments etc.
20. Discuss the legal rights, laws, and aids

### Essential Digital Skills (Duration: 10 Hours)

21. Describe the role of digital technology in today's life
22. Demonstrate how to operate digital devices and use the associated applications and features, safely and securely

23. Discuss the significance of displaying responsible online behavior while browsing, using various social media platforms, e-mails, etc., safely and securely
24. Create sample word documents, excel sheets and presentations using basic features
25. utilize virtual collaboration tools to work effectively

**Entrepreneurship (Duration: 7 Hours )**

26. Explain the types of entrepreneurship and enterprises
27. Discuss how to identify opportunities for potential business, sources of funding and associated financial and legal risks with its mitigation plan
28. Describe the 4Ps of Marketing-Product, Price, Place and Promotion and apply them as per requirement
29. Create a sample business plan, for the selected business opportunity

**Customer Service (Duration: 5 Hours)**

30. Describe the significance of analyzing different types and needs of customers
31. Explain the significance of identifying customer needs and responding to them in a professional manner.
32. Discuss the significance of maintaining hygiene and dressing appropriately

**Getting Ready for apprenticeship & Jobs (Duration: 8 Hours )**

33. Create a professional Curriculum Vitae (CV)
34. Use various offline and online job search sources such as employment exchanges, recruitment agencies, and job portals respectively
35. Discuss the significance of maintaining hygiene and confidence during an interview
36. Perform a mock interview
37. List the steps for searching and registering for apprenticeship opportunities

## Module 14: Pre checks for preparation area

Mapped to LFS/N01212, v3

### Terminal Outcomes:

- Discuss the pre-production checks performed for sterile/aseptic dosage formulation manufacturing process.

Duration: 05:00	Duration:15:00
<p><b>Theory – Key Learning Outcomes</b></p> <ul style="list-style-type: none"> <li>• Explain the importance of gowning in sterile Manufacturing</li> <li>• Discuss the important concept like gowning qualification, personal Qualifications, Sterility Assurance, MKT mean, RMCOA(Raw Material Certificate of analysis) related sterile production process</li> <li>• Describe the raw material and packaging material used for sterile/aseptic dosage formulation manufacturing process.</li> <li>• Discuss the Warehouse Management System with cleaning procedure</li> <li>• Discuss the importance of Handling of Light and temperature sensitive products.</li> <li>• Explain the material, segregation, handling and storage guidelines.</li> <li>• Discuss manufacturing process of Water for Pharma Use (WPU).</li> <li>• Explain the purpose of in process checks and their procedures for sterile/ aseptic manufacturing.</li> <li>• Discuss the Standard Operating Procedure (SOP) for maintenance of aseptic manufacturing machine.</li> <li>• Explain the safe working instructions as per SOP/ batch record.</li> <li>• Discuss the MSDS (Material Safety Data Sheets) chemical handling guidelines.</li> </ul>	<p><b>Practical – Key Learning Outcomes</b></p> <ul style="list-style-type: none"> <li>• Prepare a checklist of stocks management of required materials for the production process.</li> <li>• Perform visual inspection of material for signs of contamination and bloom.</li> <li>• Perform labelling for the containers of raw material, in process/ intermediate products and finished goods.</li> <li>• Demonstrate the use of antistatic shoes.</li> <li>• Perform job safety analysis in accordance with international/ national standards.</li> </ul>
<p><b>Classroom Aids:</b></p> <p>Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil</p>	
<p><b>Tools, Equipment and Other Requirements</b></p> <p>Material safety data sheets (MSDS), Sample SOP document, Formats for BMR &amp; BPR, Format of job cards</p>	

## Module 15: Operations at the preparation area of sterile manufacturing unit

*Mapped to LFS/N01212, v3*

### Terminal Outcomes:

- Discuss how to perform general and preventive maintenance for machines utilised at preparation area of sterile manufacturing.
- Discuss the machine operations for various machine available at preparation area manufacturing process.

