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## Training Parameters

<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceuticals, Biopharmaceuticals
<b>Occupation</b>	Research and Development
<b>Country</b>	India
<b>NSQF Level</b>	Level 5.5
<b>Aligned to NCO/ISCO/ISIC Code</b>	NCO-2015/2131.1300
<b>Minimum Educational Qualification and Experience</b>	Pursuing Final Year of post-graduation -M Sc. In relevant science field or Pursuing Final Year of post-graduation M. Pharma or Pursuing Final Year of post-graduation M.Tech Biotechnology
<b>Pre-Requisite License or Training</b>	NIL
<b>Minimum Job Entry Age</b>	21 Years
<b>Last Reviewed On</b>	29 <sup>th</sup> September 2023
<b>Next Review Date</b>	29 <sup>th</sup> September 2026
<b>NSQC Approval Date</b>	29 <sup>th</sup> September 2023
<b>QP Version</b>	1
<b>Model Curriculum Creation Date</b>	15 June 2023
<b>Model Curriculum Valid Up to Date</b>	29 <sup>th</sup> September 2026
<b>Model Curriculum Version</b>	1
<b>Minimum Duration of the Course</b>	Compulsory Notional Hours Theory=120 Practical=180 Employability Skills= 90 Hours Total Compulsory Notional Hours=390 Hours  7 Electives = 150 Hours each Theory= 60 Hours

	Practical= 90 Hours Minimum Notional Hours with one elective= 540 Hours
<b>Maximum Duration of the Course</b>	Compulsory Notional Hours Theory=120 Practical=180 Employability Skills= 90 Hours Total Compulsory Notional Hours=390Hours  7 Electives = 150 Hours each Theory= 60 Hours Practical= 90 Hours  Option Notional Hour = 270 Hours Minimum Notional Hours with one elective= 540 Hours Maximum Notional Hours with seven elective and one option = 1710 hours  Apprenticeship Duration=6 months (Recommended)

## 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.

- Demonstrate proficiency in assisting with the development of biological products, including API synthesis and medicinal chemistry-based research.
- Apply theoretical knowledge and practical skills to actively contribute to the research and development process.
- Execute experiments and protocols with precision and accuracy to support product development.
- Assist in technology transfer and process development activities from research to large-scale manufacturing.
- Contribute to the smooth transition of products from laboratory settings to commercial production.

## Compulsory Modules

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

### a) Domain

NOS/ Module Details	Total Duration Hours	Level	Credits
<b>Compulsory Bridge Module</b> Introduction to Life Sciences industry and the job role & managing environmental sustainability	30:00		1:00
<b>Compulsory Module</b> LFS/N0111: Ensure adherence to Environment, health and safety guidelines in a production facility and GMP controlled areas NOS Version-2.0	90:00	Level-5	3.00
<b>Compulsory Module</b> LFS/N0129: Coordinate and communicate with supervisor/production chemist, research teams and auditors NOS Version-1.0	90:00	Level-5.5	3.00
<b>Compulsory Module</b> LFS/N0572: Maintain experiment records ensuring data integrity and intellectual property rights NOS Version-1.0	90:00	Level-5.5	3.00
<b>DGT/VSQ/N0103: Employability Skills</b> NOS Version-1	90:00	Level-5	3.00
<b>Elective 1: API Synthesis &amp; Medicinal Chemistry</b> LFS/N0516: Assist in development of new Active Pharmaceutical Ingredient (API) / Synthetic Product Development NOS Version-2.0	90:00	Level-5.5	3.00
<b>Elective 1: API Synthesis &amp; Medicinal Chemistry</b> LFS/N0573: Assist in Medicinal Chemistry research NOS Version-1.0	60:00	Level-5.5	2.00
<b>Elective 2: Formulation Development</b> LFS/N0574: Assist in new Non Sterile formulation product development NOS Version-1.0	90:00	Level-5.5	3.00
<b>Elective 2: Formulation Development</b> LFS/N0575: Assist in aseptic product development NOS Version-1.0	60:00	Level-5.5	2.00
<b>Elective 3: Biological Product Development</b> LFS/N0576: Assist in new biological product development	150:00	Level-5.5	5.00

