Model Curriculum

QP Name: Analyst/Chemist-Quality Control

Electives (Electives:1. High-Performance Liquid Chromatography (HPLC), 2. Gas Chromatography (GC), 3. Ultraviolet-visible Spectroscopy (UV), 4. Fourier Transform Infrared Spectroscopy (FT-IR), 5. Dissolution Test Apparatus)

QP Code: LFS/Q1301

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
Occupation	Pharma Quality
Country	India
NSQF Level	5
Aligned to NCO/ISCO/ISIC Code	NCO-2015/ 2113.0601
Minimum Educational Qualification and Experience	B. Pharma (7th Sem.) or M.Sc. (Chemistry/ Analytical Chemistry / Industrial Chemistry) or Certificate-NSQF Level 4 (Junior Quality Analyst/Wet Lab Analyst- Life Sciences)- with minimum 3 Years of experience
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	06 May 2020
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 Minimum Notional Hours with one elective=840 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
5 Electives
Elective 1 Duration=360 Hours
Elective 2 Duration=360 Hours
Elective 3 Duration=210 Hours
Elective 4 Duration=210 Hours
Elective 5 Duration=360 Hours

Total Notional Hours with one elective=840 Hours
Total Notional Hours with all 5 elective= 1980 Hours

with mandatory apprenticeship of 12 months

Note: i) Minimum one Elective is MUST to be taken
ii) B. Pharma is exempted from mandatory apprenticeship

Program Overview

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

Training Outcomes

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

- Explain the aspects of the life sciences industry and its pertinent regulations.
- Investigate and analyze laboratories in line with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP).
- 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 by self and subordinates.
- Demonstrate Good Documentation Practices (GDP) and data integrity while reporting and documentation as per standard operating procedures (SOP), good laboratory practices (GLP), and Good Manufacturing Practices (GMP).
- Perform process-related checks in the quality control process.
- Conduct quality check for samples using High-Performance Liquid Chromatography (HPLC)/Gas Chromatography (GC)/ Ultraviolet (UV) - visible spectroscopy/Fourier Transform Infrared Spectroscopy (FT-IR)/Dissolution Apparatus as per standard operating procedures (SOP).
- Demonstrate emotional stability and sensitivity towards genders, cultures and specially-abled persons.

NOS/ Module Details	Total Duration Hours	Level	Credits
Compulsory Bridge Module Introduction of Life Sciences industry and applicable regulations	**30:00**	**Level-5**	**1.00**
Compulsory Module LFS/N1306: Perform laboratory investigations and analysis in compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) NOS Version No. 2.0	**150:00**	**Level-5**	**5.00**
Compulsory Module LFS/N0110: Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab by self and subordinates 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**
Compulsory Module	**60:00**	**Level-5**	**2.00**

LFS/N0314: To carry out reporting and documentation for Quality Control analysis in compliance with GDP, GLP and GMP NOS Version No. 3.0			
Compulsory Module LFS/N1307: carry out process-related checks in the quality control process NOS Version No. 2.0	**60:00**	**Level-5**	**2.00**
DGT/VSQ/N0103: Employability Skills	**90:00**		**3.00**
Elective 1: High-Performance Liquid Chromatography (HPLC) LFS/N1301 - Perform QC Analysis using High-Performance Liquid Chromatography NOS Version No.2	**360:00**	**Level-5**	**12.00**
Elective 2:Gas Chromatography(GC) LFS/N1302 – Perform QC Analysis using Gas Chromatography NOS Version No.2.0	**360:00**	**Level-5**	**12.00**
Elective 3: Ultraviolet-visible Spectroscopy (UV) LFS/N1303 – Perform QC Analysis using Ultraviolet-visible spectroscopy NOS Version No.2.0	**210:00**	**Level-5**	**7.00**
Elective 4: Fourier Transform Infrared Spectroscopy (FT-IR) LFS/N1304 – Perform QC Analysis using Fourier Transform Infrared Spectroscopy NOS Version No.2.0	**210:00**	**Level-5**	**7.00**
Elective 5: Dissolution Test Apparatus LFS/N1305 – Perform QC Analysis using Dissolution Test Apparatus NOS Version No.2.0	**360:00**	**Level-5**	**12.00**
Total Duration of Maximum Notional Hours	**1980.00**		**66.00**
Mandatory Apprenticeship	**12 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
Bridge Module	30:00	00:00	00:00	00:00	30:00
Module 1: Introduction of Life Sciences industry and applicable regulations	05:00	00:00	00:00	00:00	05:00
Module 2: Essential concepts for quality control in drug manufacturing	25:00	00:00	00:00	00:00	25:00
LFS/N1306: Perform laboratory investigations and analysis in compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) NOS Version No. 2 NSQF Level-5	30:00	120:00	00:00	00:00	150:00
Module 3:Pre- analysis checks in Quality Control laboratory	15:00	60:00	00:00	00:00	75:00
Module 4:Lab investigations and analysis	15:00	60:00	00:00	00:00	75:00
LFS/N0110: Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab by self and subordinates NOS Version No. 2 NSQF Level-5	10:00	20:00	00:00	00:00	30:00
Module 5: Comply EHS rules in GMP/GLP controlled areas	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 6:Cordination with manager, colleagues and auditors	15:00	30:00	00:00	00:00	45:00