<b>Duration: 20:00</b>	<b>Duration: 30:00</b>
<p><b>Theory – Key Learning Outcomes</b></p> <ul style="list-style-type: none"> <li>● Discuss the working principle of machines used for preparation of aseptic formulation manufacturing (Autoclave, filter integrity, Washing, Tunnel, Static pass box, DPBs, LAFS, Manufacturing Vessels, Pressure vessels, Brevetted, UAFs, Vial/ PFS/ Ophthalmic filling machine, Filtration, Track and trace, checkweighers, Labelling machine).</li> <li>● Discuss the importance of Autoclave qualification, tunnel qualification, visual inspector qualification, Tanks qualifications, aseptic area qualification</li> <li>● Discuss various sterilization techniques to be performed as per the aseptic condition mentioned</li> <li>● Explain the common issues in preparation area of aseptic manufacturing and their solutions.</li> <li>● Discuss the QMS elements like FMEA, Change control, Deviation, BMR preparations.</li> <li>● Discuss the critical parameters for various machines located at preparation area of aseptic formulation manufacturing.</li> <li>● Disinfectant preparation for sterile formulation,</li> <li>● Explain the procedure for changeover cleaning and sterilization.</li> <li>● Discuss the methods for material movement /inspection as per various</li> </ul>	<p><b>Practical – Key Learning Outcomes</b></p> <ul style="list-style-type: none"> <li>● Identify and locate various parts of machines used at preparation area for aseptic formulation manufacturing.</li> <li>● Perform product status labelling on equipment.</li> <li>● Demonstrate how to set critical parameters (cycle time, temperature, pressure, ampere load, spray rate, etc.) for the machine based on machine history located at preparation area.</li> <li>● Demonstrate the preventive maintenance of various machines at preparation area.</li> <li>● Demonstrate the inspection of equipment for its calibration and validation state.</li> <li>● Perform trial run and random tests to ensure accuracy.</li> </ul>

material utilised in aseptic formulation manufacturing. <ul style="list-style-type: none"><li>● Explain the Procedure for changeover cleaning and sterilization</li></ul>	
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
PPE, Schematic diagram of machines, Hand controller, Pharma VR Modules developed by LSSSDC for sterile formulation production, Computer Lab, AR brochure developed by LSSSDC for sterile formulation manufacturing equipment	

## Module 16: Post preparation critical activities for sterile formulation manufacturing

*Mapped to LFS/N1212, v3*

### Terminal Outcomes:

- Discuss how to perform post production critical activities for sterile formulation manufacturing process.

<b>Duration: 5:00</b>	<b>Duration: 15:00</b>
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Discuss the Standard Operating Procedures for line clearance.</li> <li>● Describe procedure for handover and takeover of the shift schedules.</li> <li>● Discuss the labelling guidelines as per GMP.</li> </ul>	<ul style="list-style-type: none"> <li>● Perform line clearance supporting activities.</li> <li>● Perform shift handover in adherence of the shift schedule.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
Sample SOP document, Shift handover logs, Sample labels	

## Module 17: Pre-checks for Filling Area

Mapped to LFS/N01213, v3

### Terminal Outcomes:

- Discuss the pre-production checks performed for sterile/aseptic dosage formulation manufacturing process.

Duration: 05:00	Duration:15:00
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Explain the process of gowning procedure as per aseptic gowning procedure</li> <li>● Discuss the important concept like gowning qualification, personal Qualifications, Sterility Assurance, MKT, RMCOA related sterile production process</li> <li>● Discuss the visual inspection procedure and associated defects, highlighting the importance of Lux levels.</li> <li>● Explain how to maintain personal hygiene in sterile filling operations and its impacts.</li> <li>● Discuss the role of movement (Personal &amp; intervention) in disturbing the sterility of environment.</li> <li>● Explain about first air breakage and its impact.</li> <li>● Explain how to setup Filling machine in aseptic while maintaining the sterility.</li> <li>● Explain the Procedure for changeover cleaning and sterilization</li> </ul>	<ul style="list-style-type: none"> <li>● Demonstrate the full gowning procedure for aseptic filling, including donning sterile garments, gloves, face masks, and headgear, ensuring no part of the body or non-sterile clothing is exposed during the process.</li> <li>● Demonstrate how to maintain personal hygiene before and during filling operations, including hand sanitization, nail cleanliness, and proper handling of sterile equipment.</li> <li>● Demonstrate the impact of movement on maintaining sterility during filling operations, including how to move within the sterile area without disrupting airflow or causing contamination.</li> <li>● Demonstrate the concept of first air breakage by using a laminar flow hood or isolator to explain how improper positioning or hand movement disrupts the sterile airflow and can contaminate sterile surfaces.</li> <li>● Demonstrate the setup of a sterile filling machine while adhering to aseptic protocols, including the handling of sterile components (e.g., vials, stoppers, syringes) and maintaining environmental sterility during the process.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
Material safety data sheets (MSDS), Sample SOP document, Formats for BMR & BPR, Format of job cards	

## Module 18: Operations at the filling area of sterile manufacturing unit

### Mapped to LFS/N01213, v3

#### Terminal Outcomes:

- Discuss how to perform general and preventive maintenance for machines utilised at Filling area of sterile manufacturing.
- Discuss the machine operations for various machine available at filling area manufacturing process.