NOS Version-1.0			
<b>Elective 4: Technology translation and Process Development</b> LFS/N0517: Assist in technology translation and process development NOS Version-2.0	150:00	Level-5.5	5.00
<b>Elective 5: Technology transfer</b> LFS/N0577: Assist in technology transfer NOS Version-1.0	150:00	Level-5.5	5.00
<b>Elective 6: Analytical - Mass Spectrometry</b> LFS/N0578: Conducts research and analysis using mass spectrometry techniques to solve complex problems, develop new products, or improve existing ones. NOS Version-1.0	150:00	Level-5.5	5.00
<b>Elective 7: Analytical - NMR</b> LFS/N0579: Conducts research and analysis using Nuclear Magnetic Resonance techniques to solve complex problems, develop new products, or improve existing ones. NOS Version-1.0	150:00	Level-5.5	5.00
<b>Optional NOS/s: Innovation driven Entrepreneurship</b> LFS/N0126: Establish innovation led enterprise and perform various entrepreneurial activities to run the regulated business NOS Version-1.0	120:00	Level-5.5	3.00
<b>Optional NOS/s: Innovation driven Entrepreneurship</b> LFS/N0127: Maintain the Critical Business documents as Innovation led entrepreneur NOS Version-1.0	30:00	Level-5.5	3.00
<b>Optional NOS/s: Innovation driven Entrepreneurship</b> LFS/N0128: Product commercialization and Intellectual Property Rights Management NOS Version-1.0	120:00	Level-5.5	3.00
<b>Total Duration of Maximum Notional Hours</b>	<b>1710</b>		
<b>Total Duration of Maximum Credits</b>			<b>57.00</b>
<b>Recommended Apprenticeship</b>	<b>6 months</b>		

NOS and Module Details	Theory Duration (hh:mm)	Practical Duration (hh:mm)	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration (hh:mm)
<b>Bridge Modules</b>	<b>30:00</b>	<b>00:00</b>	<b>00:00</b>	<b>00:00</b>	<b>30:00</b>
Module 1: Introduction to life sciences industry and applicable regulations	10:00	00:00	00:00	00:00	10:00
Module 2: Fundamentals of Manufacturing in Life Sciences Sector	10:00	00:00	00:00	00:00	10:00
Module 3:Managing environmental sustainability	10:00	00:00	00:00	00:00	05:00
<b>LFS/N0111: Ensure adherence to Environment, health and safety guidelines in a production facility and GMP controlled areas NOS Version No. 2 NSQF Level-5</b>	<b>30:00</b>	<b>60:00</b>	<b>00:00</b>	<b>00:00</b>	<b>90:00</b>
Module 4: comply EHS rules in production and GMP controlled area	30:00	60:00	00:00	00:00	90:00
<b>LFS/N0129: Coordinate and communicate with supervisor/production chemist, research teams and auditors NOS Version No. 1 NSQF Level-5.5</b>	<b>30:00</b>	<b>60:00</b>	<b>00:00</b>	<b>00:00</b>	<b>90:00</b>
Module 5: Coordination with Manager, teammates and Auditors	30:00	60:00	00:00	00:00	90:00
<b>LFS/N0572: Maintain experiment records ensuring data integrity and intellectual property rights NOS Version No. 1 NSQF Level-5.5</b>	<b>30:00</b>	<b>60:00</b>	<b>00:00</b>	<b>00:00</b>	<b>90:00</b>