Module 7: Display sensitivity towards all genders and people with disability	05:00	10:00	00:00	00:00	15:00
LFS/N0314: To carry out reporting and documentation for Quality Control analysis in compliance with GDP, GLP and GMP NOS Version No. 3 NSQF Level-5	30:00	30:00	00:00	00:00	60:00
Module 8: Reporting and documentation	30:00	30:00	00:00	00:00	60:00
LFS/N1307: carry out process-related checks in the quality control process NOS Version No. 2 NSQF Level-5	30:00	30:00	00:00	00:00	60:00
Module 9: Process related checks in the quality control process	25:00	25:00	00:00	00:00	50:00
Module 10: Managing Environment Sustainability	05:00	05:00	00:00	00:00	10:00
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
Apprenticeship Training Duration	**00:00**	**00:00**	**2010:00**	**00:00**	**2010:00**
Total Duration	**240:00**	**240:00**	**2010:00**	**00:00**	**2490:00**

Elective Modules

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

Elective 1: High-Performance Liquid Chromatography (HPLC)

NOS and Module Details	Theory Duration	Practical Duration	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration
LFS/N1301 - Perform QC Analysis using High-Performance Liquid Chromatography NOS Version No.2 NSQF Level-5	90:00	270:00	00:00	00:00	360:00
Module 12: Introduction to HPLC	30:00	40:00	00:00	00:00	70:00
Module 13: HPLC calibrations	30:00	110:00	00:00	00:00	140:00
Module 14: HPLC analysis	30:00	120:00	00:00	00:00	150:00
Total Duration	**120:00**	**240:00**	**00:00**	**00:00**	**360:00**

Elective 2: Gas Chromatography (GC)

NOS and Module Details	Theory Duration	Practical Duration	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration
LFS/N1302 – Perform QC Analysis using Gas Chromatography NOS Version No.2 NSQF Level-5	90:00	270:00	00:00	00:00	360:00
Module 15: Introduction to Gas Chromatography (GC)	30:00	40:00	00:00	00:00	70:00
Module 16:Gas Chromatography (GC) calibrations	30:00	110:00	00:00	00:00	140:00
Module 17:Gas Chromatography (GC) analysis	30:00	120:00	00:00	00:00	150:00
Total Duration	**120:00**	**240:00**	**00:00**	**00:00**	**360:00**

Elective 3: Ultraviolet-visible Spectroscopy (UV)

NOS and Module Details	Theory Duration	Practical Duration	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration
LFS/N1303 – Perform QC Analysis using Ultraviolet-visible spectroscopy **NOS Version No.2** **NSQF Level-5**	90:00	120:00	00:00	00:00	210:00
Module 18:Introduction to Ultraviolet (UV)- visible spectroscopy	30:00	10:00	00:00	00:00	40:00
Module 19:Ultraviolet (UV)- visible spectroscopy calibrations	30:00	30:00	00:00	00:00	60:00
Module 20:Ultraviolet (UV)- visible spectroscopy Analysis	30:00	80:00	00:00	00:00	110:00
Total Duration	**90:00**	**120:00**	**00:00**	**00:00**	**210:00**

Elective 4: Fourier Transform Infrared Spectroscopy (FT-IR)

NOS and Module Details	Theory Duration	Practical Duration	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration
LFS/N1304 – Perform QC Analysis using Fourier Transform Infrared Spectroscopy **NOS Version No.2** **NSQF Level-5**	90:00	120:00	00:00	00:00	210:00
Module 21: Introduction to Fourier Transform Infrared Spectroscopy (FT-IR)	30:00	10:00	00:00	00:00	40:00
Module 22: Fourier Transform Infrared Spectroscopy (FT-IR) calibrations	30:00	30:00	00:00	00:00	60:00
Module 23: Fourier Transform Infrared Spectroscopy (FT-IR) Analysis	30:00	80:00	00:00	00:00	110:00

Total Duration	**90:00**	**120:00**	**00:00**	**00:00**	**210:00**

Elective 5: Dissolution Test Apparatus

NOS and Module Details	Theory Duration	Practical Duration	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration
LFS/N1305 – Perform QC Analysis using Dissolution Test Apparatus **NOS Version No.2** **NSQF Level-5**	90:00	270:00	00:00	00:00	360:00
Module 24: Introduction to Dissolution Test Apparatus	30:00	40:00	00:00	00:00	70:00
Module 25: Routine upkeep Dissolution Test Apparatus	30:00	110:00	00:00	00:00	140:00
Module 26: QC Analysis using Dissolution Test Apparatus	30:00	120:00	00:00	00:00	150:00
Total Duration	**120:00**	**240:00**	**00:00**	**00:00**	**360:00**

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 Analyst/Chemist-Quality Control.
- Discuss the importance of skilled Analyst/Chemist-Quality Control.

Duration:*05:00*	**Duration**: *00:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Explain the overview of the Life Sciences industry in Indian and global context. • Discuss the regulatory authorities, regulations, legislation, and good practices (GMP, GLP, GDP) relevant to Analyst/Chemist-Quality Control in a life sciences manufacturing facility. • Explain the impact of non-compliance on the quality of the product and the environment. • Explain the importance of a Analyst/Chemist-Quality Control. • Explain the basic terminologies used in the quality control process.	
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 for quality control in drug manufacturing

Bridge Module

Terminal Outcomes:

- Discuss various concepts and guidelines to perform the job responsibilities of a Analyst/Chemist-Quality Control.