Duration: 20:00	Duration: 30:00
<p><b>Theory – Key Learning Outcomes</b></p> <ul style="list-style-type: none"> <li>● Discuss the working principle of machines used for aseptic filling area.</li> <li>● Explain the various addition (eg Capping) that are required during filling operations</li> <li>● Discuss various environmental conditions to be maintained as per the aseptic condition mentioned</li> <li>● Explain the common issues in filling area of aseptic manufacturing and their solutions.</li> <li>● Explain the importance of material movement as per clean room operations.</li> <li>● Discuss the critical parameters for various machines located at filling area of aseptic formulation manufacturing.</li> <li>● Explain Environmental monitoring, personal monitoring , NVPC etc.</li> <li>● Explain the procedure for changeover cleaning and sterilization.</li> <li>● Explain the in-process checks specific to the filling stage, including volume accuracy and contamination checks.</li> <li>● Discuss machine calibration, sanitization, and preventive maintenance procedures.</li> <li>● Explain SOP-based safe working instructions for filling operators.</li> <li>● Discuss risks associated with sterile media and handling of filling solutions.</li> </ul>	<p><b>Practical – Key Learning Outcomes</b></p> <ul style="list-style-type: none"> <li>● Identify and locate various parts of machines used at filling area for aseptic formulation manufacturing.</li> <li>● Demonstrate the capping process that follows filling, including vial sealing, stopper placement, and ensuring airtight closures.</li> <li>● Demonstrate how to monitor and maintain environmental conditions such as temperature, humidity, etc in cleanrooms as per aseptic requirements.</li> <li>● Perform product status labeling on equipment.</li> <li>● Demonstrate proper material movement protocols in a sterile environment to avoid cross-contamination and disruption of sterile conditions.</li> <li>● Perform in-process checks such as measuring fill volumes, inspecting for contamination, and ensuring correct sealing.</li> <li>● Identify and explain the risks related to handling sterile media (e.g., contamination, exposure to hazardous substances) and demonstrate preventive measures.</li> <li>● Perform trial run and random tests to ensure accuracy.</li> </ul>
<p><b>Classroom Aids:</b></p> <p>Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil</p>	
<p><b>Tools, Equipment and Other Requirements</b></p>	

PPE, Schematic diagram of machines, Hand controller, Pharma VR Modules developed by LSSSDC for sterile formulation production, Computer Lab, AR brochure developed by LSSSDC for sterile formulation manufacturing equipment

## Module 19: Post filling critical activities for sterile formulation manufacturing

*Mapped to LFS/N1213, v3*

### Terminal Outcomes:

- Discuss how to perform post production critical activities for sterile formulation manufacturing process.

Duration: 05:00	Duration: 15:00
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Discuss the Standard Operating Procedures for line clearance.</li> <li>● Describe procedure for handover and takeover of the shift schedules.</li> <li>● Discuss the labelling guidelines as per GMP.</li> </ul>	<ul style="list-style-type: none"> <li>● Perform line clearance supporting activities.</li> <li>● Perform shift handover in adherence of the shift schedule .</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
Sample SOP document, Shift handover logs, Sample labels	

