Model Curriculum

QP Name: Microbiologist-Quality Control

QP Code: LFS/Q0308

QP Version: 3.0

NSQF Level: 5

Model Curriculum Version: 1.0

Life Sciences Sector Skill Development Council
14, Palam Marg, 2nd Floor Rear, Vasant Vihar, New Delhi, 110057

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Training Parameters

Sector	Life Sciences
Sub-Sector	Pharmaceuticals and Biopharmaceuticals
Occupation	Quality
Country	India
NSQF Level	5
Aligned to NCO/ISCO/ISIC Code	NCO-2015/2131.12 NCO-2015/2131.07
Minimum Educational Qualification and Experience	B.Sc. (Biochemistry/Biology/ Chemistry/Immunology /Biomedical Science/Biotechnology/Microbiology) **OR** B. Pharma 7th Semester OR B. Tech (Biotechnology) 3rd year **OR** M.Sc. (Microbiology) Age: 21 years
Pre-Requisite License or Training	NIL
Minimum Job Entry Age	21 Years
Last Reviewed On	30 December 2021
Next Review Date	30 December 2024
NSQC Approval Date	30 December 2021
QP Version	3.0
Model Curriculum Creation Date	23 July 2021
Model Curriculum Valid Up to Date	30 December 2024
Model Curriculum Version	1.0
Minimum Duration of the Course	Compulsory Notional Hours Theory= 150 Hours Practical=240 Hours Employability Skills= 90 Hours Total Compulsory Notional Hours= 480 Hours
Maximum Duration of the Course	Compulsory Notional Hours Theory= 150 Hours

	Practical=240 Hours Employability Skills= 90 Hours Total Compulsory Notional Hours= 480 Hours with mandatory apprenticeship of 6 months Total Notional Hours duration is 480 Hours Note: ● B. Tech Biotech/ B. Pharma/ M.Sc. Microbiology is exempted from Mandatory Apprenticeship ● B. Tech Biotech 3rd Year students has mandatory Project Duration of 300 hours

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 control microbiology operations in compliance with Good Manufacturing Practices (GMP)/ Good Laboratory Practices (GLP) and other environmental regulatory guidelines.
- Explain the fundamental concepts of Microbiology and its various process.
- Demonstrate how to conduct routine quality control checks in a Microbiology lab.
- Discuss the techniques and process of microbiological analysis.
- Demonstrate the operating procedures for various equipments used in microbiological analysis.
- Investigate and analyze laboratory in line with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP).
- Discuss how to maintain a healthy, safe and secure working environment at the pharmaceutical manufacturing shop floor, laboratory and area around in conformance with Environment 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.

NOS/ Module Details	Total Duration Hours	Level	Credits
Compulsory Bridge Module Introduction to Life Sciences industry and the job role	**60:00**	Level-5	**2.00**
Compulsory Module LFS/N0344: Perform checks in a microbiology lab before the start of the microbiological test NOS Version No. 2.0	**90:00**	Level-5	**3.00**
Compulsory Module LFS/N0342: Perform microbial analysis tests in compliance with regulatory guidelines NOS Version No. 2.0	**120:00**	Level-5	**4.00**
Compulsory Module LFS/N0110: Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab NOS Version No. 2.0	**30:00**	Level-5	**1.00**
Compulsory Module LFS/N0343: Perform reporting and documentation to meet quality and regulatory standards NOS Version No. 2.0	**30:00**	Level-5	**1.00**
Compulsory Module LFS/N0302: Coordinate with Manager, colleagues and auditors NOS Version No. 3.0	**60:00**	Level-5	**2.00**
DGT/VSQ/N0103: Employability Skills NOS Version No. 1.0	**90:00**		**3.00**
Total Duration (A)	**480:00**		
Total Credits (A)			**16.00**

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
Bridge Module	**20:00**	**40:00**	**00:00**	**00:00**	**60:00**
Module 1: Introduction to Life Sciences industry and the job role	04:00	00:00	00:00	00:00	04:00
Module 2: Essential concepts of Microbiology for quality control	16:00	40:00	00:00	00:00	56:00
LFS/N0344: Perform checks in a microbiology lab before the start of the microbiological test NOS Version No. 2.0 NSQF Level-5	**30:00**	**60:00**	**00:00**	**00:00**	**90:00**
Module 3: Laboratory specific routine checks	20:00	40:00	00:00	00:00	60:00
Module 4: Managing environmental sustainability	10:00	20:00	00:00	00:00	30:00
LFS/N0342: Perform microbial analysis tests in compliance with regulatory guidelines NOS Version No. 2.0 NSQF Level-5	**60:00**	**60:00**	**00:00**	**00:00**	**120:00**
Module 5: Microbial analysis tests	35:00	30:00	00:00	00:00	65:00
Module 6: Research and development for new products	25:00	30:00	00:00	00:00	55:00
LFS/N0110: Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab Version No. 2 NSQF Level-5	**10:00**	**20:00**	**00:00**	**00:00**	**30:00**
Module 7: Comply with EHS rules in production and GMP controlled area	10:00	20:00	00:00	00:00	30:00