Duration: *25:00*	**Duration**: *00:00*
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 and quality risk management. • Explain the concepts of organic chemistry and analytical chemistry including measurement, mathematical, and statistical concepts. • Discuss the types of tests performed in quality control lab in various formulations, Active Pharmaceutical Ingredient (API) and packaging material. • Recall the procedures for handling, processing, preservation of samples • Explain the procedures for safe handling of hazardous and poisonous substances. • Discuss relevant regulatory guidelines along with ICH-GMP, GLP, Schedule M, NABL and WHO guidelines including interpretation of pharmacopoeia and application of its standards. • Explain the properties of reagents, solvents and hazardous chemicals, and their storage as per Hazard Classification.	• Demonstrate adherence of safety rules while working in lab • Perform pipetting and micro pipetting • Demonstrate safe handling of standards, solvents, reagents and chemicals • Demonstrate handling of glassware and lab plasticware without contamination • Perform analytical calculations to measure molarity, normality, percentage concentration and part per million • Demonstrate how to perform chemistry experiments of electrochemistry, thermal analysis, spectroscopy and chromatography • Demonstrate how to perform dilution methods • Demonstrate how to prepare buffer solutions • Demonstrate the sample processing and preservation • Prepare a checklist of steps followed in method development and method validation
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector/ screen, Scanner, Computer speakers, Pencil	
Tools, Equipment and Other Requirements	
Lab glassware, lab plasticware, pipette, micro pipette, PPE kit, lab coat	

Module 3: Pre-analysis checks in quality control laboratory

Mapped to LFS/N1306, v2

Terminal Outcomes:

- Discuss the pre-analysis checks performed in the Quality Control (QC) laboratory.

Duration: *15:00*	**Duration**: *60:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
● Explain the procedure to check the status and accuracy of instruments used for measurement. ● Discuss the Standard Operating Procedure (SOP), GMP and GLP guidelines for performing pre-analysis checks. ● Discuss the operation, calibration and common errors for laboratory instruments ● Discuss the Quality parameters of Milli Q Water System. ● Discuss the climatic zones and climatic conditions needed for stability analysis.	● Demonstrate how to check the status and accuracy of instruments used for measurement. ● Demonstrate performing pre-analysis checks as per SOP, GMP, and GLP guidelines. ● Demonstrate the operation of laboratory instruments. ● Demonstrate the precautions to be taken while operating lab instruments to eliminate common errors. ● Demonstrate operation of stability chambers.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
Analytical balance, autoclave, auto titrator, incubator, calculator, centrifuge, colony counter, concentric water bath, conductivity meter, cyclo-mixer, digital Vernier calliper, fuming cupboard, heating mantle, hot air oven, hot plate, titrator, laminar airflow, magnetic stirrer, melting point apparatus, microscope, Mili-Q water system, muffle furnace, pH meter, polarimeter, refractometer, refrigerated water bath, refrigerator, sieve shaker, single pan balance, sonicator, stability chambers, thermometer, viscometer, glassware, plastic wares, glassware drying oven, micropipette, PPE kit, goggles, and lab coat.	

Module 4: Laboratory investigations and analysis

Mapped to LFS/N1306, v2

Terminal Outcomes:

- Discuss the importance of laboratory investigations and analysis.
- Check the validity of chemicals and reagents on a routine basis.
- Discuss the importance of corrective action and preventive action (CAPA)/Change Control Procedures to improve the product's quality.

Duration: *15:00*	**Duration**: *60:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Explain the concepts of incidents and deviations in context of quality control analysis. • Recall various statistical concepts used in laboratory investigation and analysis. • Explain steps to prepare and standardize volumetric solutions and test solutions. • Explain the concepts of re-standardization and acceptance criteria. • Discuss the requirement and of importance equipment qualification. • Discuss the importance of preventative maintenance. • Explain the procedures for instrument calibration and instrument accuracy test. • Explain the procedures for laboratory investigations and validation tests performed in the QC lab of the life sciences sector. • Discuss the concepts of Corrective Action and Preventive Action (CAPA) and change control.	• Demonstrate use of statistical methods in laboratory investigation and analysis • Prepare and standardize volumetric solutions and test solutions • Perform calibration and accuracy test for lab instruments • Perform laboratory investigations experiments and tests using various lab instruments • Perform validation experiments and tests • Follow change control procedure to manage and document a change in a simulated environment • Solve a CAPA investigation case study and suggest steps for CAPA strategy investigation in a simulated environment
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
Analytical balance, autoclave, auto titrator, incubator, calculator, centrifuge, colony counter, concentric water bath, conductivity meter, cyclo mixer, digital Vernier calliper, fuming cupboard, heating mantle, hot air oven, hot plate, titrator, laminar airflow, magnetic stirrer, melting point	

apparatus, microscope, Mili-Q water system, muffle furnace, pH meter, polarimeter, refractometer, refrigerated water bath, refrigerator, sieve shaker, single pan balance, sonicator, stability chambers, thermometer, viscometer, glassware, plasticware, PPE kit, goggles, and lab coat.