Module 6: Data integrity and IPR	30:00	60:00	00:00	00:00	90:00
<b>DGT/VSQ/N0103 : Employability Skills (90 Hours)</b>					
<b>Module 7: Employability Skills</b>					
<b>NOS Version No. 1</b>					
Introduction to Employability Skills	03:00	00:00	00:00	00:00	03:00
Constitutional values - Citizenship	01:30	00:00	00:00	00:00	01:30
Becoming a Professional in the 21st Century	05:00	00:00	00:00	00:00	05:00
Basic English Skills	10:00	00:00	00:00	00:00	10:00
Career Development & Goal Setting	04:00	00:00	00:00	00:00	04:00
Communication Skills	10:00	00:00	00:00	00:00	10:00
Diversity and Inclusion	02:30	00:00	00:00	00:00	02:30
Financial and Legal Literacy	10:00	00:00	00:00	00:00	10:00
Essential Digital Skills	20:00	00:00	00:00	00:00	20:00
Entrepreneurship	07:00	00:00	00:00	00:00	07:00
Customer Service	09:00	00:00	00:00	00:00	09:00
Getting ready for apprenticeship & Jobs	08:00	00:00	00:00	00:00	08:00
<b>On the Job Training</b>	<b>00:00</b>	<b>00:00</b>	<b>00:00</b>	<b>990:00</b>	<b>990:00</b>
<b>Total Duration</b>	<b>210:00</b>	<b>180:00</b>	<b>00:00</b>	<b>990:00</b>	<b>1380:00</b>

\*detailed Curriculum of employability skills is enclosed as Annexure-2

## Elective Modules

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

### Elective 1: API Synthesis & Medicinal Chemistry

NOS and Module Details	Theory Duration (hh:mm)	Practical Duration (hh:mm)	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration (hh:mm)
LFS/N0516: Assist in development of new Active Pharmaceutical Ingredient (API) / Synthetic Product Development NOS Version No.2 NSQF Level-5.5	30:00	60:00	00:00	00:00	90:00

Module 8: New Active Pharmaceutical Ingredient (API) / Synthetic Product Development	30:00	60:00	00:00	00:00	90:00
<b>LFS/N0573: Assist in Medicinal Chemistry research NOS Version No.1 NSQF Level-5.5</b>	<b>30:00</b>	<b>30:00</b>	<b>00:00</b>	<b>00:00</b>	<b>60:00</b>
Module 9: Medicinal Chemistry Research in drug discovery	30:00	30:00	00:00	00:00	60:00
<b>Total Duration</b>	<b>60:00</b>	<b>90:00</b>	<b>00:00</b>	<b>00:00</b>	<b>150:00</b>

### Elective 2: Formulation Development

NOS and Module Details	Theory Duration (hh:mm)	Practical Duration (hh:mm)	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration (hh:mm)
<b>LFS/N0574: Assist in new Non Sterile formulation product development NOS Version No.1 NSQF Level-5.5</b>	<b>30:00</b>	<b>60:00</b>	<b>00:00</b>	<b>00:00</b>	<b>90:00</b>
Module 10: Non Sterile formulation product development	30:00	60:00	00:00	00:00	90:00
<b>LFS/N0575: Assist in aseptic product development NOS Version No.1 NSQF Level-5.5</b>	<b>30:00</b>	<b>30:00</b>	<b>00:00</b>	<b>00:00</b>	<b>60:00</b>
Module 11: Aseptic product development	30:00	30:00	00:00	00:00	60:00
<b>Total Duration</b>	<b>60:00</b>	<b>90:00</b>	<b>00:00</b>	<b>00:00</b>	<b>150:00</b>

### Elective 3: Biological Product Development

NOS and Module Details	Theory Duration (hh:mm)	Practical Duration (hh:mm)	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration (hh:mm)
<b>LFS/N0576: Assist in new biological product development NOS Version No.1</b>	<b>60:00</b>	<b>90:00</b>	<b>00:00</b>	<b>00:00</b>	<b>150:00</b>

<b>NSQF Level-5.5</b>					
Module 12: New Biological product development	60:00	90:00	00:00	00:00	150:00
<b>Total Duration</b>	<b>60:00</b>	<b>90:00</b>	<b>00:00</b>	<b>00:00</b>	<b>150:00</b>

