



Model Curriculum

QP Name: Lab Technician-Pharma, Biologics and Medical devices

Electives: Wet Lab/ Scale-up or Kilo Lab

QP Code: LFS/Q0509

QP Version: 4.0

NSQF Level: 3.5

Model Curriculum Version: 1.0

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Training Parameters

Sector	Life Sciences
Sub-Sector	Pharmaceuticals, Biopharmaceuticals
Occupation	Research and Development
Country	India
NSQF Level	Level 3.5
Aligned to NCO/ISCO/ISIC Code	NCO2015/ 3141.9900
Minimum Educational Qualification and Experience	11 grade pass Or 10th Grade pass with 1.5 Year of Experience In Lifesciences sector
Pre-Requisite License or Training	NIL
Minimum Job Entry Age	18 Years
Last Reviewed On	17 December 2024
Next Review Date	17 December 2027
NSQC Approval Date	17 December 2024
QP Version	4
Model Curriculum Creation Date	17 December 2024
Model Curriculum Valid Up to Date	17 December 2027
Model Curriculum Version	1
Minimum Duration of the Course	Compulsory Notional Hours Theory=80 Hours Practical= 160 Hours Employability Skills= 30 Hours Total Compulsory Notional Hours=270 Hours Minimum Notional Hours with one elective=360Hours
Maximum Duration of the Course	Compulsory Notional Hours Theory=80 Hours Practical= 160 Hours Employability Skills= 30Hours Total Compulsory Notional Hours=270 Hours 2 Electives = 90 Hours each Theory= 30 Hours Practical= 60 Hours Total Notional Hours with one elective=360 Hours



Total Notional Hours with all 2 elective= 450 Hours Apprenticeship Duration= 6 months
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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 Life Science industry and its applicable regulations.
- Perform the processing of the laboratory glassware/plasticware for experimentation.
- Demonstrate how to handle, label, and store materials/ chemicals while maintaining records.
- Explain how to maintain a hygienic, clean, and contamination-free work area and hoods in laboratory.
- Explain the Environment, Health, and Safety (EHS) norms at work in the life sciences facility/ laboratory.
- Demonstrate ways to coordinate with chemist/researchers and cross-functional teams.
- Demonstrate emotional stability and sensitivity towards all genders, cultures, and specially abled persons.
- Set up experiments in a wet lab under the guidance and supervision of the QC team/ Research teams in compliance with Good Laboratory Practices (GLP) and Standard Operating Procedures (SOP).
- Set up for scale-up operations in an R&D/Kilo lab under the guidance and supervision of researchers in the Synthesis R&D/Kilo lab in compliance with Good Laboratory Practices (GLP) and SOP.
- Demonstrate professional skills at work, such as decision making, planning & organizing, problem-solving, analytical thinking, critical thinking skills, and customer-centricity.

NOS/ Module Details	Total Duration Hours	Level	Credits
Compulsory Module Discuss about life sciences industry and basics of Research & Development	30:00	Level-3.5	1.00
Compulsory Module LFS/N0531: Process the laboratory glassware/ plasticware for experimentation	60:00	Level-3.5	2.00
Compulsory Module LFS/N0533: Store & handle laboratory chemicals and maintain records	60:00	Level-3.5	2.00
Compulsory Module LFS/N0109: Ensure hygienic, clean and contamination-free work area and hoods in laboratory	30:00	Level-3.5	1.00

Compulsory Module LFS/N0101 – Follow Environment, health and safety guidelines in GMP/ GLP controlled areas and laboratory	30:00	Level-3.5	1.00
Compulsory Module LFS/N0561: Coordinate with chemist/researchers and cross-functional teams	30:00	Level-3.5	1.00
DGT/VSQ/N0101: Employability Skills	30:00	Level- 2	1.00
Elective 1: Lab Technician-Pharma, Biologics and Medical devices- Wet Lab LFS/N0530– Assist the QC / Research team in performing the wet-lab experiments	90.00	Level-3.5	3.00
Elective 2: Lab Technician-Pharma, Biologics and Medical devices- Scale-up/Kilo Lab LFS/N0562– Perform Scale-up operations under the supervision of researchers in the Synthesis R&D/Kilo lab	90.00	Level-3.5	3.00
Total Duration of Maximum Notional Hours	450.00		15
Apprenticeship	6 months		