Module 5: Comply EHS rules in GMP/GLP controlled areas

Mapped to LFS/N0110, v2

Terminal Outcomes:

- Explain the importance of following health and hygiene protocols.
- Describe safety and security procedures at the workplace.
- Explain emergency procedures promptly, calmly, and efficiently.

Duration: *10:00*	**Duration**: *20:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Explain relevant legislative requirements and company's procedures for environment, health and safety. • Discuss workplace hazards and their reporting in the laboratory and manufacturing facility in the life sciences sector. • Explain all the emergency procedures for different emergencies. • Explain evacuation procedures for employees, contract staff and visitors • Discuss health, safety and accident reporting procedures. • Explain different types of breaches in the environment, health, safety and security. • Discuss how to provide medical assistance and the emergency services of reported accidents. • Explain the importance of material segregation and 5S system. • Explain WHO guidelines for personal hygiene, handling and storing hazardous material. • Discuss the different types of safety gears and how to use them.	• Demonstrate how to perform reporting of hazards at the workplace. • Demonstrate how to evacuate employees, contract staff and visitors as per procedures in case of emergency. • Demonstrate how to act in case of emergencies as per health, safety and accident reporting procedures. • Demonstrate how to apply 5S system for handling and storing hazardous material. • Demonstrate the adherence to WHO guidelines for maintaining personal hygiene. • Demonstrate how to use different types of safety gears. • Demonstrate the procedure to douse the fire during lab accidents
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
Printouts of WHO guidelines, Flashcards of signage, coding, and instructions, CO2 Type Fire Extinguisher, ABC Type Fire Extinguisher, Personal Protective Equipment and gowning material	

Module 6: 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, colleagues and auditors.
- Demonstrate the effective coordination and collaboration with manager.
- Demonstrate how to participate in audit interviews.

Duration: *15:00*	**Duration**: *30:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
● Explain the reporting structure of the organization. ● Discuss efficient and clear communication methods for reporting the incidents/ deviations. ● Explain the techniques for collaborating with other groups and divisions. ● Discuss the importance of team management and team building. ● Discuss how to apply emotions and stress management strategies. ● Explain how to apply problem and conflict solving skills in the workplace. ● Discuss how to respond to auditors with integrity.	● Demonstrate how to effectively communicate and collaborate with manager and colleagues for multiple scenarios. ● Respond to regulatory audit questions in a mock audit situation. ● Demonstrate how to resolve conflict in multiple scenarios.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
N/A	

Module 7: Display sensitivity towards all genders and people with disability

Mapped to LFS/N0302, 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: *05:00*	**Duration**: *10:00*
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, Scanner, Computer speakers, flip charts	
Tools, Equipment and Other Requirements	
N/A	

Module 8: Reporting & documentation

Mapped to LFS/N0314, v3

Terminal Outcomes:

- Explain the methods of reporting and documentation for the Quality Control Department.
- Discuss how to maintain quality control related documents.
- Discuss how to use Lab Information Management System (LIMS).

Duration: *30:00*	**Duration**: *30:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Explain the method of reporting and documentation as per Good Documentation Practices (GDP), 21CFR (Code of Federal Regulation) and Attributable, Legible, Contemporaneous, Original, and Accurate Plus (ALCOA +) principle. • Discuss guidelines for electronic records & electronic signatures, audit trails, date & time stamps and data integrity in the Life Sciences sector. • Explain the procedures for reporting any hazards, non-conformance, deviations, OOS / OOT, validation results. • Discuss the documentation requirements in management of controlled documents and change control management • Explain the procedure for Standardization and validation related documentation • Explain the procedure to use the manual lab note book as well as e-Lab Note Book (eLNB) for documenting experiments and analysis reports • Discuss the operating procedure of the lab information management system (LIMS).	• Record the quality parameters and investigation results in the sample formats and log book of QC records for experiments done in lab • Demonstrate adherence of Data integrity and ALCOA+ guidelines during reporting and recording in the lab • Demonstrate how to report an OOS or OOT incidents or a process deviation. • Demonstrate documentation of a simulated change control scenario • Demonstrate use of manual Lab note book and eLNB in the lab • Demonstrate the operation of LIMS.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speakers	
Tools, Equipment and Other Requirements	
Sample Log book, Sample QC formats, sample Lab Note book, eLNB simulated module, LIMS simulated module	

Module 9: Process related checks in the quality control process

Mapped to LFS/N01307, v2

Terminal Outcomes:

- Perform process-related checks in the quality control process.
- Inspect instruments used in the quality control process on a routine basis.
- Identify non-conformities in working quality standards.
- Inspect labels for proper mentioning of dosages and storage conditions.

