



Model Curriculum Version: 1.0

**Life Sciences Sector Skill Development Council**  
14, Palam Marg, 2<sup>nd</sup> Floor Rear, Vasant Vihar, New Delhi, 110057

## Table of Contents

Training Parameters.....	2
Program Overview .....	4
Training Outcomes.....	4
Compulsory Modules .....	4
Module Details.....	7
Module 1: Introduction to Life Sciences industry and the job role .....	7
Module 3: Quality checks in production.....	9
Module 4: Managing environmental sustainability .....	10
Module 5: Comply with EHS rules in production and GMP controlled area .....	11
Module 6: Reporting and documentation .....	12
Module 7: Coordinate with manager, colleagues and auditors .....	13
Module 8: Display sensitivity towards all genders and people with disability .....	14
Annexure.....	17
Trainer Requirements .....	17
Assessor Requirements.....	18
Assessment Strategy.....	19
References .....	22
Glossary.....	22
Acronyms and Abbreviations.....	23

## Training Parameters

<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceuticals and Biopharmaceuticals
<b>Occupation</b>	Quality
<b>Country</b>	India
<b>NSQF Level</b>	5
<b>Aligned to NCO/ISCO/ISIC Code</b>	NCO 2015/ 2113.0901
<b>Minimum Educational Qualification and Experience</b>	B. Pharma (7th Semester) or B. Tech (Biotechnology/Chemical Engineering/Instrumentation & Electronics) 3rd year or M.Sc. (Chemistry/ Microbiology/ Biotechnology/ Life Sciences)
<b>Pre-Requisite License or Training</b>	NA
<b>Minimum Job Entry Age</b>	21 Years
<b>Last Reviewed On</b>	30 December 2021
<b>Next Review Date</b>	30 December 2024
<b>NSQC Approval Date</b>	30 December 2021
<b>QP Version</b>	2.0
<b>Model Curriculum Creation Date</b>	20 April 2021
<b>Model Curriculum Valid Up to Date</b>	30 December 2024
<b>Model Curriculum Version</b>	1.0
<b>Minimum Duration of the Course</b>	Compulsory Notional Hours Theory= 155 Hours Practical=265 Hours Employability Skills= 90 Hours Total Compulsory Notional Hours= 510 Hours  with mandatory apprenticeship training for 12 months  Note:

	<ul style="list-style-type: none"> <li>• B. Tech Biotech/ B. Pharma is exempted from Mandatory Apprenticeship</li> <li>• B. Tech (Biotechnology/Chemical Engineering/Instrumentation &amp; Electronics) 3rd Year students has mandatory Project Duration of 225 hours</li> </ul>
<b>Maximum Duration of the Course</b>	<p>Compulsory Notional Hours  Theory= 155 Hours  Practical=265 Hours  Employability Skills= 90 Hours  Total Compulsory Notional Hours= 510 Hours</p> <p>with mandatory apprenticeship training for 12 Months</p> <p>Note:</p> <ul style="list-style-type: none"> <li>• B. Tech Biotech/ B. Pharma is exempted from Mandatory Apprenticeship</li> <li>• B. Tech (Biotechnology/Chemical Engineering/Instrumentation &amp; Electronics) 3<sup>rd</sup> Year students has mandatory Project Duration of 225 hours</li> </ul>

## 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 quality assurance chemist in compliance with Good Manufacturing Practices (GMP)/GLP(Good Laboratory Practices) and other environmental regulatory guidelines.
- Explain the essential concepts of quality assurance for production.
- Demonstrate how to conduct quality checks in production units.
- Discuss how to maintain a healthy, safe and secure working environment at the pharmaceutical manufacturing shop floor, laboratory and area around in conformance with environmental health and safety (EHS) rules.
- Demonstrate good documentation practice (GDP) and data integrity while reporting and documentation as per standard operating procedures (SOP), good laboratory practices (GLP), and Good Manufacturing Practices (GMP).
- 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.