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
LFS/N0581: Discuss about life sciences industry and basics of Research & Development NOS Version No.1 NSQF Level-3.5	10:00	20:00	00:00	00:00	30:00
Module 1: Introduction to life sciences industry and applicable regulations	5:00	10:00	00:00	00:00	15:00
Module 2: Environment Sustainability	5:00	10:00	00:00	00:00	15:00

LFS/N0531: Process the laboratory glassware/ plasticware for experimentation NOS Version No.4 NSQF Level-3.5	20:00	40:00	00:00	00:00	60:00
Module 3: Processing of Glassware/Plastic Ware used in a Lab	20:00	40:00	00:00	00:00	60:00
LFS/N0533: Store & handle laboratory chemicals and maintain records NOS Version No. 4 NSQF Level-3.5	20:00	40:00	00:00	00:00	60:00
Module 4: Storage and Handling of Chemicals	10:00	20:00	00:00	00:00	30:00
Module 5: Maintenance of Lab Records	10:00	20:00	00:00	00:00	30:00
LFS/N0109: Ensure hygienic, clean and contamination-free work area and hoods in laboratory NOS Version No. 3 NSQF Level-3.5	10:00	20:00	00:00	00:00	30:00
Module 6: Cleaning and Sanitization in a Life Sciences laboratory	10:00	20:00	00:00	00:00	30:00
LFS/N0101 – Follow Environment, health and safety guidelines in GMP/ GLP controlled areas and laboratory NOS Version No. 4 NSQF Level-4	10:00	20:00	00:00	00:00	30:00
Module 7: Comply with EHS rules in GMP/GLP Controlled Lab Area	10:00	20:00	00:00	00:00	30:00
LFS/N0561: Coordinate with chemist/researchers and cross-functional teams NOS Version No. 3 NSQF Level-3.5	10:00	20:00	00:00	00:00	30:00
Module 8: Coordination with QC Team, Researcher and Cross-functional teams	05:00	10:00	00:00	00:00	15:00

Module 9: Sensitivity towards genders and people with disability	05:00	10:00	00:00	00:00	15:00
DGT/VSQ/N0101 : Employability Skills (30 Hours)					
NOS Version No. 1					
Module 10 : 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	02:00	00:00	00:00	00:00	02:00
Communication Skills	04:00	00:00	00:00	00:00	04:00
Diversity and Inclusion	01:00	00:00	00:00	00:00	01:00
Financial and Legal Literacy	04:00	00:00	00:00	00:00	04:00
Essential Digital Skills	03:00	00:00	00:00	00:00	03:00
Entrepreneurship	07:00	00:00	00:00	00:00	07:00
Customer Service	04:00	00:00	00:00	00:00	04:00
Getting ready for apprenticeship & Jobs	02:00	00:00	00:00	00:00	02:00
Apprenticeship Training Duration	00:00	00:00	00:00	990:00	990:00
Total Duration	90:00	180:00	00:00	990:00	1260:00

Elective Modules

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

Elective 1: Wet Lab

NOS and Module Details	Theory Duration	Practical Duration	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration
LFS/N0530– Assist the QC / Research team in performing the wet-lab experiments NOS Version No.4 NSQF Level-3.5	30:00	60:00	00:00	00:00	90:00
Module 11: Set-up wet lab analysis	30:00	60:00	00:00	00:00	90:00
Total Duration	30:00	60:00	00:00	00:00	90:00

Elective 2: Scale-up/Kilo Lab

NOS and Module Details	Theory Duration	Practical Duration	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration
LFS/N0562– Perform Scale-up operations under the supervision of researchers in the Synthesis R&D/Kilo lab NOS Version No.3 NSQF Level-3.5	30:00	60:00	00:00	00:00	90:00
Module 12: Set up for scale-up operations in R&D/Kilo lab	30:00	60:00	00:00	00:00	90:00
Total Duration	30:00	60:00	00:00	00:00	90:00

Module Details

Module 1: Introduction to Life Sciences industry and the Research and development LFS/N0581

Terminal Outcomes:

- Explain the overview of the Life Sciences industry.
- Explain the skills and knowledge required to perform the job responsibilities of the Research and development.