LFS/N0343: Perform reporting and documentation to meet quality and regulatory standards NOS Version No. 2 NSQF Level-5	**10:00**	**20:00**	**00:00**	**00:00**	**30:00**
Module 8: Reporting and documentation	10:00	20:00	00:00	00:00	30:00
LFS/N0302: Coordinate with Manager, colleagues and auditors NOS Version No. 3 NSQF Level-5	**20:00**	**40:00**	**00:00**	**00:00**	**60:00**
Module 9: Coordinate with manager, colleagues and auditors	12:00	25:00	00:00	00:00	37:00
Module 10: Display sensitivity towards all genders and people with disability	08:00	15:00	00:00	00:00	23:00
DGT/VSQ/N0103: Employability Skills (90 Hours) NOS Version No. 1					
Module 11: Employability Skills					
Introduction to Employability Skills	03:00	00:00	00:00	00:00	01:00
Constitutional values - Citizenship	1:50	00:00	00:00	00:00	01:00
Becoming a Professional in the 21st Century	05:00	00:00	00:00	00:00	01:00
Basic English Skills	10:00	00:00	00:00	00:00	02:00
Career Development & Goal Setting	04:00	00:00	00:00	00:00	01:00
Communication Skills	10:00	00:00	00:00	00:00	04:00
Diversity and Inclusion	02:50	00:00	00:00	00:00	01:00
Financial and Legal Literacy	10:00	00:00	00:00	00:00	04:00
Essential Digital Skills	20:00	00:00	00:00	00:00	03:00
Entrepreneurship	07:00	00:00	00:00	00:00	07:00
Customer Service	09:00	00:00	00:00	00:00	04:00
Getting ready for apprenticeship & Jobs	08:00	00:00	00:00	00:00	02:00
On the Job Training	**00:00**	**00:00**	**990:00**	**00:00**	**990:00**
Total Duration	**240:00**	**240:00**	**990:00**	**00:00**	**1470:00**

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 Microbiologist-Quality Control.
- Discuss the importance of a skilled Microbiologist-Quality Control.

Duration: *04:00*	**Duration**: *00:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Discuss the Life Sciences industry in Indian and global context. • Discuss the regulatory authorities, regulations, legislation, and good practices relevant to the quality assurance in a life sciences manufacturing facility. • Explain the basic skills required to perform the job of Microbiologist-Quality Control. • Explain the impact of non-compliance on the quality of the product and the environment.	
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD Projector/ Screen, Scanner, Computer Speakers, Pencil	
Tools, Equipment and Other Requirements	
N/A	

Module 2: Essential concepts of Microbiology for quality control

Bridge Module

Terminal Outcomes:

- Demonstrate how to perform job activities of Microbiologist-Quality Control .

Duration: *16:00*	**Duration**: *40:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Discuss quality principles and concepts applied in the life sciences sector. • Explain the basic concept of Quality by Design (QbD) and its application in quality control, quality risk management. • Explain the fundamental concepts of Microbiology. • Explain the principle of biochemical characterization of microbes by Gram stain and biochemical cards and their standard detection limits. • Explain the units of measurements of microbial growth. • Describe sampling plans for microbiological sampling.	• Demonstrate sampling methods for conducting microbial test according to SOP. • Demonstrate sample handling and preparation of microbial samples. • Demonstrate the use of Good Storage Practices (GSP) guidelines for storage of samples. • Identify microbes using phenotypic and genotypic methods.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD Projector/ Screen, Scanner, Computer Speakers, Pencil	
Tools, Equipment and Other Requirements	
Flask, Petri plates, Spreader, Laminar Airflow 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: Laboratory specific routine checks

Mapped to LFS/N0344, v2

Terminal Outcomes:

- Discuss the specific routine checks performed in the Quality Control (QC) laboratory.

