



# Model Curriculum

QP Name: Secondary & Tertiary Packaging – Assistant (Pharma,  
Biologics and Medical device)

QP Code: LFS/Q0217

QP Version: 4.0

NSQF Level: 2

Model Curriculum Version: 1.0

Life Sciences Sector Skill Development Council  
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# Table of Contents

## Contents

Training Parameters	2
Program Overview	3
Module Details	6
Module 1: Introduction to Life Sciences industry and the Packaging Operations	6
Module 2: Managing environmental sustainability	7
Module 3: Fundamentals of packaging	8
Module 4: Packaging activities	9
Module 5: Comply with EHS rules in production and GMP controlled area	10
Module 6: Cleaning and sanitization at workplace	11
Module 7: Coordination with supervisor, teammates and cross-functional teams	12
Module 8: Display sensitivity towards genders and people with disability	13
Module 9: Employability Skills (30 Hours)	14
Module 10: Apprenticeship Training	15
Annexure	16
Assessor Requirements	17
Assessment Strategy	18
References	21
Glossary	21
Acronyms and Abbreviations	21

# Training Parameters

<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceuticals, Biopharmaceuticals
<b>Occupation</b>	Manufacturing
<b>Country</b>	India
<b>NSQF Level</b>	Level 2
<b>Aligned to NCO/ISCO/ISIC Code</b>	NCO 2015/ 9321.0101
<b>Minimum Educational Qualification and Experience</b>	8 <sup>th</sup> Class pass
<b>Pre-Requisite License or Training</b>	NIL
<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>	4.0
<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>	Compulsory Notional Hours Theory= 115 Hours Practical=155 Hours Employability Skills= 30 Hours Total Compulsory Notional Hours= 300 Hours
<b>Maximum Duration of the Course</b>	Compulsory Notional Hours Theory= 115 Hours Practical=155 Hours Employability Skills= 30 Hours Total Compulsory Notional Hours= 300 Hours  Recommended apprenticeship: 12 Months

# 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.

- Explain the aspects of the life sciences industry and its pertinent regulations.
- Explain the fundamental concepts of packaging and its various components.
- Perform the Secondary and tertiary packaging support operations in compliance with good manufacturing practices (GMP) and other regulatory guidelines.
- Discuss the environment, health and safety (EHS) norms to be followed at work in the production and GMP controlled areas.
- Demonstrate how to maintain production area and equipment clean and calibrated as per GMP and standard operating procedures (SOP).
- Demonstrate how to coordinate with supervisor, teammates and respond to audit queries during GMP/ regulatory audits.
- Demonstrate emotional stability and sensitivity towards genders, cultures and specially-abled persons.
- Show how to understand, speak, read and write basic English language.

## 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/N0275: Discuss about Life Sciences Industry and basics of Packaging Operations NOS Version No. 1 NSQF Level-2</b>	<b>20:00</b>	<b>10:00</b>	<b>00:00</b>	<b>00:00</b>	<b>30:00</b>
Module 1: Introduction to life sciences industry and Packaging Operations	15:00	00:00	00:00	00:00	15:00
Module 2: Managing environment sustainability	5:00	10:00	00:00	00:00	15:00
<b>LFS/N0264: Perform the secondary and tertiary packaging of drug products in adherence to Good Manufacturing Practices (GMP) guidelines NOS Version No. 3 NSQF Level-2</b>	<b>60:00</b>	<b>90:00</b>	<b>00:00</b>	<b>00:00</b>	<b>150:00</b>
Module 3: Fundamentals of packaging	30:00	40:00	00:00	00:00	70:00
Module 4: Packaging activities	30:00	50:00	00:00	00:00	80:00
<b>LFS/N0112: Adhere to Environment, health and safety guidelines in a production facility and GMP controlled areas NOS Version No. 4 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 5: Comply EHS rules in production and GMP controlled area	10:00	20:00	00:00	00:00	30:00
<b>LFS/N0103: Clean and sanitize work area and machines to avoid cross-contamination NOS Version No. 4 NSQF Level-2</b>	<b>15:00</b>	<b>15:00</b>	<b>00:00</b>	<b>00:00</b>	<b>30:00</b>