Duration: *25:00*	**Duration**: *25:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Explain how to monitor and conduct regular checks on equipment and instrument conditions by checking precision in instrument calibrations. • Explain calibrations, installation qualification (IQ), operational qualification (OQ), performance qualification (PQ) and techniques for improving instrumental analysis. • Discuss the methods of handling and storage of reference standard and working standard. • Discuss potential causes of non-conformities to working standards. • Discuss the methods of handling and storage of various type of samples • Explain the requirements and procedures of labelling in a lab	• List the routine check points for lab instruments available in the skill lab • Demonstrate the procedures for routine calibrations and verification of lab instrument precision • Perform experiments related to IQ, OQ and PQ • Demonstrate how to identify causes of non-conformities at the workplace. • Demonstrate the procedures for storing standards and samples • Perform the labeling inspection of samples used in experiments and label them as per labelling requirements
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
Material Safety Data Sheet for consumable chemicals, sample calibration and verification record, calibration record formats, sample labelling stickers, storage logs, laboratory glassware and plasticware	

Module 10: Managing environmental sustainability

Mapped to LFS/N01307, v2

Terminal Outcomes:

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

Duration: *05:00*	**Duration**: *05:00*
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 minimize environmental pollution at work. • Explain various guidelines to be followed for hazardous waste management and disposal.	• 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 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.ngr.gov.in/national-skills-qualification-framework

Module 12: Introduction of High-Performance Liquid Chromatography (HPLC)

Mapped to LFS/N1301, v2

Terminal Outcomes:

- Explain the working principle of the HPLC instrument.
- Identify the various components of the HPLC instrument.
- Operate the HPLC instrument.

Duration: *30:00*	**Duration**: *40:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Explain the working principle and the instrumentation of High-Performance Liquid Chromatography (HPLC) and its various applications in QC analysis. • Explain the operations of each component of HPLC like stationary phase, chromatographic column, mobile phase, apparatus, and gradient elution. • Discuss the precautions to be taken while working on HPLC. • Explain different types of HPLC columns used in the analysis. • Explain the operating procedure for HPLC and its software system. • Explain the protocols to be followed for the HPLC method development and validation • Explain the documentation process for HPLC analysis	• Identify and locate the different parts/ components of the HPLC on a schematic diagram or in a simulated module • Demonstrate the safe handling of a HPLC system • Demonstrate how to operate HPLC.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
PPE kit, goggles, lab coat, hand controller, HPLC instrument set up, Schematic diagram of HPLC instrument, laboratory glassware	

Module 13: HPLC calibration

Mapped to LFS/N1301, v2

Terminal Outcomes:

- Perform HPLC calibrations and validation activities in the QC lab.

Duration: *30:00*	**Duration**: *110:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Discuss the need and importance of HPLC instrument calibrations. • Discuss the principles and procedure of calibration and validation of HPLC instrument. • Discuss different techniques/inspection methods used to identify defects.	• Demonstrate how to perform HPLC calibrations. • Demonstrate the inspection of HPLC for its state of calibration and, validation in QC laboratory. • Perform troubleshooting and rectification of the minor issues of HPLC instrument.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
PPE Kit, goggles, lab coat, hand controller, calibration record formats, HPLC instrument set up	

Module 14: HPLC analysis

Mapped to LFS/N1301, v2

Terminal Outcomes:

- Prepare the checklist of chemicals and reagents to be used for HPLC analysis.
- Perform sample preparation for HPLC test analysis.
- Perform QC testing by HPLC method.

Duration: *30:00*	**Duration**: *120:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Explain the properties of different chemicals, reagents and reference standards and working standards used for HPLC analysis. • Recall the safety measures to be taken while operating the HPLC instrument. • Discuss the analytical calculations required in a HPLC analysis • Discuss the procedures of sample preparation for HPLC test analysis. • Explain the scientific principles behind the HPLC test performed. • Explain the methods of recording and analysis of HPLC chromatogram. • Explain the concepts of HPLC data deviations in case of deviations in the results.	• Prepare a checklist of different chemicals, reagents and working standards required for HPLC analysis. • Demonstrate safety measures to be taken while handling chemicals, reagents, working standards and reference materials. • Demonstrate how to perform sample preparation for HPLC analysis considering stability and storage requirement. • Demonstrate how to perform sample analysis by HPLC method in a QC lab. • Record the observations of test results and analyse the chromatogram. • Identify data deviations in case of deviation in results and raise/log an incident in the system.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
PPE Kit, goggles, lab coat, hand controller, chemical and reagents, working standards, reference materials, buffer, Glassware, Mortar and Pestle, analytical balance, water bath, Motor grinder, Muffle Furnace, Hot Air Oven, Rotary shaker, Glassware drying oven, Micropipette, Refrigerator, HPLC instrument set up	

Module 15: Introduction to Gas Chromatography (GC)

Mapped to LFS/N1302, v2

Terminal Outcomes:

- Explain the fundamental principle of Gas Chromatography.
- Explain various types of columns and detectors used in GC.
- Demonstrate how to operate the GC instrument.

Duration: *30:00*	**Duration**: *40:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Explain the working principles and instrumentation concepts of GC instrument. • Discuss the types of columns and detectors used in GC instrument. • Discuss the applications of GC instrument in QC testing. • Explain the application of GC instrument in various type of analysis • Explain the operating procedure for GC instrument and its software system • Explain the standard protocols to be followed for GC method development and validation.	• Identify and locate the various parts of the GC instrument on a schematic diagram. • Demonstrate how to operate GC instrument. • Identify the various types of columns and detectors used in the GC instrument on a schematic diagram or in a simulation module
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
PPE Kit, goggles, lab coat, GC instrument setup, Schematic diagram of GC instrument	

Module 16: Gas Chromatography (GC) calibration

Mapped to LFS/N1302, v2

Terminal Outcomes:

- Perform GC instrument calibration and validation activities in the QC lab.
- Troubleshoot minor issues in the GC instrument operations.