Duration: *20:00*	**Duration**: *40:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• List all the Personal Protective Equipment (PPE) used in the microbiology lab. • Explain the different quality management systems, quality specifications and policy of the company. • Explain the properties and storage conditions of different chemicals and reagents used in a microbiology lab. • Discuss the principle of calibration and validation of equipment/glassware used in the lab. • Discuss the strategies to minimize the risks of cross-contamination, false-positive and false-negative results. • Describe different strategies used for decontamination in a microbiology laboratory. • Explain different sterilization processes used in a microbiology laboratory.	• Demonstrate the use of PPE in a Microbiology lab. • Conduct regular checks for lab equipment and instrument for their calibration and validation state. • Identify out of order/ non-calibrated/ non-validated equipment. • Demonstrate how to apply the decontamination strategies for contamination control in a microbiology laboratory. • Demonstrate the steps of sterility testing. • Demonstrate how to maintain positive and negative controls during testing. • Demonstrate how to perform laboratory specific checks as per Standard Operating Procedures (SOP).
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD Projector/ Screen, Scanner, Computer Speakers, Pencil	
Tools, Equipment and Other Requirements	
PPE, Chemicals and reagents, Glassware, Various types of cleaning material, Cleaning equipment, Half Face Mask, Full Face Mask, Various Cartridges, Safety Goggles, Safety Shoes, Gum Boots, Chemical absorbent, Self-contained breathing apparatus, PVC Apron, Gloves (Nitrile, {Heat, acid, chemical} resistant, washing etc..), Lab coat, Surgical gloves (used in Microbiology lab), Eye washer with sprinkler/ manual bottle eye washer, Sterility test apparatus (Closed system)	

Module 4: Managing environmental sustainability

Mapped to LFS/N0344, 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.

Duration: *10:00*	**Duration**: *20:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
● Explain the concept and importance of energy conservation. ● Describe the possible actions to optimize energy consumption and minimize energy wastage. ● Explain the concept of environmental pollution and its impact on the health of self, community, and planet. ● Describe the possible actions to be taken to minimize environmental pollution at work. ● Explain various guidelines to be followed for hazardous waste management and disposal of waste.	● Create a checklist of energy conservation practices during and post-work. ● Segregate waste into recyclable, non-recyclable, and hazardous. ● Demonstrate the sustainable waste disposal- process.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD Projector/ Screen, Scanner, Computer Speakers, Pencil	
Tools, Equipment and Other Requirements	
Color-coded waste bin bag, Color-coded waste container	

Module 5: Microbial analysis tests

Mapped to LFS/N0342, v2

Terminal Outcomes:

- Explain the procedure for qualitative and quantitative microbial test.
- Discuss the working principle and procedure of laboratory equipment.
- Explain the procedure to identify the reason for unwanted growth of microorganisms.
- Discuss how to identify and report non-conformity of the sample as per SOP.

Duration: *35:00*	**Duration**: *30:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Describe the properties of different microbial culture. • Explain the basic techniques used for microbiological analysis. • Explain the working principle and application of equipment used in a microbiology lab. • Describe the optimum growth conditions for different microorganisms. • Explain the method and importance of containment of microorganisms within the laboratory facility. • Discuss about Out of Trend (OOT) and Out of Specification (OOS) samples.	• Demonstrate how to prepare media to conduct quality analysis on the samples. • Demonstrate how to prepare and maintain standard cultures. • Perform microbial isolation, plate pouring, serial dilutions and screening of microbes. • Demonstrate how to operate equipment in a microbiology lab. • Demonstrate how to perform sample-specific microbial tests for detection of different microorganisms in samples. • Demonstrate the how to identify the reason for unwanted growth of microorganisms. • Demonstrate how to record and report the observations of the microbial test performed.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD Projector/ Screen, Scanner, Computer Speakers, Pencil	
Tools, Equipment and Other Requirements	
Glassware washing machine, Autoclave, Laboratory microscopes(40X and 100X),pH meter ,Hot plate with magnetic stirrer, Analytical balance with printer (of different capacity and sensitivity 0.001 mg, 0.01 mg,0.1 mg,1 mg sensitivity),Water bath, Lab Management Information System (demonstration), Syringes (2 ml),Syringes (5 ml), Syringes (10 ml), Milli-Q / TKA water for HPLC, Centrifuge, Centrifuge tubes (10ml) , Centrifuge tubes (25ml), Centrifuge tubes (50ml), Conductivity meter, Vortex mixer, Micropipette (20 to 200 Quality Control Chemist-Microbiology 4 microlitre), Micropipette (100 to 1000 microlitre),Micropipette (0.5 ml to 5 ml) , Biosafety cabinet, Laminar air flow (Vertical), Tube heating block, Water Filtration assembly (multihead), Vacuum pump, Hot Plate, Dry Heat Air Oven, Depyrogenation oven, Refrigerator, Deep freezer, Laboratory incubator for different temperature range, Anaerobic jar, Gas burner, Gas lighter, LPG cylinder, Shaker incubator, Garment cubicle, Needle burner, Hygrometer, Heat sealing machine, Glass slides, TOC analyser, Air sampler, Particle counter, TOC Tubes, Half Face Mask, Full Face Mask, Various Cartridges, Safety Goggles, Safety Shoes, Gum Boots, Chemical Absorbent Roll, Self Contained Breathing Apparatus, PVC Apron, Gloves (Nitrile), Gloves ({Heat, acid, chemical} resistant) Gloves(washing), Lab Coat, Non sterile Surgical Gloves (in Microbiology), Eye washer with sprinkler	