Duration: 05:00	Duration: 10:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<ul style="list-style-type: none"> ● Explain the Life Sciences industry in Indian and global context. ● Discuss the regulatory authorities and local rules and regulations in the context of the R&D wet lab and Scale-up laboratory. ● Explain typical laboratory functions in a life sciences organization. ● Explain Good Laboratory Practices (GLP), current Good Manufacturing Practices (cGMP), and Good Documentation Practices (GDP). ● Describe the laboratory-related guidelines of National Accreditation Board (NABL) and WHO (World Health Organization). ● Discuss the quality management systems guidelines from ISO-9000, ISO-14001, OHSAS-18000, ICH Q7 and 21 CFR ● Explain the organizational structure and employment benefits in the Life Sciences Industry. ● Explain the role of a Lab Technician 	<ul style="list-style-type: none"> ● Develop a regulatory compliance checklist for R&D wet labs and scale-up laboratories. ● List down the functions of a research and quality control lab, including sample preparation, documentation, data analysis, and equipment maintenance. ● Perform a mock internal audit to check for adherence to GLP, cGMP, and GDP in a simulated lab environment. ● Demonstrate the role of a lab technician by carrying out sample preparation, data collection, testing, and quality control tasks.
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: Environmental sustainability

LFS/N0581, v1

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: 5:00	Duration: 10:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<ul style="list-style-type: none"> ● 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 minimize environmental pollution at work. ● Explain various guidelines to be followed for waste management and disposal of waste. 	<ul style="list-style-type: none"> ● Create a checklist of energy conservation practices during and post-work. ● Classify 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, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
Colour-coded waste bin bag, colour-coded waste container	

Module 3: Processing of glassware/plastic-ware used in a lab

Mapped to LFS/N0531, v4

Terminal Outcomes:

- Explain how to wash and clean the glassware/plastic ware for experimentation as per SOP.
- Perform cleaning validation, reprocessing, and sterilization.

Duration: 20:00	Duration: 40:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<ul style="list-style-type: none"> ● Discuss the characteristics and compatibility of detergents with area water, laboratory ware, and equipment. ● Explain the steps and solutions for preparation and testing of reagent water in the laboratory as per SOP. ● Describe the standard operating procedures (SOP) and regulatory guidelines like GLP/ cGMP for the use of solvents and chemicals during cleaning and washing. ● Explain the principles of autoclave for drying and sterilization of the glassware. ● Discuss the safety measures to be taken while handling any accidental exposure. 	<ul style="list-style-type: none"> ● Demonstrate the use of PPEs for glassware cleaning and processing. ● Demonstrate how to select and use compatible detergent for the cleaning glassware/plasticware and other equipment. ● Show how to operate autoclave for drying and sterilization of the glassware before experimental use. ● Prepare a list of actions to be take in case of various instrument faults while taking proper safety measures.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector/ screen, Scanner, Computer speakers, Pencil	
Tools, Equipment and Other Requirements	
Hot air oven, Glassware drying oven, Cleaning agents (soap/alconox etc.), Glassware for Lab, Columns, Autoclave, PPE and Lab Coat	

Module 4: Storage and handling of chemicals

Mapped to LFS/N0533, v4

Terminal Outcomes:

- Demonstrate how to handle and store chemicals in a laboratory.

Duration: 20:00	Duration: 40:00
<p>Theory – Key Learning Outcomes</p> <ul style="list-style-type: none"> ● Explain the properties of all chemicals/reagents/solutions used in the laboratory. ● Explain the use of Material Safety Datasheets (MSDS) for each chemical. ● Describe the methods of routine lab maintenance and use of lab equipment. ● Discuss the process of inspecting washed laboratory-ware and equipment for acid/reagent residues. ● Describe the importance of labelling the laboratory ware and equipment. ● Explain the guidelines for handling and storing for chemical/biological material and hazardous substance in the lab. ● Discuss the guidelines to return/dispose of expired and unused laboratory chemicals. 	<p>Practical – Key Learning Outcomes</p> <ul style="list-style-type: none"> ● Demonstrate how to handle chemicals/reagents/solutions as per their chemical properties. ● Prepare MSDS sheets for chemicals as per their coding and properties. ● Demonstrate how to perform general housekeeping, storage and maintenance of chemicals and equipment. ● Demonstrate storing of chemicals/biological materials using 5S system. ● Demonstrate how to handle chemical/biological material spillage in the lab. ● Demonstrate steps for quenching the unused chemicals.
<p>Classroom Aids:</p> <p>Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil</p>	
<p>Tools, Equipment and Other Requirements</p> <p>Half Face Mask, Gloves (Nitrile, {Heat, acid, chemical} resistant, washing etc..), and Lab Coat</p>	