### 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>Bridge Module</b>	<b>35:00</b>	<b>55:00</b>	<b>00:00</b>	<b>00:00</b>	<b>90:00</b>
Module 1: Introduction of Life Sciences industry and the job role	05:00	00:00	00:00	00:00	05:00
Module 2: Quality Assurance for production	30:00	55:00	00:00	00:00	85:00
<b>LFS/N0341: Perform quality checks in the manufacturing/production units in compliance with regulatory guidelines NOS Version No. 2.0 NSQF Level-5</b>	<b>70:00</b>	<b>110:00</b>	<b>00:00</b>	<b>00:00</b>	<b>180:00</b>
Module 3: Quality checks in production process	60:00	90:00	00:00	00:00	150:00
Module 4: Managing environmental sustainability	10:00	20:00	00:00	00:00	30:00
<b>LFS/N0110: Ensure adherence to</b>	<b>10:00</b>	<b>20:00</b>	<b>00:00</b>	<b>00:00</b>	<b>30:00</b>

<b>Environment, health and safety guidelines in GMP/GLP controlled areas and Lab</b> <b>NOS Version No. 2.0</b> <b>NSQF Level-5</b>					
Module 5: Comply EHS rules in GMP/GLP controlled area	10:00	20:00	00:00	00:00	30:00
<b>LFS/N0345: Perform reporting and documentation to meet regulatory standards</b> <b>NOS Version No. 2.0</b> <b>NSQF Level-5</b>	<b>20:00</b>	<b>40:00</b>	<b>00:00</b>	<b>00:00</b>	<b>60:00</b>
Module 6: Reporting and documentation	20:00	40:00	00:00	00:00	60:00
<b>LFS/N0346: Coordinate with supervisor, functional team, cross-functional teams and auditors</b> <b>NOS Version No. 2.0</b> <b>NSQF Level-5</b>	<b>20:00</b>	<b>40:00</b>	<b>00:00</b>	<b>00:00</b>	<b>60:00</b>
Module 7: Coordination with manager, colleagues and auditors	10:00	30:00	00:00	00:00	40:00
Module 8: Sensitivity towards genders and people with disability	10:00	10:00	00:00	00:00	20:00
<b>DGT/VSQ/N0103: Employability Skills (90 Hours)</b> <b>NOS Version No. 1</b>					
Module 9: Employability Skills					
Introduction to Employability Skills	03:00	00:00	00:00	00:00	01:30
Constitutional values - Citizenship	01:30	00:00	00:00	00:00	01:30
Becoming a Professional in the 21st Century	05:00	00:00	00:00	00:00	02:30
Basic English Skills	10:00	00:00	00:00	00:00	10:00
Career Development & Goal Setting	04:00	00:00	00:00	00:00	02:00
Communication Skills	10:00	00:00	00:00	00:00	05:00
Diversity and Inclusion	02:30	00:00	00:00	00:00	02:30
Financial and Legal Literacy	10:00	00:00	00:00	00:00	05:00
Essential Digital Skills	20:00	00:00	00:00	00:00	10:00
Entrepreneurship	07:00	00:00	00:00	00:00	07:00
Customer Service	09:00	00:00	00:00	00:00	05:00

Getting ready for apprenticeship & Jobs	08:00	00:00	00:00	00:00	08:00
<b>Apprenticeship Training</b>	<b>00:00</b>	<b>00:00</b>	<b>2010:00</b>	<b>00:00</b>	<b>2010:00</b>
<b>Total Duration</b>	<b>255:00</b>	<b>285:00</b>	<b>2010:00</b>	<b>00:00</b>	<b>2550:00</b>

## Module Details

### Module 1: Introduction to Life Sciences industry and the job role

#### Bridge Module

#### Terminal Outcomes:

- Explain the overview of the Life Sciences industry in regulation applicable to Chemist-In-Process Quality Assurance.
- Discuss the importance of a skilled Chemist-In-Process Quality Assurance.

<b>Duration:</b> 05:00	<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, legislation, and good practices relevant to the quality assurance in a life sciences manufacturing facility.</li> <li>• Explain the basic skills required to perform the job of Chemist-In-Process Quality Assurance.</li> <li>• Explain the importance of a Chemist-In-Process Quality Assurance.</li> <li>• Discuss the basic terminologies used in the quality assurance department.</li> <li>• Explain the impact of non-compliance on the quality of the product and the environment.</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: Essential concepts of quality assurance for production

### Bridge Module

#### Terminal Outcomes:

- Demonstrate how to perform job activities of Chemist-In-Process Quality Assurance.