Module 6: Research and development for new products

Mapped to LFS/N0342, v2

Terminal Outcomes:

- Explain the various scientific search tools used for the development of new products.

Duration: *25:00*	**Duration**: *30:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Describe the different scientific literature search tools. • Explain how to develop new testing protocols for microbiological analysis. • Explain the procedure to grow different strains of bacteria in various conditions for their molecular and cellular characterization.	• Demonstrate how to perform the literature search for culture/media development for different microbial strains. • Demonstrate how to grow different microbial strains in various conditions to understand their reactions.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD Projector/ Screen, Scanner, Computer Speakers, Pencil	
Tools, Equipment and Other Requirements	
N/A	

Module 7: 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**
● Describe the relevant legislative requirements and company's procedures for the environment and health. ● Discuss the workplace hazards and their reporting in a manufacturing facility in the life sciences sector. ● Recall the guidelines and procedures for hazards, accidents, safety signs and signals, and Heinrich pyramid used in a manufacturing plant. ● Explain health, safety, and accident reporting procedures. ● Describe the importance of the gowning, medical assistance and emergency services. ● Discuss the procedures for evacuation for employees, contract staff, and visitors in controlled areas. ● Discuss the types of safety gears and procedure to use them. ● Discuss WHO guidelines for personal hygiene, handling, and storage of hazardous material. ● Explain the importance of material segregation and 5S system.	● Demonstrate how to ascertain the breach of EHS protocols in a given situation. ● Demonstrate how to communicate hazards, safety instructions and accidents to teammates and cross-functional teams. ● Demonstrate how and when to follow instructions, guidelines, procedures, rules, signage, codes for different situations and processes.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD Projector/ Screen, Scanner, Computer Speakers, Pencil	
Tools, Equipment and Other Requirements	
Printouts of WHO guidelines, Flashcards of signages, coding, and instructions, CO_2 Type Fire Extinguisher, ABC Type Fire Extinguisher, Personal Protective Equipment and Gowning material	

Module 8: Reporting & documentation

Mapped to LFS/N0343, 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: *10:00*	**Duration: *20:00***
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Describe the types of documentation in an organization and the importance of maintaining the same. • Explain the method of reporting and documentation as per Good Documentation Practices (GDP) and other regulatory guidelines. • Describe the Attributable, Legible, Contemporaneous, Original, and Accurate Plus (ALCOA +) principle and its importance. • Discuss how to use lab information management system. • Explain statistical concepts and application of statistical tools. • Discuss guidelines for Electronic Records & Electronic Signatures, Audit Trails, Date and Time Stamps, Data Integrity in the life sciences sector.	• Demonstrate how to perform reporting and documentation as per GDP and other regulatory guidelines. • Prepare inspection reports as per inspection activity performed. • Demonstrate the use of computer/ and software like MS Office, or its alternative for reporting.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD Projector/ Screen, Scanner, Computer Speakers, Pencil	
Tools, Equipment and Other Requirements	
N/A	

Module 9: Coordinate with manager, colleagues and auditors

Mapped to LFS/N0302, 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.