Module 5: Maintenance of lab records

Mapped to LFS/N0533, v4

Terminal Outcomes:

- Demonstrate how to maintain lab records.

Duration: 20:00	Duration: 40:00
Theory – Key Learning Outcomes <ul style="list-style-type: none"> ● Explain the importance of maintaining lab records using basic principles of ALCOA. ● Discuss the need for all the quality manuals and SOPs for all the experiments at the designated place. ● Discuss the importance of instrument maintenance log and test specific reports/records. ● Explain the guidelines for chemical storage. ● Explain the importance of sample log, registers, quality control data, incident reports and SOPs. ● Describe methods of safe and secure storing and archiving of documents. 	Practical – Key Learning Outcomes <ul style="list-style-type: none"> ● Prepare sample records as per given format and compliance with ALCOA principle. ● Demonstrate the application of ALCOA principles to ensure data integrity in laboratory records. ● Demonstrate how to organize all SOPs and quality manuals for a lab experiment or process in the designated area, ensuring accessibility and proper organization of the documentation. ● Demonstrate how securely storing lab documents, such as reports, protocols, and records, to maintain confidentiality and ensure regulatory compliance.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
N/A	

Module 6: Cleaning and sanitization in a life sciences laboratory

Mapped to LFS/N0109, v3

Terminal Outcomes:

- Discuss the hygiene standards for labs and how to maintain them.
- Demonstrate how to perform cleaning and sanitation activities before, during and post work.

Duration: 10:00	Duration: 20:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<ul style="list-style-type: none"> ● List the hygiene standards required in the lab area and the importance of maintaining the same. ● Explain the methods, materials, and checks required for cleaning a variety of surfaces and equipment. ● Explain the list of various equipment, different materials, and chemicals used in cleaning and sanitation of the lab area. ● Discuss the cleaning and sanitation activities performed before, during, and after completion of work. 	<ul style="list-style-type: none"> ● Prepare a checklist of the hygiene standards required in the lab area. ● Prepare list of various equipment, different materials, and chemicals used in cleaning and sanitation of the lab area. ● Demonstrate how to perform cleaning and sanitation activities as per GMP, GLP and, WHO rules.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
Hot air oven, Glassware drying oven, Cleaning agents (soap/alconox etc.), Glassware for Lab, Columns, autoclave, Half Face Mask, Gloves(Nitrile, {Heat, acid, chemical} resistant, washing etc..), and Lab Coat	

Module 7: Comply with EHS rules in GMP/GLP controlled lab area

Mapped to LFS/N0101, v3

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
<p>Theory – Key Learning Outcomes</p> <ul style="list-style-type: none"> ● Describe the relevant legislative requirements and company’s procedures for the environment, health, and safety responsibilities. ● Discuss the workplace hazards and their reporting in the 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 lab. ● Describe the importance of the gowning, medical assistance and emergency services. ● Explain health, safety, and accident reporting procedures. ● 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. ● Explain the importance of material segregation and 5S system. 	<p>Practical – Key Learning Outcomes</p> <ul style="list-style-type: none"> ● Demonstrate how to ascertain the breach of EHS protocols. ● Demonstrate how to communicate hazards, safety instructions and accidents to teammates, a lab in charge and cross-functional teams. ● Demonstrate how and when to follow instructions, guidelines, procedures, rules, signage, coding for different situations and processes.
<p>Classroom Aids:</p> <p>Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil</p>	
<p>Tools, Equipment and Other Requirements</p> <p>Printouts of WHO guidelines, Flashcards of signages, coding, and instructions, CO2 Type Fire Extinguisher, ABC Type Fire Extinguisher Personal Protective Equipments and gowning material</p>	

Module 8: Coordination with QC team, researcher, and cross-functional teams

Mapped to LFS/N0561, v3

Terminal Outcomes:

- Describe effective coordination and collaboration with QC team, researchers, and cross-functional teams.