<b>Duration:</b> 30:00	<b>Duration:</b> 55:00
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>• Discuss quality principles and concepts applied in the life sciences sector.</li> <li>• Describe the quality assurance procedures and schedules.</li> <li>• Explain the fundamental science in formulation, production and packaging.</li> <li>• Explain Quality Management System (QMS) for quality assurance in Life Sciences.</li> <li>• Explain the basic concept of Quality by Design (QbD) and its application in quality control and quality risk management.</li> <li>• Explain the procedures for sample handling, processing, preservation, hazardous and poisonous substances handling.</li> </ul>	<ul style="list-style-type: none"> <li>• Perform material verification and status of material release.</li> <li>• Review collection of stability and control samples during packing operations.</li> <li>• Prepare compliance report for audits observations.</li> <li>• Demonstrate how to prepare quality manual and master validation plan (MVP).</li> <li>• Demonstrate the methods of maintaining training documents for trainings imparted.</li> <li>• Perform the Quality Management System (QMS) elements checks on the shop floor.</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>	
Flask, Petri plates, Spreader, Laminar Air flow chamber, Incubator, Apron, Gloves, Face mask, , pH meter, Hot air oven, Glassware, Half face mask, Autoclave, Chemicals, Pipettes, Test tubes, Extraction tubes cotton, Microbial identification system	

## Module 3: Quality checks in production

Mapped to LFS/N0341, v2

### Terminal Outcomes:

- Discuss the quality checks performed in the manufacturing/production units.

<b>Duration:</b> 60:00	<b>Duration:</b> 90:00
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>Discuss the various in-process checks performed during manufacturing and packing operations.</li> <li>Describe the concept of Critical Quality Attributes (CQA), Critical Process Parameters (CPP) and Critical Process Controls (CPC).</li> <li>Discuss the standard procedures of CAPA (Corrective and Preventive Action) follow-up and closure.</li> <li>Explain the equipment qualification &amp; validation procedures.</li> <li>Describe the concept of incidents, deviations, OOS (Out of Specification) and OOT (Out of Trend) measures.</li> <li>Discuss instrument management and calibration procedures.</li> </ul>	<ul style="list-style-type: none"> <li>Perform in-process checks as per the requisite acceptance criteria/specifications.</li> <li>Identify critical quality attributes (CQA), critical process parameters (CPP) and critical process controls (CPC).</li> <li>Demonstrate how to carry out investigation of deviations and Out of Specifications (OOS).</li> <li>Monitor the validation and qualification activities of machines.</li> <li>Perform sampling activities for quality assurance audit across stages.</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>	
Manufacturing equipment models/ diagrams (API & Formulations), Sample production plan, Sample log books, Sample BMR and BPR Sample, Sample formats of method transfer, method validation and calibration reports, GMP and GLP guidelines, Sample labels, Sample audit reports and sample audit responses, Diagrams of engineering instruments, Sample calibration and change control records	

## Module 4: Managing environmental sustainability

Mapped to LFS/N0341, v2

### 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> 10:00	<b>Duration:</b> 20:00
<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 given 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 5: Comply with EHS rules in production and GMP controlled area

### Mapped to LFS/N0110, v2

#### 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.

Duration: 10:00	Duration: 20:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<ul style="list-style-type: none"> <li>• Describe the relevant legislative requirements and company's procedures for the environment and 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 in a given situation.</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: Reporting and documentation

Mapped to LFS/N0345, v2

### Terminal Outcomes:

- Explain the methods of reporting and documentation for the quality control operations.
- Discuss how to perform documentation for quality control operations in compliance with Good Documentation Practices(GDP) and other regulatory guidelines.