Module 6: Cleaning and sanitization at workplace	15:00	15:00	00:00	00:00	30:00
<b>LFS/N0114: Coordinate with supervisor, teammates and cross-functional teams NOS Version No. 3 NSQF Level-2</b>	<b>10:00</b>	<b>20:00</b>	<b>00:00</b>	<b>00:00</b>	<b>30:00</b>
Module 7: Coordination with supervisor, teammates and cross-functional teams	05:00	15:00	00:00	00:00	18:00
Module 8: Display sensitivity towards all genders and people with Disability	05:00	05:00	00:00	00:00	12:00
<b>DGT/VSQ/N0101: Employability Skills (30 Hours) NOS Version No. 1</b>					
Module 9: Employability Skills					
Introduction to Employability Skills	01:00	00:00	00:00	00:00	01:00
Constitutional values – Citizenship	01:00	00:00	00:00	00:00	01:00
Becoming a Professional in the 21st Century	01:00	00:00	00:00	00:00	01:00
Basic English Skills	01:00	01:00	00:00	00:00	02:00
Communication Skills	02:00	02:00	00:00	00:00	04:00
Diversity & Inclusion	01:00	00:00	00:00	00:00	01:00
Financial and Legal Literacy	02:00	02:00	00:00	00:00	04:00
Essential Digital Skills	01:00	02:00	00:00	00:00	03:00
Entrepreneurship	03:00	04:00	00:00	00:00	07:00
Customer Service	02:00	02:00	00:00	00:00	04:00
Getting ready for apprenticeship & Jobs	01:00	01:00	00:00	00:00	02:00
<b>Recommended Apprenticeship</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>130:00</b>	<b>170:00</b>	<b>00:00</b>	<b>2010:00</b>	<b>2310:00</b>

# Module Details

## Module 1: Introduction to Life Sciences industry and the Packaging Operations Module- LFS/N0275 V1.0

### Terminal Outcomes:

- Explain the overview of the Life Sciences industry in regulation applicable to Packaging Operations.
- Discuss the importance of a skilled Packaging individual in Pharma, Biologics and Medical device

<b>Duration:</b> 15:00	<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 regulatory authorities, regulations and legislation to be followed in a life sciences manufacturing facility.</li> <li>● Discuss the good practices i.e. GMP and good documentation practices (GDP) relevant to secondary and tertiary packaging operation.</li> <li>● Explain the basic skills required to perform the job of Packaging operations</li> <li>● Explain the importance of Packaging individual in Pharma, Biologics and Medical device</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: Managing environmental sustainability

Mapped to NOS- LFS/N0275, v1.0

### Terminal Outcomes:

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

<b>Duration: 5:00</b>	<b>Duration: 10:00</b>
<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 the 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 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 environment sustainable waste disposal- 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>	
Colour-coded waste bin bag, colour-coded waste container	

## Module 3: Fundamentals of packaging

Mapped to LFS/N0264, v3

### Terminal Outcomes:

- Explain the packaging process and its various components.
- Differentiate between different types of packaging process and packaging material used.

<b>Duration:</b> 30:00	<b>Duration:</b> 40:00
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Discuss the basic principle of the packaging and its functions.</li> <li>● Explain different types of packaging in the Pharma and Bio-pharma sector.</li> <li>● Discuss the application of different types of packaging material used for Pharma and Bio-pharma packaging.</li> <li>● Discuss different types of machines used in the packaging process and their operating procedure.</li> </ul>	<ul style="list-style-type: none"> <li>● Draw a flow chart illustrating the packaging process with the names of machines used.</li> <li>● Classify the given packaging materials used in Pharma and Bio-pharma packaging based on the nature of the drug product.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector/ screen, Scanner, Computer speakers	
<b>Tools, Equipment and Other Requirements</b>	
Different types of packaging materials, machines used in secondary and tertiary packaging process.	