Duration: *30:00*	**Duration**: *110:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Explain the principles of GC instrument calibration and validation. • Discuss the importance and need of GC instrument calibrations. • Explain the process of GC instrument calibration.	• Demonstrate how to perform GC instrument calibrations. • Perform troubleshooting and rectification of the minor issues of GC instrument operations.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
PPE Kit, goggles, lab coat, calibration record formats, GC instrument set up	

Module 17: Gas Chromatography (GC) analysis

Mapped to LFS/N1302, v2

Terminal Outcomes:

- List different chemicals and reagents to be used for GC analysis.
- Perform sample preparation for GC test analysis.
- Demonstrate how to perform sample analysis by GC instrument.

Duration: *30:00*	**Duration**: *120:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Explain the properties of different chemicals, reagents and standard solutions used for GC analysis. • Recall the safety measures to be taken while operating GC. • Discuss the procedures of sample preparation for GC analysis. • Explain the scientific principles behind the GC test performed. • Explain methods of recording and analysis of GC chromatograms. • Explain the concepts of GC data deviations in case of deviation in the results.	• Prepare a checklist of different chemicals, reagents and standard solutions used for GC analysis. • Demonstrate safety measures to be taken while handling chemicals, reagents and reference materials. • Demonstrate how to perform sample preparation considering stability and storages requirement. • Demonstrate how to perform QC sample analysis by GC method. • Record the observations of test results and analyse the chromatogram. • Identify data deviations in case of deviation in results and raise logs in the system.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
PPE Kit, goggles, lab coat, hand controller, chemical and reagents, reference standards buffers, Glassware, Mortar and Pestle, analytical balance, Pipettes, water bath, Motor grinder, Muffle Furnace, Hot Air Oven, Rotary shaker, Glassware drying oven, Micropipette, Refrigerator, GC columns, GC instrument set up	

Module 18: Introduction to Ultraviolet (UV)- visible spectroscopy

Mapped to LFS/N1303, v2

Terminal Outcomes:

- Discuss the fundamental principles of (UV)-visible spectroscopy.
- Identify various components of (UV)-visible spectroscopy.
- Operate (UV)-visible spectroscopy in QC lab.

Duration: *30:00*	**Duration**: *10:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Explain the working principles of Ultraviolet (UV)- visible spectroscopy. • Discuss the instrumental components of Ultraviolet (UV)- visible spectrophotometer. • Explain the measurement principles of UV/VIS spectrophotometry. • Discuss the application of Ultraviolet (UV)-visible spectroscopy in QC testing. • Explain the operating procedure for Ultraviolet (UV)- visible spectroscopy its software system.	• Identify and locate the various parts/components on the schematic diagram of Ultraviolet (UV)-visible spectroscopy. • Demonstrate how to operate (UV)-visible spectroscopy.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
PPE Kit, goggles, lab coat, (UV)-visible spectroscopy instrument setup, Schematic diagram of (UV)-visible spectroscopy	

Module 19: Ultraviolet (UV)- visible spectroscopy calibrations

Mapped to LFS/N1303, v2

Terminal Outcomes:

- Perform UV spectrophotometer calibrations.
- Troubleshoot minor issues in the UV- visible spectroscopy instrument operations.

Duration: *30:00*	**Duration**: *30:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Explain the scientific principle behind the calibrations of UV- visible spectroscopy. • Explain the procedures to be followed for calibrations of UV- visible spectroscopy.	• Perform calibration and performance qualification of UV spectrophotometer. • Perform trouble-shooting and reconciliation of the minor issues of UV- visible spectroscopy instrument operations.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
PPE Kit, goggles, lab coat, (UV)-visible spectroscopy instrument setup, Calibration records	

Module 20: Ultraviolet (UV)- visible spectroscopy Analysis

Mapped to LFS/N1303, v2

Terminal Outcomes:

- List different chemicals, reagents and standard solutions to be used for (UV)- visible spectroscopy analysis.
- Perform sample preparation for (UV)- visible spectroscopy test analysis.
- Perform QC testing by (UV)- visible spectroscopy.

Duration: *30:00*	**Duration**: *80:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Explain the properties of different chemicals, reagents and standard solutions used for Ultraviolet (UV)- visible spectroscopy analysis. • Recall the safety measure to be taken while handling Ultraviolet (UV)- visible spectroscopy. • Discuss the procedures of sample preparation for Ultraviolet (UV)- visible spectroscopy analysis. • Explain the principle behind the Ultraviolet (UV)- visible spectroscopy test methods. • Explain methods of recording and analysis of UV- visible spectroscopy test results.	• Prepare a checklist of different chemicals, reagents and standard solutions used for (UV)- visible spectroscopy. • Demonstrate safety measures to be taken while handling chemicals, reagents and reference materials. • Demonstrate how to perform sample preparation for UV- visible spectroscopy analysis. • Demonstrate how to perform QC testing by (UV)- visible spectroscopy. • Record the test observations and analyse the results.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
PPE Kit, goggles, lab coat, hand controller, chemical and reagents, reference standards buffers, Glassware, Mortar and Pestle, analytical balance, Pipettes, water bath, Motor grinder, Muffle Furnace, Hot Air Oven, Rotary shaker, Glassware drying oven, Micropipette, Refrigerator, (UV)- visible spectroscopy instrument set up	

Module 21: Introduction to Fourier Transform Infrared Spectroscopy (FT-IR)

Mapped to LFS/N1304, v2

Terminal Outcomes:

- Discuss the working principle of Fourier Transform Infrared Spectroscopy (FT-IR).
- Operate Fourier Transform Infrared Spectroscopy (FT-IR) in a QC lab.
- Identify various components of Fourier Transform Infrared Spectroscopy (FT-IR).