## Module 20: Operations at the cleaning area of sterile manufacturing unit

### Mapped to LFS/N01215, v3

#### Terminal Outcomes:

Duration: 20:00	Duration: 40:00
<p><b>Theory – Key Learning Outcomes</b></p> <ul style="list-style-type: none"> <li>● Describe the various cleaning agents (e.g., disinfectants, detergents, sanitizers) used in sterile manufacturing and their appropriate application.</li> <li>● Explain the various process like Disinfectant preparation and cleaning validation</li> <li>● Explain the principles, procedures, and regulatory requirements for washing qualification, including key parameters such as temperature, time, detergent concentration, and analytical testing methods.</li> <li>● Discuss the different types of contaminants (e.g., biological, particulate, chemical) that can affect the sterile environment.</li> <li>● Discuss the process of flow of cleaning design movement</li> <li>● Explain the common issues in cleaning area of aseptic manufacturing and their solutions.</li> <li>● Explain the Standard Operating Procedures (SOPs) for cleaning different areas of a sterile manufacturing plant.</li> <li>● Explain the different cleaning and disinfection techniques (e.g., wiping, spraying, mopping) and how to perform effective disinfection.</li> <li>● Explain the Procedure for changeover cleaning and sterilization</li> <li>● Explain the use and maintenance of cleaning tools and Personal Protective Equipment (PPE) in a sterile environment.</li> <li>● Explain the importance of documenting cleaning activities and maintaining logs as per SOPs.</li> </ul>	<p><b>Practical – Key Learning Outcomes</b></p> <ul style="list-style-type: none"> <li>● Demonstrate the correct dilution, application, and removal of cleaning agents like disinfectants, detergents, and sanitizers ensuring thorough sanitization without residue.</li> <li>● Demonstrate a scenario where contaminants are present and demonstrate the cleaning procedures that help reduce or eliminate them (e.g., proper gowning, use of disinfectants).</li> <li>● Demonstrate the correct cleaning movement to maintain sterility and prevent cross-contamination, following the unidirectional flow from clean to dirty areas.</li> <li>● Demonstrate the correct use, cleaning, and maintenance of cleaning tools (mops, buckets, sprayers) and PPE in a sterile environment.</li> <li>● Perform a cleaning task and then fill out the appropriate cleaning logs, ensuring all details are accurate and complete according to GMP standards.</li> </ul>
<p><b>Classroom Aids:</b></p>	

Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil

**Tools, Equipment and Other Requirements**

PPE, Schematic diagram of machines, Hand controller, Pharma VR Modules developed by LSSSDC for sterile formulation production, Computer Lab, AR brochure developed by LSSSDC for sterile formulation manufacturing equipment

## Module 21: Post cleaning critical activities for sterile formulation manufacturing

*Mapped to LFS/N1215, v3*

### Terminal Outcomes:

- Discuss how to perform post production critical activities for sterile formulation manufacturing process.

<i>Duration: 10:00</i>	<i>Duration: 20:00</i>
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Describe procedure for handover and takeover of the shift schedules.</li> <li>● Discuss the labelling guidelines as per GMP.</li> </ul>	<ul style="list-style-type: none"> <li>● Perform line clearance supporting activities.</li> <li>● Perform shift handover in adherence of the shift schedule.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
Sample SOP document, Shift handover logs, Sample labels	



## Module 22: Apprenticeship Training

Mapped to Production Machine Operator- Sterile Formulation

Mandatory Duration:00:00	Recommended Duration: 2010:00
<b>Module Name:</b> Apprenticeship Training Location: On-Site	
<b>Terminal Outcomes</b> <ul style="list-style-type: none"> <li>● Maintain compliance with WHO regulations and ICH-Good Manufacturing Practices(GMP).</li> <li>● Maintain a healthy, safe and secure working environment in a production facility and GMP controlled area.</li> <li>● Perform reporting and documentation with data integrity.</li> <li>● Ensure a hygienic and clean work area to avoid cross-contamination.</li> <li>● Coordinate and communicate with Supervisor, teams and auditors.</li> <li>● Prepare machines and perform pre-preparation check and operation activities at preparation area of sterile dosage manufacturing or</li> <li>● Prepare machines and perform Pre-Filling check and operation activities at filling area of sterile dosage manufacturing or</li> <li>● Perform cleaning &amp; disinfection operations at cleaning area of sterile dosage manufacturing</li> </ul>	

## Annexure

### Trainer Requirements

Trainer Prerequisites						
Minimum Educational Qualification	Specialization	Relevant Industry Experience		Training Experience		Remarks
		Years	Specialization	Years	Specialization	
<b>Science Graduate/ B.Tech/B. Pharm.</b>	Chemistry/ Pharmacy/ Chemical Engg./ Biotechnology Engg.	4	Pharmaceutical/ Biopharmaceutical Manufacturing for Sterile Formulations	1	NA	
<b>Post Graduate</b>	Life Sciences Subject/ Chemistry/Pharmacy / Chemical Engg./ Biotech Engg.	3	Pharmaceutical/ Biopharmaceutical Manufacturing for Sterile Formulations	1	NA	
<b>Production Chemist/ Production Biologist Level 5 QP</b>	Sterile Manufacturing/ Biologics Manufacturing	2	Pharmaceutical/ Biopharmaceutical Manufacturing for Sterile Formulations	1	NA	
<b>Assistant Professor/ Associate Professor/ Professor</b>	MSc/ M.Tech / MBA/ PhD			4	teaching and /or research experience in a relevant academic or research position	With Recognition of Prior Learning Certification in Production Machine Operator-Sterile Formulation “LFS/Q1203, v3.0” post completion of Faculty Development Program of LSSSDC

Trainer Certification	
Domain Certification	Platform Certification
Certified for Job Role: “Production Machine Operator-Sterile Formulation” mapped to QP: “LFS/Q1203, v3.0” with minimum accepted score of 80%.	Recommended that the Trainer is certified for the Job Role: “Trainer (VET and Skills)”, mapped to the Qualification Pack: “MEP/2601, v3.0” with minimum score of 80%.