## Module 4: Packaging activities

Mapped to LFS/N0264, v3

### Terminal Outcomes:

- Demonstrate the secondary and tertiary packaging support operation in a packaging facility and its processes.
- Demonstrate how to maintain packaging process related records and documents.

<b>Duration:</b> 30:00	<b>Duration:</b> 50:00
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Explain the essential current GMP (cGMP) guidelines for secondary and tertiary packaging.</li> <li>● Describe the labeling requirement as per regulatory and legal guidelines.</li> <li>● Describe the documentation method for secondary and tertiary packaging as per cGMP and GDP guidelines.</li> <li>● Explain the methods of packaging waste disposal.</li> <li>● Discuss the cleanroom behaviour to be followed at the workplace.</li> <li>● Explain the importance of using appropriate personal protection equipment (PPE) during secondary and tertiary packaging operations.</li> <li>● Discuss the Standard Operating Procedures (SOP) for cleaning packaging equipment.</li> <li>● Explain the importance of line-clearance for smooth flow of work.</li> <li>● Recall the regulatory/ statutory guidelines for the process of handover and takeover, documentation and data integrity.</li> </ul>	<ul style="list-style-type: none"> <li>● Practice cleanroom behaviour during each practical in the skill lab</li> <li>● Demonstrate how to use appropriate PPE during the secondary and tertiary packaging process.</li> <li>● Prepare a checklist of packaging material like sheets, pallets, stretch wrap and strapping labels used for tertiary packaging.</li> <li>● Demonstrate how to perform the stacking, wrapping and cartoning of different drug batches in suitable containers.</li> <li>● Practice the labelling of containers/cartons with appropriate marker and barcode with proper handling and storage conditions.</li> <li>● Demonstrate documentation for secondary and tertiary packaging in a sample Batch Packaging Record (BPR) as per cGMP and GDP.</li> <li>● Demonstrate the process of line-clearance in the packaging area.</li> <li>● Perform cleaning of packaging machines as per SOP.</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>	
Gowns, Mask (full and half), gloves, Material Data safety sheet, Safety shoes, Manual eye wash bottle, Formats of BPR, secondary and Tertiary Packaging machines videos, Automatic Packaging Line, Checkweigher, Vari Counter, Metal Detector, Cotton Inserter, Desiccant or Silica gel Inserter, Induction Sealing Machine, Labelling Machine, Product Information Leaflet machine, Glue Dispenser, Weighing machines, Weighing Balances, Sachet Filling Machine, Cartoning Machine , Band Sealing Machine (Pouch),SOPs for packaging equipment cleaning and Line clearance, Sample labels used in packaging, PPE.	

## Module 5: Comply with EHS rules in production and GMP controlled area

*Mapped to LFS/N0112, v4*

### Terminal Outcomes:

- Demonstrate how to comply with health and personal hygiene-related protocols.
- Demonstrate how to comply with safety and security policies and procedures.
- Demonstrate how to follow emergency procedures.

<b>Duration: 10:00</b>	<b>Duration: 20:00</b>
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Describe the relevant legislative requirements and company’s procedures for the environment, health.</li> <li>● Discuss the workplace hazards and their reporting in a manufacturing facility in the life sciences sector.</li> <li>● Recall the guidelines and procedures for hazards, accidents, safety signs and signals, and Heinrich pyramid used in a manufacturing plant.</li> <li>● Explain health, safety, and accident reporting procedures.</li> <li>● Describe the importance of the gowning, medical assistance and emergency services.</li> <li>● Discuss the procedures for evacuation for employees, contract staff, and visitors in controlled areas.</li> <li>● Discuss the types of safety gears and procedure to use them.</li> <li>● Discuss WHO guidelines for personal hygiene, handling, and storage of hazardous material.</li> <li>● Explain the importance of material segregation and 5S system.</li> </ul>	<ul style="list-style-type: none"> <li>● Demonstrate how to ascertain the breach of EHS protocols.</li> <li>● Demonstrate how to communicate hazards, safety instructions and accidents to teammates and cross-functional teams.</li> <li>● Demonstrate how and when to follow instructions, guidelines, procedures, rules, signage, codes for different situations and processes.</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, CO <sub>2</sub> Type Fire Extinguisher, ABC Type Fire Extinguisher, Personal Protective Equipment and gowning material	