Duration: 10:00	Duration: 20:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<ul style="list-style-type: none"> ● Explain the reporting structure of the organization. ● Discuss the functional and cross-functional stakeholders for Lab Technician-Pharma, Biologics and Medical devices ● Explain efficient and clear communication methods for reporting the incidents/deviations. ● Explain the techniques for collaborating with other groups and divisions. ● Describe the techniques for gaining emotional stability. ● Describe the problem-solving techniques for routine work-related issues. ● Discuss the role of an auditee in a regulated manufacturing plant. 	<ul style="list-style-type: none"> ● Demonstrate effective communication and collaboration with cross-functional teams in a simulated environment for multiple scenarios including for problem-solving. ● Demonstrate application of emotion and stress management strategies in mock situations. ● Respond to regulatory audit questions and communicate the audit observations in a mock audit situation.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
N/A	

Module 9: Sensitivity towards genders and people with disability

Mapped to LFS/N0561, v3

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.

Duration: 10:00	Duration: 20:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<ul style="list-style-type: none"> ● 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 behaviour. ● Explain the procedure to report inappropriate behaviour 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. 	<ul style="list-style-type: none"> ● Demonstrate appropriate verbal and nonverbal communication that is respectful of gender, religion, race, etc. ● Prepare a list of gender-neutral communication terms. ● Demonstrate through Role-play different workplace situations where gender-sensitive behaviour is required. ● Prepare a report suggesting improvements to promote equal opportunities across gender, race, religion, and ability levels. ● Demonstrate how to communicate and collaborate with people with different disabilities (e.g., visual, hearing, mobility impairments) using proper methods and language.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speakers, flip charts	
Tools, Equipment and Other Requirements	
N/A	

Module 10: Employability Skills (30 Hours)

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 11: Set-up for wet lab analysis

Mapped to LFS/N0530, v4

Terminal Outcomes:

- Prepare the checklist of chemicals and organic matter to be used for the set-up for wet lab analysis.
- Demonstrate how set-up instruments, equipment, chemicals, and other materials for a wet lab.

Duration: 20:00	Duration: 40:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<ul style="list-style-type: none"> ● Contrast the basic concepts of wet lab analysis. ● Discuss the chemical properties, measuring units, simple chemical calculation, and principles of the wet lab processes. ● Explain the analytical tests performed in a wet lab and basic chemical calculations. ● Describe the procedures for setting up the instruments, equipment, glassware, and other materials for various wet lab analysis tests. ● Explain the selection and operating procedure for personal protection equipment (which protective equipment to be used and how). ● Discuss identification of non-conforming products and storage of the same. ● Define risk and impact of not following defined procedures/work instructions. 	<ul style="list-style-type: none"> ● Demonstrate how to apply basic concepts and principles of chemistry while setting up for experiments. ● Demonstrate how to set up for analytical tests performed in a wet lab. ● Demonstrate how to use Personal Protective Equipment (PPE). ● Identify non-conformities and storage of products used in a wet lab. ● Demonstrate adherence to work instructions for risks, deviations, and hazards.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speakers, Pencil	
Tools, Equipment and Other Requirements	
Setup of a wet lab and scaleup laboratory, Goggles, and Lab Coat	

Module 12: Set-up for scale-up operations in R&D/kilo lab

Mapped to LFS/N0562, v3

Terminal Outcomes:

- Prepare the checklist of chemicals and organic matter to be used for the set-up for wet lab analysis.
- Demonstrate how set-up instruments, equipment, chemicals, and other materials for a wet lab.