Duration: *30:00*	**Duration**: *10:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Explain the working principles of Fourier Transform Infrared Spectroscopy (FT-IR). • Discuss the instrumental components of Fourier Transform Infrared Spectroscopy (FT-IR). • Discuss the application of Fourier Transform Infrared Spectroscopy (FT-IR) in QC testing. • Explain the operating procedure for Fourier Transform Infrared Spectroscopy (FT-IR) and its software system.	• Identify and locate the various parts/components on the schematic diagram of Fourier Transform Infrared Spectroscopy (FT-IR). • Demonstrate how to operate Fourier Transform Infrared Spectroscopy (FT-IR).
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
PPE Kit, goggles, lab coat, Fourier Transform Infrared Spectroscopy (FT-IR) instrument setup, Schematic diagram of Fourier Transform Infrared Spectroscopy (FT-IR)	

Module 22: Fourier Transform Infrared Spectroscopy (FT-IR) calibrations

Mapped to LFS/N1304, v2

Terminal Outcomes:

- Perform Fourier Transform Infrared Spectroscopy (FT-IR) calibrations.
- Perform troubleshooting of minor issues in the Fourier Transform Infrared Spectroscopy (FT-IR) instrument operations.

Duration: *30:00*	**Duration**: *30:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Explain the scientific principles behind the calibrations of Fourier Transform Infrared Spectroscopy (FT-IR). • Explain how to check the resolution performance of the instrument. • Explain the procedures for calibrations of Fourier Transform Infrared Spectroscopy (FT-IR).	• Demonstrate how to perform calibration of Fourier Transform Infrared Spectroscopy (FT-IR) instrument. • Perform troubleshooting and rectification of the minor issues of Fourier Transform Infrared Spectroscopy (FT-IR) instrument operations.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
PPE Kit, goggles, lab coat, Fourier Transform Infrared Spectroscopy (FT-IR) instrument setup, Calibration records	

Module 23: Fourier Transform Infrared Spectroscopy (FT-IR) Analysis

Mapped to LFS/N1304, v2

Terminal Outcomes:

- List different chemicals, reagents and standard solutions to be used for (FT-IR) test analysis.
- Perform sample preparation for (FT-IR) test analysis.
- Perform (FT-IR) test analysis in the QC lab.

Duration: *30:00*	**Duration**: *80:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Explain the properties of different chemicals, reagents and standard solutions used for Fourier Transform Infrared Spectroscopy (FT-IR) analysis. • Recall the safety measures to be taken while handling Fourier Transform Infrared Spectroscopy (FT-IR) instrument. • Explain analysis procedure for solids, liquids and mineral oil dispersion. • Discuss the procedures of sample preparation for Fourier Transform Infrared Spectroscopy (FT-IR) analysis. • Explain the principles of Fourier Transform Infrared Spectroscopy (FT-IR) test analysis. • Explain methods of recording and analysis of Fourier Transform Infrared Spectroscopy (FT-IR) test results.	• Prepare a checklist of different chemicals, reagents and standard solutions used for (FT-IR) test analysis. • Demonstrate safety measures to be taken while handling chemicals, reagents and reference materials. • Demonstrate how to perform sample preparation for Fourier Transform Infrared Spectroscopy (FT-IR). • Demonstrate how to perform sample analysis by (FT-IR). • Record the test observations and analyse the results.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
PPE Kit, goggles, lab coat, hand controller, chemical and reagents, reference standards buffers, Glassware, Mortar and Pestle, analytical balance, Pipettes, water bath, Motor grinder, Muffle Furnace, Hot Air Oven, Rotary shaker, Glassware drying oven, Micropipette, Refrigerator, (FT-IR) test analysis set up	

Module 24: Introduction to Dissolution Test Apparatus

Mapped to LFS/N1305, v2

Terminal Outcomes:

- Explain the working principle of the Dissolution test apparatus.
- Identify and classify the different types of dissolution test apparatus.

Duration: *30:00*	**Duration**:*40:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
● Explain the fundamental concepts of Dissolution test apparatus. ● Explain the purpose of Dissolution test and types of dissolution apparatus used for testing. ● Explain the process of Dissolution method development and validation.	● Identify different components of the dissolution test apparatus on a schematic diagram. ● Demonstrate the working of dissolution test apparatus in the QC lab.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
PPE Kit, goggles, lab coat, schematic diagram of dissolution test apparatus, dissolution test apparatus instrument setup	

Module 25: Routine upkeep Dissolution Test Apparatus

Mapped to LFS/N1305, v2

Terminal Outcomes:

- Perform general and preventive maintenance of the dissolution test apparatus.
- Perform troubleshooting of minor issues in the operations of the dissolution test apparatus.