## Module 6: Cleaning and sanitization at workplace

Mapped to LFS/N0103, v4

### Terminal Outcomes:

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

<b>Duration: 15:00</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>● 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), WHO guidelines and rules for cleaning, sanitation, and hygiene activity.</li> <li>● Explain waste disposal guidelines as per WHO and good laboratory practices (GLP)/GMP and relevant organizational standard operating procedures (SOPs).</li> <li>● Explain waste disposal guidelines as per WHO and GMP and relevant organizational SOPs.</li> <li>● Discuss the concept of cleaning validation and its importance.</li> </ul>	<ul style="list-style-type: none"> <li>● Prepare a checklist of the hygiene standards required in the production area.</li> <li>● Demonstrate how to inspect and check surfaces, equipment, and instruments for soil/dirt/residue by applying appropriate methods and materials</li> <li>● Demonstrate how to clean and sanitize production area by using various equipment, machines, instruments, different materials, and chemicals.</li> <li>● Demonstrate how to perform cleaning, sanitation, and hygiene activity by following guidelines from GMP, rules from WHO and essential guidelines from GLP rules.</li> <li>● Perform disposal of waste as per regulatory guidelines and SOPs.</li> <li>● Demonstrate how to handle different types of hazards by applying critical thinking skills.</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>	
Cleaning agents (soap/alconox etc.), Glassware for cleaning, Half Face Mask, Gloves (Nitrile, Heat, acid, chemical resistant etc.), and PPE	

## Module 7: Coordination with supervisor, teammates and cross-functional teams

Mapped to LFS/N0114, v3

### Terminal Outcomes:

- Describe various scenarios at work that demand coordination and collaboration with the supervisor, team, and cross-functional teams.
- Demonstrate the effective coordination and collaboration with supervisor, cross-functional teams.

<b>Duration:</b> 05:00	<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 reporting structure of the organization.</li> <li>● List the functional and cross-functional stakeholders for Assistant- Secondary &amp; Tertiary Packaging (Pharma, Biologics and Medical device).</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 of communication at workplace.</li> <li>● Explain the best strategies for collaborating with others.</li> <li>● Describe the problem-solving techniques for routine work-related issues.</li> <li>● Discuss the role of an auditee in a regulated manufacturing plant.</li> </ul>	<ul style="list-style-type: none"> <li>● Demonstrate the effective ways to communicate and collaborate with various stakeholders in a simulated environment for multiple scenarios.</li> <li>● Respond to regulatory audit questions and communicate the audit observations in a mock audit situation.</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>	
NIL	

## Module 8: Display sensitivity towards genders and people with disability

*Mapped to LFS/N0114, v3*

### Terminal Outcomes:

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

<b>Duration:</b> 05:00	<b>Duration:</b> 05:00
<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) (POSH) 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 their negative consequences.</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> <li>● Participate in gender sensitivity training</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 9: Employability Skills (30 Hours)

*Mapped to DGT/VSQ/N0101- v1.0*

### Introduction to Employability Skills

After completing this programme, participants will be able to:

1. Discuss the importance of Employability Skills in meeting the job requirements

### Constitutional values - Citizenship

2. Explain constitutional values, civic rights, duties, citizenship, responsibility towards society etc. that are required to be followed to become a responsible citizen.
3. Show how to practice different environmentally sustainable practices

### Becoming a Professional in the 21st Century

4. Discuss 21st century skills.
5. Display positive attitude, self -motivation, problem solving, time management skills and continuous learning mindset in different situations.