#### Elective 4: Technology translation and Process Development

NOS and Module Details	Theory Duration (hh:mm)	Practical Duration (hh:mm)	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration (hh:mm)
<b>LFS/N0517: Assist in technology translation and process development. NOS Version No.2 NSQF Level-5.5</b>	<b>60:00</b>	<b>90:00</b>	<b>00:00</b>	<b>00:00</b>	<b>150:00</b>
Module 13: Prepare for technology translation and process development	60:00	90:00	00:00	00:00	150:00
<b>Total Duration</b>	<b>60:00</b>	<b>90:00</b>	<b>00:00</b>	<b>00:00</b>	<b>150:00</b>

#### Elective 5: Technology transfer

NOS and Module Details	Theory Duration (hh:mm)	Practical Duration (hh:mm)	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration (hh:mm)
<b>LFS/N0577: Assist in technology transfer NOS Version No.1 NSQF Level-5.5</b>	<b>60:00</b>	<b>90:00</b>	<b>00:00</b>	<b>00:00</b>	<b>150:00</b>
Module 14: Prepare for Technology transfer	60:00	90:00	00:00	00:00	150:00
<b>Total Duration</b>	<b>60:00</b>	<b>90:00</b>	<b>00:00</b>	<b>00:00</b>	<b>150:00</b>

#### Elective 6: Analytical - Mass Spectrometry

NOS and Module Details	Theory Duration (hh:mm)	Practical Duration (hh:mm)	On-the-Job Training Duration	On-the-Job Training Duration	Total Duration (hh:mm)

			(Mandatory )	(Recommended )	
LFS/N0578: Conducts research and analysis using mass spectrometry techniques to solve complex problems, develop new products, or improve existing ones. NOS Version No.1 NSQF Level-5.5	60:00	90:00	00:00	00:00	150:00
Module 15: Mass Spectrometry analysis	60:00	90:00	00:00	00:00	150:00
<b>Total Duration</b>	<b>60:00</b>	<b>90:00</b>	<b>00:00</b>	<b>00:00</b>	<b>150:00</b>

### Elective 7: Analytical - NMR

NOS and Module Details	Theory Duration (hh:mm)	Practical Duration (hh:mm)	On-the-Job Training Duration (Mandatory )	On-the-Job Training Duration (Recommended )	Total Duration (hh:mm)
LFS/N0579: Conducts research and analysis using Nuclear Magnetic Resonance techniques to solve complex problems, develop new products, or improve existing ones. NOS Version No.1 NSQF Level-5.5	60:00	90:00	00:00	00:00	150:00
Module 16: Nuclear Magnetic Resonance analysis	60:00	90:00	00:00	00:00	150:00
<b>Total Duration</b>	<b>60:00</b>	<b>90:00</b>	<b>00:00</b>	<b>00:00</b>	<b>150:00</b>

### Option 1 : Regulated Entrepreneurship

NOS and Module Details	Theory Duration (hh:mm)	Practical Duration (hh:mm)	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration (hh:mm)
LFS/N0126: Establish innovation led enterprise and perform various entrepreneurial activities to run the	60:00	60:00	00:00	00:00	120:00

<b>regulated business operations NOS Version No.1 NSQF Level-5.5</b>					
Module 17: Entrepreneurial activities to start and run the business operations	60:00	60:00	00:00	00:00	120:00
<b>LFS/N0127: Maintain the Critical Business documents as Innovation led entrepreneur. NOS Version No.1 NSQF Level-5.5</b>	10:00	20:00	00:00	00:00	30:00
Module 18: Manage the critical documents for business activities and for statutory and regulatory compliance	10:00	20:00	00:00	00:00	30:00
<b>LFS/N0128: Product commercialization and Intellectual Property Rights Management</b>	20:00	100:00	00:00	00:00	120:00
Module 19: Product commercialization and Intellectual Property Rights Management	20:00	100:00	00:00	00:00	120:00
<b>Total Duration</b>	<b>90:00</b>	<b>180:00</b>	<b>00:00</b>	<b>00:00</b>	<b>270:00</b>