Duration: *12:00*	**Duration**: *25:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Explain the reporting structure of the organization. • List the functional and cross-functional stakeholders for Microbiologist-Quality Control . • Explain efficient and clear communication methods for reporting incidents/ deviations. • Explain the techniques for gaining emotional stability. • Discuss various ways for conflict resolution. • Explain the best strategies of collaborating with others. • Describe the problem-solving techniques for routine work-related issues. • Explain the type of audits in the life sciences sector for the quality operations.	• Demonstrate how to effectively communicate and collaborate with various stakeholders (e.g. manager, groups etc.) in a simulated environment for multiple scenarios. • Demonstrate how to resolve conflict in multiple scenarios. • Demonstrate how to communicate with auditors and regulatory inspectors during inspections/audits. • Demonstrate the training procedures to train lab assistants and trainees.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD Projector/ Screen, Scanner, Computer Speakers, Pencil	
Tools, Equipment and Other Requirements	
N/A	

Module 10: Display sensitivity towards all genders and people with disability

Mapped to LFS/N0302, v3

Terminal Outcomes:

- Describe 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: *08:00*	**Duration**: *15:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Discuss the rules laid by the Sexual Harassment of Women at Workplace (Prevention, Prohibition, and Redressal) Act and the provided penalties for violation. • Explain the importance of gender sensitive behavior. • Explain the procedure to report inappropriate behavior e.g. sexual harassment. • Describe the importance of an equal opportunity work culture. • Discuss the importance of respecting other's cultures, religion, and caste. • Explain the need for sensitivity towards people with disabilities. • Explain the correct ways of communication and collaboration with people with disabilities in compliance with the legal framework. • Identify stereotypes and prejudices associated with people with disabilities and the negative consequences of prejudice and stereotypes.	• Demonstrate appropriate verbal and nonverbal communication that is respectful of gender, religion, disability, etc. • Prepare a list of gender-neutral communication terms.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD Projector/ Screen, Scanner, Computer Speakers, Pencil	
Tools, Equipment and Other Requirements	
N/A	

Module 11: 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 Directorate General of Training (DGT). For further details regarding module please find at below link. https://www.nqr.gov.in/national-skills-qualification-framework

Module 12: Apprenticeship Training

Mapped to Microbiologist-Quality Control

Mandatory Duration: *990*:00	**Recommended Duration**: *00:00*
Module Name: On the Job Training **Location: On-Site**	
Terminal Outcomes ● Perform checks in a microbiology lab before the start of the microbiological test. ● Perform test for microbial analysis in compliance to regulatory guidelines and support R&D activities. ● Follow Environment, health and safety guidelines in GMP/GLP controlled areas and Lab by ensuring the same is followed by subordinates as well. ● Perform reporting and documentation for Quality Control analysis. ● Coordinate with manager and colleagues and respond to audit queries.	

Annexure

Trainer Requirements

Trainer Prerequisites						
Minimum Educational Qualification	**Specialization**	**Relevant Industry Experience**		**Training Experience**		**Remarks**
		Years	***Specialization***	***Years***	***Specialization***	
B.Sc.	Microbiology/Biochemistry	5	Quality control Microbiology/ Biologist operations	0	NA	
B. Tech	Biotechnology	4	Quality control Microbiology/ Biologist operations	0	NA	
M.Sc.	Microbiology/Biochemistry	3	Quality control Microbiology/ Biologist operations	0	NA	
M. Tech	Biotechnology	2	Quality control Microbiology/ Biologist operations	0	NA	

Trainer Certification	
Domain Certification	**Platform Certification**
Certified for Job Role: "Microbiologist-Quality Control" mapped to QP: "LFS/Q0308, 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***	
B.Sc.	Microbiology/Biochemistry	6	Quality control Microbiology/ Biologist operations	1	NA	
B. Tech	Biotechnology	5	Quality control Microbiology/ Biologist operations	1	NA	
M.Sc.	Microbiology/Biochemistry	4	Quality control Microbiology/ Biologist operations	1	NA	
M. Tech	Biotechnology	3	Quality control Microbiology/ Biologist operations	1	NA	

Assessor Certification	
Domain Certification	**Platform Certification**
Microbiologist-Quality Control mapped to the Qualification Pack: "LFS/Q0308, 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 Microbiologist-Quality Control 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 License, 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
Declarative Knowledge	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.
Key Learning Outcome	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).
OJT (M)	On-the-job training (Mandatory); trainees are mandated to complete specified hours of training on-site
OJT (R)	On-the-job training (Recommended); trainees are recommended the specified hours of training on-site
Procedural Knowledge	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.
Training Outcome	Training outcome is a statement of what a learner will know, understand, and be able to do **upon the completion of the training**.
Terminal Outcome	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
QC	Quality Control
GDP	Good Documentation Practices
EHS	Environment Health Safety
PPE	Personal Protective Equipment
GSP	Good Storage Practices
QbD	Quality by Design
OOT	Out of trend
OOS	Out of Specification
EHS	Environment Health and Safety