## Assessor Requirements

Assessor Prerequisites						
Minimum Educational Qualification	Specialization	Relevant Industry Experience		Training/Assessment Experience		Remarks
		Years	Specialization	Years	Specialization	
<b>Science Graduate/ B.Tech/B. Pharma</b>	Chemistry/ Pharmacy/ Chemical Engg./ Biotechnology Engg.	4	Pharmaceutical/ Biopharmaceutical Manufacturing for Sterile Formulations	1	On the job assessment/ Training experience/ Vocational assessment/ Academic assessment	
<b>Post Graduate</b>	Life Sciences Subject/ Chemistry/Pharmacy / Chemical Engg./ Biotech Engg.	3	Pharmaceutical/ Biopharmaceutical Manufacturing for Sterile Formulations	1	On the job assessment/ Training experience/ Vocational assessment/ Academic assessment	
<b>Production Chemist/ Production Biologist Level 5 QP</b>	Sterile Manufacturing/ Biologics Manufacturing	2	Pharmaceutical/ Biopharmaceutical Manufacturing for Sterile Formulations	1	On the job assessment/ Training experience/ Vocational assessment/ Academic assessment	
<b>Assistant Professor/ Associate Professor/ Professor</b>	MSc/ M.Tech / MBA/ PhD			4	teaching and /or research experience in a relevant academic or research position	With Recognition of Prior Learning Certification in Production Machine Operator-Sterile Formulation "LFS/Q1203, v3.0" post completion of Faculty Development Program of LSSSDC

Assessor Certification	
Domain Certification	Platform Certification
Production Machine Operator- Sterile formulation mapped to the Qualification Pack: "LFS/Q1203, v3." with minimum accepted score of 80%.	Recommended that the Assessor is certified for the Job Role: "Assessor (VET and Skills)", mapped to the Qualification Pack: "MEP/Q2701, v3.0" with minimum score of 80%.

## Assessment Strategy

This section includes the processes involved in identifying, gathering, and interpreting information to evaluate the learner on the required competencies of the program.

The assessment for the Training will be conducted toward the end of the training duration.

### Assessment Process:

For Execution of the assessment for training, LSSSDC will be engaging more than one assessment agency/ body.

#### 1.1 Criteria of selection of assessment body/agency:

The assessment body/agency is selected based on

- Prior experience and understanding of Life Sciences or similar sector.
- Experience in conducting assessments for similar job roles.
- Manpower and Technical capabilities.
- Geographical reach
- Existing Network in the Life Sciences Sector
- Agencies internal policies to maintain standards, quality & professional Integrity
- Agencies policy in assessor management

#### 1.2 Assessment tool for Training:

For the Training assessment, the assessment instrument development is done by the selected assessment body with close monitoring and support of LSSSDC at every stage.

##### 1.2.1 Digital Written test for knowledge assessment:

**Scope** – Is used to test the knowledge component of the QP.

**Tools** –computer or tab based online or offline.

**Method** – objective type questions, match the columns, fill in the blanks, tick the odd man out, choose the correct option, choose the best answer, True or false, Identify the object, tool or machinery, arrange in proper sequence, case study, scenario-based responses.

**Analysis** – Question paper is divided into sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section-wise calculation of marks gives a clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.

##### 2.2.2 Digital Written test for skill assessment:

**Scope** – Is used to test primarily the Skill component of the QP. Trainee's expertise in handling and managing the situation is tested.

**Tools** – computer or tab based online or offline questions

**Method** – A situation is narrated or created in the question posed to the trainee and he is asked objective type questions to select the correct reaction to the situation. The selected situations are based on real situations.

**Analysis** – Question paper is divided into sections. Each Section intends to assess a particular skill field of the trainee. Thus, section-wise calculation of marks gives a clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.