# Module Details

## Module 1: Introduction to Life Sciences industry and applicable regulations

### Bridge Module

#### Terminal Outcomes:

- Explain the overview of the Life Sciences industry in regulation applicable
- Discuss the importance of a skilled Research Associate

<i>Duration: 10:00 hrs</i>	<i>Duration: 00:00 hrs</i>
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Discuss the Life Sciences industry in Indian and global context.</li> <li>● Discuss the regulatory authorities, regulations, legislation, and good practices (GMP, GLP, GDP) relevant to the Production operation in a life sciences manufacturing facility.</li> <li>● Explain the basic skills required to perform the job of Research Associate</li> <li>● Explain the importance of a Research Associate in a manufacturing plant.</li> <li>● Explain the opportunities of entrepreneurship for Research Associate in Life Sciences Sector</li> </ul>	
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector/ screen, Scanner, Computer speakers, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
As equipment list mentioned in the annexure 2 and the item No are 7,8,9,10,45,46	

## Module 2: Fundamentals of Manufacturing in Life Sciences Sector

### Bridge Module

#### Terminal Outcomes:

- Discuss the fundamental concepts of Manufacturing and its various process.

<i>Duration: 10:00 hrs</i>	<i>Duration: 00:00 hrs</i>
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>• Discuss the basic concepts of biology and pharmacology required to interpret the manufacturing specifications.</li> <li>• Discuss fundamental science in production including size separation, mixing and homogenization process, mass transfer, fluid flow, heat transfer and size reduction.</li> <li>• Explain the role of API in typical pharmaceutical manufacturing and role of API particle size in formulations.</li> <li>• Explain the role of assay in biopharmaceutical formulation.</li> <li>• Explain standard quantity effect in formulation.</li> <li>• Describe drug manufacturing plant components.</li> <li>• Demonstrate how to perform job activities of Research Associate by recalling all the essential concepts of manufacturing in life sciences manufacturing facility.</li> </ul>	
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector/ screen, Scanner, Computer speakers, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
Flip charts, Periodic table of elements and As equipment list mentioned in the annexure 2 and the item No are 7,8,9,10,45,46	

### Module 3: Managing environmental sustainability

#### Mapped to Bridge Module

#### 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:** 10:00 hrs

**Duration:** 00:00 hrs

#### 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.

#### 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 and As equipment list mentioned in the annexure 2 and the item No are 7,8,9,10,45,46,

## Module 4: Comply EHS rules in production and GMP controlled area

*Mapped to LFS/N0111, V2*

### Terminal Outcomes:

- Explain the health and hygiene protocols to be followed in production and GMP controlled area.
- Describe safety ,security and emergency procedures at the production and GMP controlled area.

<b>Duration: 30:00 hrs</b>	<b>Duration: 60:00 hrs</b>
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Explain relevant legislative requirements and company’s procedures for the environment, health and safety including an individual’s role and responsibilities.</li> <li>● Discuss workplace hazards in the manufacturing facility in the life sciences sector including how and when to report hazards.</li> <li>● Explain all the emergency procedures for different emergencies.</li> <li>● Identify evacuation procedures for employees, contract staff and visitors</li> <li>● Discuss health, safety and accident reporting procedures, different types of breaches in the environment, health, safety and security and how and when to report including medical assistance and the emergency services.</li> <li>● Explain the importance of material segregation and 5S system, WHO guidelines for personal hygiene, handling and storing hazardous material</li> <li>● Discuss the type of safety gears and procedure to use them</li> </ul>	<ul style="list-style-type: none"> <li>● Demonstrate how and when to report hazards at the workplace.</li> <li>● Demonstrate emergency procedures to be followed in different emergencies.</li> <li>● Demonstrate how to evacuate employees, contract staff and visitors as per procedures in case of emergency.</li> <li>● Demonstrate how to act in case of emergencies by following health, safety and accident reporting procedures.</li> <li>● Recall 5S system, WHO guidelines for personal hygiene, handling and storing hazardous material.</li> <li>● Demonstrate how to use different types of safety gears by following the procedures to use them.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
Printouts of WHO guidelines, Flashcards of signages, coding, and instructions, CO2 type Fire Extinguisher, ABC Type Fire Extinguisher, Personal Protective Equipments and gowning material	