Duration: *30:00*	**Duration***: 110:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Explain the procedures to be followed for preventive maintenance of dissolution test apparatus. • Discuss methods used for cleaning of dissolution test apparatus.	• Demonstrate the routine upkeep of the dissolution test apparatus. • Inspect the cleaning status of the dissolution test apparatus.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
PPE Kit, goggles, lab coat, dissolution test apparatus set up	

Module 26: QC Analysis using Dissolution Test Apparatus

Mapped to LFS/N1305, v2

Terminal Outcomes:

- Prepare the dissolution medium for QC testing.
- Perform sample preparation for HPLC Dissolution test analysis.
- Demonstrate how to perform QC testing by using Dissolution test Apparatus.

Duration: *30:00*	**Duration**: *120:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Explain the properties of different dissolution medium. • Recall the safety measures to be taken while handling the dissolution test apparatus. • Explain the procedures of sample preparation for dissolution test. • Explain the sample withdrawal procedures for dissolution testing. • Explain the principle behind QC analysis using a dissolution test apparatus. Analysis using Dissolution Test Apparatus	• Demonstrate safety measures to be taken while handling the dissolution test apparatus. • Demonstrate how to perform sample preparation for dissolution test. • Demonstrate the testing methods for QC analysis using a dissolution test apparatus.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
PPE Kit, goggles, lab coat, hand controller, chemical and reagents, reference standards buffers, Glassware, Mortar and Pestle, analytical balance, Pipettes, water bath, Motor grinder, Muffle Furnace, Hot Air Oven, Rotary shaker, Glassware drying oven, Micropipette, Refrigerator, dissolution test apparatus set up	

Module 26: Apprenticeship Training

Mapped to: Analyst/Chemist-Quality Control

Mandatory Duration: *2010:00(12 months)*	**Recommended Duration:** *00:00*

Module Name: Apprenticeship Training
Location: On-Site
Terminal Outcomes

- Perform laboratory investigations and analysis in adherence to GMP and GLP guidelines.
- Follow Environment, health and safety guidelines in GMP/GLP controlled areas and Lab by ensuring the same is followed by subordinates as well.
- Coordinate with Manager, colleagues and auditors.
- Perform reporting and documentation for Quality Control analysis.
- Conduct process-related checks in the quality control process.
- Perform QC Analysis by handling High-Performance Liquid Chromatography/Gas Chromatography/ Ultraviolet-visible spectroscopy/ Fourier Transform Infrared Spectroscopy/ Dissolution Test Apparatus.

Annexure

Trainer Requirements

Trainer Prerequisites						
Minimum Educational Qualification	**Specialization**	**Relevant Industry Experience**		**Training Experience**		**Remarks**
		Years	***Specialization***	***Years***	***Specialization***	
Graduate	B. Pharma/ B. Tech Chemical Engg.	4	Analyst/Chemist -Quality Control	0	NA	(Relevant Specialization in HPLC/ GC/ UV/ FT-IR/ Dissolution Apparatus)
Post Graduate	M.Sc. Chemistry/ M. Pharm./ M. Tech.- Chemical Engg	2	Analyst/Chemist -Quality Control	0	NA	(Relevant Specialization in HPLC/ GC/ UV/ FT-IR/ Dissolution Apparatus)
Graduate	Analyst/Chemist -Quality Control (LFS/Q1301, V1.0 or Ver 2.0) Level-5 qualified	3	Analyst/Chemist -Quality Control		NA	(Relevant Specialization in HPLC/ GC/ UV/ FT-IR/ Dissolution Apparatus)
Post Graduate	Analyst/Chemist -Quality Control (LFS/Q1301, V1.0 or Ver 2.0) Level-5 qualified	2	Analyst/Chemist -Quality Control		NA	(Relevant Specialization in HPLC/ GC/ UV/ FT-IR/ Dissolution Apparatus)

Trainer Certification	
Domain Certification	**Platform Certification**
Certified for Job Role: "Analyst/Chemist-Quality Control" mapped to the Qualification Pack: "LFS/Q1301, 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/Q2601, 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	B. Pharma/ B. Tech Chemical Engg.	5	Analyst/Chemist -Quality Control	2	On the job assessment/ Training experience/ Vocational assessment/ Academic assessment	Relevant Specialization in HPLC/ GC/ UV/ FT-IR/ Dissolution Apparatus
Post Graduate	M.Sc. Chemistry/ M. Pharm./ M. Tech.- Chemical Engg	3	Analyst/Chemist -Quality Control	2	On the job assessment/ Training experience/ Vocational assessment/ Academic assessment	Relevant Specialization in HPLC/ GC/ UV/ FT-IR/ Dissolution Apparatus

Assessor Certification	
Domain Certification	**Platform Certification**
Analyst/Chemist-Quality Control" mapped to the Qualification Pack: "LFS/Q1301, 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 ver 2.0" 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 Analyst/Chemist-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 pharma 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, 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
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
WHO	World Health Organization
SOP	Standard Operating Procedure
MSDS	Material Safety Datasheets
ALCOA	Attributable, Legible, Contemporaneous, Original and Accurate
CAPA	Corrective Active Preventive Action
DQ	Design Qualification
IQ	Installation Qualification
PQ	Performance Qualification
OQ	Operation Qualification
GDP	Good Documentation Practices
API	Active Pharmaceutical Ingredient
CFR	Code of Federal Regulation
LIMS	Lab Information Management System
HPLC	High Performance Liquid Chromatography
GC	Gas Chromatography
FTIR	Fourier Transform Infrared Spectroscopy