### Basic English Skills

6. Use appropriate basic English sentences/phrases while speaking

### Communication Skills

7. Demonstrate how to communicate in a well -mannered way with others.
8. Demonstrate working with others in a team

### Diversity & Inclusion

9. Show how to conduct oneself appropriately with all genders and PwD
10. Discuss the significance of reporting sexual harassment issues in time

### Financial and Legal Literacy

11. Discuss the significance of using financial products and services safely and securely.
12. Explain the importance of managing expenses, income, and savings.
13. Explain the significance of approaching the concerned authorities in time for any exploitation as per legal rights and laws

### Essential Digital Skills

14. Show how to operate digital devices and use the associated applications and features, safely and securely
15. Discuss the significance of using internet for browsing, accessing social media platforms, safely and securely

### Entrepreneurship

16. Discuss the need for identifying opportunities for potential business, sources for arranging money and potential legal and financial challenges

### Customer Service

17. Differentiate between types of customers
18. Explain the significance of identifying customer needs and addressing them
19. Discuss the significance of maintaining hygiene and dressing appropriately

### Getting ready for apprenticeship & Jobs

20. Create a biodata
21. Use various sources to search and apply for jobs
22. Discuss the significance of dressing up neatly and maintaining hygiene for an interview
23. Discuss how to search and register for apprenticeship opportunities

## Module 10: Apprenticeship Training

Mapped to Secondary & Tertiary Packaging Assistant- (Pharma, Biologics and Medical device)

Mandatory Duration: 00:00	Recommended Duration: 2010:00
Module Name: On the Job Training Location: On-Site	
<ul style="list-style-type: none"><li>• Ensure environment sustainability and sensitivity towards all genders and people with disability.</li><li>• perform cleaning and sanitation activities before, during, and after work.</li><li>• maintain packaging process related records and documents</li></ul>	

# Annexure

## Trainer Requirements

Trainer Prerequisites						
Minimum Educational Qualification	Specialization	Relevant Industry Experience		Training Experience		Remarks
		Years	Specialization	Years	Specialization	
12 <sup>th</sup> Class	Science Subjects	6	Secondary and Tertiary packaging operations	0	NA	
Graduate in Sciences	B. Sc. / B. Pharma	3	Secondary and Tertiary packaging operations	0	NA	
Assistant Professor/ Associate Professor/ Professor	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 Secondary & Tertiary Packaging Assistant- (Pharma, Biologics and Medical device)- "LFS/Q0217, v4.0" post completion of Faculty Development Program of LSSSDC

Trainer Certification	
Domain Certification	Platform Certification
Certified for job role: "Secondary & Tertiary Packaging Assistant- (Pharma, Biologics and Medical device)" mapped to Qualification Pack: "LFS/Q0217, v4.0" 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	
12 <sup>th</sup> Class	Science Subjects	6	Secondary and Tertiary packaging operations	1	On the job assessment/ Training experience/ Vocational assessment/ Academic assessment	
Graduate in Sciences	B. Sc. / B. Pharma	4	Secondary and Tertiary packaging operations	1	On the job assessment/ Training experience/ Vocational assessment/ Academic assessment	
Assistant Professor/ Associate Professor/ Professor	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 Secondary & Tertiary Packaging Assistant-(Pharma, Biologics and Medical device)-“LFS/Q0217, v4.0” post completion of Faculty Development Program of LSSSDC

Assessor Certification	
Domain Certification	Platform Certification
Secondary & Tertiary Packaging Assistant-(Pharma, Biologics and Medical device)-mapped to the Qualification Pack: “LFS/Q0217, v4.0” 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 Secondary & Tertiary Packaging Assistant- (Pharma, Biologics and Medical device) 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, and 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
<b>QP</b>	Qualification Pack
<b>NSQF</b>	National Skills Qualification Framework
<b>NSQC</b>	National Skills Qualification Committee
<b>NOS</b>	National Occupational Standards
<b>GLP</b>	Good Laboratory Practices
<b>GMP</b>	Good Manufacturing Practices
<b>WHO</b>	World Health Organization
<b>SOP</b>	Standard Operating Procedure
<b>MSDS</b>	Material Safety Datasheets
<b>GDP</b>	Good Documentation Practices
<b>EHS</b>	Environment Health Safety
<b>PPE</b>	Personal Protective Equipment