## Module 5: Coordination with Manager, teammates and Auditors

### Mapped to LFS/N0129, v1

#### Terminal Outcomes:

- Describe various scenarios at work that demand coordination and collaboration with the manager, team, and cross-functional stakeholders.
- Demonstrate the effective coordination and collaboration with manager, cross-functional teams.
- Explain the importance of sensitivity towards people with disability.

<i>Duration: 30:00 hrs</i>	<i>Duration: 60:00 hrs</i>
<b>Theory – Key Learning Outcomes</b> <ul style="list-style-type: none"> <li>● List the functional and cross-functional stakeholders for Biologist</li> <li>● Explain efficient and clear communication methods for reporting incidents/ deviations.</li> <li>● Explain the techniques for gaining emotional stability.</li> <li>● Discuss various ways for conflict resolution.</li> <li>● Explain the best strategies of collaborating with others.</li> <li>● Describe the problem-solving techniques for routine work-related issues.</li> <li>● Explain the process of development of a production plan and shift schedule</li> <li>● Explain the strategies for efficient manpower management and optimization of team productivity</li> <li>● Explain the type of audits in the life sciences sector for the manufacturing operations.</li> <li>● Discuss the rules laid by the Sexual Harassment of Women at Workplace (Prevention, Prohibition, and Redressal) Act and the provided penalties for violation.</li> <li>● Explain the importance of gender sensitive behaviour.</li> <li>● Explain the procedure to report inappropriate behaviour e.g. sexual harassment.</li> <li>● Describe the importance of an equal opportunity work culture.</li> <li>● Discuss the importance of respecting other’s cultures, religion, and caste.</li> <li>● Explain the need for sensitivity towards people with disabilities.</li> <li>● Explain the correct ways of communication and collaboration with people with disabilities in compliance with the legal framework.</li> </ul>	<b>Practical – Key Learning Outcomes</b> <ul style="list-style-type: none"> <li>● Demonstrate how to effectively communicate and collaborate with various stakeholders (e.g. manager, groups etc.) in a simulated environment for multiple scenarios.</li> <li>● Respond to regulatory audit questions in a mock audit situation.</li> <li>● Demonstrate how to resolve conflict in multiple scenarios.</li> <li>● Demonstrate appropriate verbal and nonverbal communication that is respectful of gender, religion, disability, etc.</li> <li>● Prepare a list of gender-neutral communication terms.</li> </ul>

<ul style="list-style-type: none"><li>• Identify stereotypes and prejudices associated with people with disabilities and the negative consequences of prejudice and stereotypes.</li></ul>	
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
As equipment list mentioned in the annexure 2 and the item No are 7,8,9,10,45,46,	

## Module 6: Reporting, Data integrity and IPR

### Mapped to LFS/N0572, v1

#### Terminal Outcomes:

- Explain different strategies for reporting, data integrity and IPR.

<b>Duration: 30:00 hrs</b>	<b>Duration: 60:00 hrs</b>
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Describe the process of documenting test methods and procedures according to written documentation protocols.</li> <li>● Prepare analytical reports that include detailed findings and recommendations according to Standard Operating Procedures (SOPs).</li> <li>● Explain laboratory records both physical Logbook (LNB) and electronic Laboratory Notebook (eLNB) .</li> <li>● Explain the concept of data integrity in research, highlighting its importance in maintaining the accuracy, reliability, and authenticity of scientific data.</li> <li>● Explain different strategies for data management, including data collection, storage, organization, and documentation, to ensure data integrity throughout the research process.</li> <li>● Describe ethical principles and guidelines governing data integrity in research, including responsible conduct and avoidance of research misconduct.</li> <li>● Understand the basics of Intellectual Property Rights (IPR) and their relevance in protecting intellectual creations, inventions, and research outcomes.</li> </ul>	<ul style="list-style-type: none"> <li>● Generate comprehensive analytical reports that summarize experimental procedures, results, and findings in a clear and organized manner, adhering to Standard Operating Procedures (SOPs).</li> <li>● Implement data integrity practices, including maintaining accurate records, securely storing data, and conducting regular data audits to ensure data reliability.</li> <li>● Apply techniques for data validation and verification to confirm the accuracy and authenticity of research data.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
As equipment list mentioned in the annexure 2 and the item No are 7,8,9,10,45,46,	