Duration: 20:00	Duration: 40:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<ul style="list-style-type: none"> ● Contrast the basic concepts of chemistry, the chemicals used in the industry and their properties, measuring units, simple chemical calculation, and principles of the process. ● Explain basic concepts of analytical tests performed in an R&D/Kilo lab and basic chemical calculations. ● Describe the procedures for setting up the instruments, equipment, glassware, and other materials for various wet lab analysis tests. ● Explain the selection and operating procedure for personal protection equipment (which protective equipment to be used and how). ● Discuss identification of non-conforming products and storage of the same. ● Define risk and impact of not following defined procedures/work instructions. 	<ul style="list-style-type: none"> ● Demonstrate how to apply basic concepts and principles of chemistry while setting up for experiments. ● Demonstrate how to set up for analytical tests performed in an R&D/Kilo lab. ● Demonstrate how to use Personal Protective Equipment (PPE). ● Demonstrate identifying non- conformities in a given set of products and their storage.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speakers, Pencil	
Tools, Equipment and Other Requirements	
Setup of a wet lab and scaleup laboratory, Goggles, and Lab Coat	

Module 13: Apprenticeship

Mandatory Duration: 00:00	Recommended Duration: 990:00
Module Name: Apprenticeship Training	
Location: On-Site	
Terminal Outcomes <ul style="list-style-type: none">● Carry out washing, processing, and drying of the glassware/plastic ware for experimentation.● Handle chemicals and solvents in the lab.● Maintain Lab records and perform labelling.● Reprocess the instruments before carrying out experiments.● Maintain a healthy, safe, and secure working environment.● Ensure workplace cleanliness Coordinate with supervisor and teammates and respond to audit queries.● Assist QC/Research team in performing the wet lab experiments and analysis.● Assist QC/Research team in performing the Scale-up/Kilo Lab experiments and analysis.	

Annexure

Trainer Requirements

Trainer Prerequisites						
Minimum Educational Qualification	Specialization	Relevant Industry Experience		Training Experience		Remarks
		Years	Specialization	Years	Specialization	
Graduate in Sciences	B. Sc. With Chemistry/ Biotechnology/ Biochemistry/ Microbiology subject	4	Lab Technician-Pharma, Biologics and Medical devices	0	NA	
Postgraduate in Sciences	M. Sc. With Chemistry/ Biotechnology/ Biochemistry/ Microbiology subject	3	Lab Technician-Pharma, Biologics and Medical devices	0	NA	
Lab Technician/ Assistant	Lab Technician/ Assistant-Life Sciences (LFS/Q0509) Level-3.5 qualification	2	Lab Technician-Pharma, Biologics and Medical devices	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 Lab Technician-Pharma, Biologics and Medical devices "LFS/Q0509, v4.0" post completion of Faculty Development Program of LSSSDC

Trainer Certification	
Domain Certification	Platform Certification
Certified for the job role: "Lab Technician-Pharma, Biologics and Medical devices" mapped to the qualification pack: "LFS/Q0509, 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/Q2601 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	
Graduate in Sciences	Chemistry/ Biotechnology/ Biochemistry/ Microbiology	5	Lab Technician/Assistant	2	On the job assessment/ Training experience/ Vocational assessment/ Academic assessment	
Post Graduate in Sciences	M.Sc. with Chemistry/ Biotechnology/ Biochemistry/ Microbiology	3	Lab Technician/Assistant or Lab Supervisor	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 Lab Technician-Pharma, Biologics and Medical devices "LFS/Q0509, v4.0" post completion of Faculty Development Program of LSSSDC

Assessor Certification	
Domain Certification	Platform Certification
Certified for the job role: "Lab Technician-Pharma, Biologics and Medical devices" mapped to the qualification pack : "LFS/Q0509, 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 v 3.0" 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 Lab Technician-Pharma, Biologics and Medical devices 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 research and development occupation.
- SME is screened and approved by LSSSDC. He is oriented by both LSSSDC and Assessment agency on – creating question Bank, level of questions, end the desired outcome of the assessment.

2.4 Execution of Training Assessment:

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

2.4.1 Tab based assessment using physical proctoring

2.4.2 Smartphone-based assessment using e-proctoring

2.4.1 Tab-based assessment using physical proctoring

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

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

2.4.2 Smartphone-based assessment using e-proctoring

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

References

Glossary

Term	Description
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
EHS	Environment Health Safety
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
WHO	World Health Organization
NABL	National Accreditation Board of Laboratories
MSDS	Material Safety Datasheets
PPE	Personal protective Equipment
ALCOA	Attributable, Legible, Contemporaneous, Original and Accurate