### 2.3 Steps for assessment development:

- The selection of assessment tool(s) is done as per the assessment criteria prescribed in Qualification Pack.
- For Production Machine Operator- Sterile Formulation assessment a blueprint of the question paper is part of the assessment tool for training.
- Development of layout of Question paper is such that the entire PCs (Performance Criteria) of that QP are covered.
- Score per question maps with the weightage given to that PC, in the assessment criteria, and the level of difficulty of the question.
- An expert from industry is selected who is called “Subject Matter Expert” (SME). This SME must have over 13-15 years of experience in the industry in manufacturing occupation.
- SME is screened and approved by LSSSDC. He is oriented by both LSSSDC and Assessment agency on – creating question Bank, level of questions, end the desired outcome of the assessment.

### 2.4 Execution of Training Assessment:

- Once LSSSDC receives the OJT assessment results, the assessment date for training is decided with common agreement of Industry and LSSSDC, and turn is directed to an assessment body/agency.
- Assessment agency ensures the availability of required infrastructure, tools for the assessment.
- The assessment is executed in two possible ways depending on the choice of the industry:

2.4.1 Tab based assessment using physical proctoring

2.4.2 Smartphone-based assessment using e-proctoring

#### 2.4.1 Tab-based assessment using physical proctoring

- A representative from the Assessment agency is present on the day of assessment to executing the assessment at the venue in case of physical proctoring.
- The assessment agency representative carries an identity card and letter from the council authorizing to conduct the assessment.
- Assessment agency representative ensures the authenticity of Trainee’s identity by verifying the documents (any document issued by GOI, such as Ration card, Aadhaar Card, Driving Licence, Passport, Election card, etc)

- The assessment agency representative maintains the records of attendance, verified documents, and tablet instruments used in the assessment.
- Assessment agency representative collects evidence of the assessment in the best possible way (videos, pictures, voice recordings, etc)
- Assessment agency representative transfers the assessment scores from tab to assessment agency server, using a secure, encrypted web-based program.
- The assessment agency after processing the results and putting them in standard format hands over to LSSSDC within 7 days of assessment.

#### **2.4.2 Smartphone-based assessment using e-proctoring**

- All trainees due for assessments are registered on an assessment tool application using their unique mobile number and e-mail ID along with a Govt. ID issued proof.
- An assessment link is sent to the mail ID of each trainee with a defined expiry date of the link.
- Trainee at any location can click on the link using his/her smartphone or a web camera-enabled computer system
- Using the unique credentials and Govt ID number, the trainee logs in for the start of assessment and completes the assessment.
- The authenticity of Trainee's identity is done by assessment application by verifying the documents (any document issued by GOI, such as Ration card, Aadhaar Card, Driving Licence, Passport, election card, etc.) and a live photo capture
- A live video of the candidate during the assessment is captured to collect the evidence of the assessment
- Once the assessment is complete, the assessment application automatically assessment scores to the assessment agency server, using a secure, encrypted web-based program.
- The assessment agency after processing the results and putting them in standard format hands over to LSSSDC within 7 days of assessment.

## References

## Glossary

Term	Description
<b>Declarative Knowledge</b>	Declarative knowledge refers to facts, concepts, and principles that need to be known and/or understood to accomplish a task or to solve a problem.
<b>Key Learning Outcome</b>	The key learning outcome is the statement of what a learner needs to know, understand, and be able to do to achieve the terminal outcomes. A set of key learning outcomes will make up the training outcomes. Training outcome is specified in terms of knowledge, understanding (theory), and skills (practical application).
<b>OJT (M)</b>	On-the-job training (Mandatory); trainees are mandated to complete specified hours of training on-site
<b>OJT (R)</b>	On-the-job training (Recommended); trainees are recommended the specified hours of training on-site
<b>Procedural Knowledge</b>	Procedural knowledge addresses how to do something, or how to perform a task. It is the ability to work or produce a tangible work output by applying cognitive, affective, or psychomotor skills.
<b>Training Outcome</b>	Training outcome is a statement of what a learner will know, understand, and be able to do <b>upon the completion of the training.</b>
<b>Terminal Outcome</b>	The terminal outcome is a statement of what a learner will know, understand, and be able to do <b>upon the completion of a module.</b> A set of terminal outcomes helps to achieve the training outcome.

## Acronyms and Abbreviations

Term	Description
QP	Qualification Pack
NSQF	National Skills Qualification Framework
NSQC	National Skills Qualification Committee
NOS	National Occupational Standards
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
WHO	World Health Organization
SOP	Standard Operating Procedure
MSDS	Material Safety Datasheets
GDP	Good Documentation Practices
EHS	Environment Health Safety
PPE	Personal Protective Equipment