## Module 7: Employability Skills (90 Hours)

### Mapped to DGT/VSQ/N0103 - v1.0

**Mandatory Duration: 90:00 hrs**

This is compulsory module introduced by Directorate General of Training (DGT).

Key Learning Outcomes

#### Introduction to Employability Skills Duration: 3 Hours

1. Outline the importance of Employability Skills for the current job market and future of work
2. List different learning and employability related GOI and private portals and their usage
3. Research and prepare a note on different industries, trends, required skills and the available opportunities

#### Constitutional values - Citizenship Duration: 01:30 Hours

4. Explain the constitutional values, including civic rights and duties, citizenship, responsibility towards society and personal values and ethics such as honesty, integrity, caring and respecting others that are required to become a responsible citizen
5. Demonstrate how to practice different environmentally sustainable practices

#### Becoming a Professional in the 21st Century Duration: 5 Hours

6. Discuss relevant 21st century skills required for employment
7. Highlight the importance of practicing 21st century skills like Self-Awareness, Behavior Skills, time management, critical and adaptive thinking, problem-solving, creative thinking, social and cultural awareness, emotional awareness, learning to learn etc. in personal or professional life
8. Create a pathway for adopting a continuous learning mindset for personal and professional development

#### Basic English Skills Duration: 10 Hours

9. Show how to use basic English sentences for everyday conversation in different contexts, in person and over the telephone
10. Read and understand text written in basic English
11. Write a short note/paragraph / letter/e -mail using correct basic English

#### Career Development & Goal Setting Duration: 4 Hours

12. Create a career development plan
13. Identify well-defined short- and long-term goals

#### Communication Skills Duration: 10 Hours

14. Demonstrate how to communicate effectively using verbal and nonverbal communication etiquette
15. Write a brief note/paragraph on a familiar topic

16. Explain the importance of communication etiquette including active listening for effective communication
17. Role play a situation on how to work collaboratively with others in a team

**Diversity and Inclusion Duration: 02:30 Hours**

18. Demonstrate how to behave, communicate, and conduct appropriately with all genders and PwD
19. Discuss the significance of escalating sexual harassment issues as per POSH act

**Financial and Legal Literacy Duration: 10 Hours**

20. Discuss various financial institutions, products, and services
21. Demonstrate how to conduct offline and online financial transactions, safely and securely and check passbook/statement
22. Explain the common components of salary such as Basic, PF, Allowances (HRA, TA, DA, etc.), tax deductions
23. Calculate income and expenditure for budgeting
24. Discuss the legal rights, laws, and aids

**Essential Digital Skills Duration: 20 Hours**

25. Describe the role of digital technology in day-to-day life and the workplace
26. Demonstrate how to operate digital devices and use the associated applications and features, safely and securely
27. Demonstrate how to connect devices securely to internet using different means
28. Follow the dos and don'ts of cyber security to protect against cyber crimes
29. Discuss the significance of displaying responsible online behavior while using various social media platforms
30. Create an e-mail id and follow e-mail etiquette to exchange e-mails
31. Show how to create documents, spreadsheets and presentations using appropriate applications
32. utilize virtual collaboration tools to work effectively

**Entrepreneurship Duration: 7 Hours**

33. Explain the types of entrepreneurship and enterprises
34. Discuss how to identify opportunities for potential business, sources of funding and associated financial and legal risks with its mitigation plan
35. Describe the 4Ps of Marketing-Product, Price, Place and Promotion and apply them as per requirement
36. Create a sample business plan, for the selected business opportunity