Duration: 20:00	Duration: 40:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<ul style="list-style-type: none"> <li>• Describe the types of documentation in an organization and the importance of maintaining the same.</li> <li>• Explain the method of reporting and documentation as per Good Documentation Practices(GDP) and other regulatory guidelines.</li> <li>• Describe the Attributable, Legible, Contemporaneous, Original, and Accurate Plus (ALCOA +) principle and its importance.</li> <li>• Discuss how to use lab information management system.</li> <li>• Explain statistical concepts and application of statistical tools.</li> <li>• Discuss guidelines for Electronic Records &amp; Electronic Signatures, Audit Trails, Date and Time Stamps, Data Integrity in the life sciences sector.</li> </ul>	<ul style="list-style-type: none"> <li>• Demonstrate how to perform reporting and documentation as per GDP and other regulatory guidelines.</li> <li>• prepare inspection reports as per inspection activity performed.</li> <li>• Demonstrate the use of computer/ and software like MS Office, or its alternative for reporting.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speakers	
<b>Tools, Equipment and Other Requirements</b>	
N/A	

## Module 7: Coordinate with manager, colleagues and auditors

Mapped to LFS/N0346, v2

### 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 and cross-functional teams.

<b>Duration: 10:00</b>	<b>Duration: 30:00</b>
<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 Chemist- In-process Quality Assurance(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 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 type of audits in the life sciences sector for the quality 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>• Demonstrate how to resolve conflict in multiple scenarios.</li> <li>• Demonstrate how to communicate with auditors and regulatory inspectors during inspections/audits.</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 8: Display sensitivity towards all genders and people with disability

*Mapped to LFS/N0346, v2*

### Terminal Outcomes:

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

<b>Duration: 10:00</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>• 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 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> </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 (90 Hours)

Mapped to DGT/VSQ/N0103- v1.0

Mandatory Duration: 90:00

Module Name: Employability Skills

This is a compulsory module introduced by the Directorate General of Training (DGT). For further details regarding modules please find at below link.

<https://www.nqr.gov.in/national-skills-qualification-framework>



## Module 10: Apprenticeship Training

### *Mapped to Associate-Clinical Research Management*

<b>Mandatory Duration:</b> 2010:00	<b>Recommended Duration:</b> 00:00
<b>Module Name:</b> Apprenticeship Training	
<b>Location:</b> On-Site	
<b>Terminal Outcomes</b> <ul style="list-style-type: none"> <li>• Perform quality checks in the manufacturing/production units in compliance with regulatory guidelines.</li> <li>• Follow environment, health and safety guidelines in GMP/GLP controlled areas and lab and ensure the same is followed by subordinates as well.</li> <li>• Perform reporting and documentation to meet quality standards.</li> <li>• Coordinate with manager and colleagues, and respond to audit queries.</li> </ul>	

## Annexure

### Trainer Requirements

Trainer Prerequisites						
Minimum Educational Qualification	Specialization	Relevant Industry Experience		Training Experience		Remarks
		Years	Specialization	Years	Specialization	
Graduate	Pharmacy / Biotechnology Engg.	5	Quality Assurance	0	NA	
Post Graduate	Pharmacy/ Chemistry/ Biotechnology	3	Quality Assurance	0	NA	
Post Graduate in Sciences (Chemistry/ Life Sciences Subject)	Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) (LFS/Q0302, V1.0/ V2.0) Level-5 qualified	2	Quality Assurance		N/A	

Trainer Certification	
Domain Certification	Platform Certification
Certified for Job Role: “Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) (In-process Quality Assurance) ” mapped to QP: “LFS/Q0302, 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, v2.0” with minimum score of 80%.

## Assessor Requirements

Assessor Prerequisites						
Minimum Educational Qualification	Specialization	Relevant Industry Experience		Training/Assessment Experience		Remarks
		Years	Specialization	Years	Specialization	
Graduate	Pharmacy / Biotechnology Engg.	6	Quality Assurance	1	On the job assessment/ Training experience/ Vocational assessment/ Academic assessment	
Post Graduate	Pharmacy/ Chemistry/ Biotechnology	4	Quality Assurance	1	On the job assessment/ Training experience/ Vocational assessment/ Academic assessment	
Post Graduate	Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) (LFS/Q0302, V1.0/ V2.0) Level-5 qualified	4	Quality Assurance	1	On the job assessment/ Training experience/ Vocational assessment/ Academic assessment	

Assessor Certification	
Domain Certification	Platform Certification
Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) mapped to the Qualification Pack: "LFS/Q0302, v3.0 " 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, v2.0" 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 Chemist- In-process Quality Assurance (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 quality 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 upon the completion of the training.
<b>Terminal Outcome</b>	The terminal outcome is a statement of what a learner will know, understand, and be able to do upon the completion of a module. 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
OOS	Out of Specification
OOT	Out of Trend