**Customer Service Duration: 9 Hours**

37. Classify different types of customers
38. Demonstrate how to identify customer needs and respond to them in a professional manner

39. Discuss various tools used to collect customer feedback
40. Discuss the significance of maintaining hygiene and dressing appropriately

**Getting ready for apprenticeship & Jobs Duration: 8 Hours**

41. Draft a professional Curriculum Vitae (CV)
42. Use various offline and online job search sources to find and apply for jobs
43. Discuss the significance of maintaining hygiene and dressing appropriately for an interview
44. Role play a mock interview
45. List the steps for searching and registering for apprenticeship opportunities

## Module 8: New Active Pharmaceutical Ingredient (API) / Synthetic Product Development

*Mapped to LFS/N0516, v2*

### Terminal Outcomes:

- Discuss key stages of new API/synthetic product development.
- Explain the regulatory requirements and guidelines governing API/synthetic product development

**Duration:** 30:00 hrs

**Duration:** 60:00 hrs

#### Theory – Key Learning Outcomes

#### Practical – Key Learning Outcomes

- Describe the key stages and principals involved in new API/synthetic product development.
- Explain the regulatory requirements and guidelines governing API/synthetic product development, including Good Manufacturing Practices (GMP).
- Demonstrate the ability to design synthetic processes to produce new APIs, considering efficiency, safety, and scalability.
- Identify potential risks and challenges associated with API/synthetic product development, including chemical hazards and regulatory risks.

- Perform API synthesis reactions, including reaction setup, monitoring, and work-up, while adhering to safety and quality standards.
- Demonstrate safe laboratory practices, including handling hazardous materials and emergency response procedures.

#### Classroom Aids:

Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil

#### Tools, Equipment and Other Requirements

As equipment list mentioned in the annexure 2 and the item No are 1-46

## Module 9: Medicinal Chemistry Research in drug discovery

Mapped to LFS/N0573, v1

### Terminal Outcomes:

- Explain the process of new medicinal chemistry research in drug discovery

Duration: 30:00 hrs	Duration: 30:00 hrs
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<ul style="list-style-type: none"> <li>● Describe the stages and key principles of medicinal chemistry product development, from lead optimization to preclinical development.</li> <li>● Explain fundamental concepts of medicinal chemistry, including structure-activity relationships (SAR), pharmacokinetics etc.</li> <li>● Explain the criteria and methodologies for selecting lead compounds from a pool of potential candidates.</li> <li>● Explain the process of lead optimization to improve potency, selectivity, and pharmacological properties</li> <li>● Describe formulation development principles for converting drug candidates into suitable dosage forms, considering stability and bioavailability.</li> </ul>	<ul style="list-style-type: none"> <li>● Perform chemical synthesis of drug candidates and intermediates, following established protocols.</li> <li>● Utilize various analytical techniques, such as spectroscopy and chromatography, to analyze synthesized compounds.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
As equipment list mentioned in the annexure 2 and the item No are 1-46	

## Module 10: New Non Sterile formulation product development

### Mapped to LFS/N0574, v1

#### Terminal Outcomes:

- Explain the methods of New Non Sterile formulation product development.

**Duration:** 30:00 hrs

#### Theory – Key Learning Outcomes

- Describe the fundamental principles and objectives of non-sterile formulation development in pharmaceuticals.
- Explain the regulatory requirements and guidelines governing non-sterile formulation development, including Good Manufacturing Practices (GMP).
- Explain the development of exploratory development proposals for innovative product ideas.
- Demonstrate the ability to design synthetic processes to produce new non-sterile, considering efficiency, safety, and scalability.
- Discuss the various dosage forms suitable for non-sterile pharmaceutical products and their advantages and limitations.
- Explain the process of optimizing non-sterile formulations to achieve desired drug release profiles and stability.

**Duration:** 60:00 hrs

#### Practical – Key Learning Outcomes

- Demonstrate non-sterile formulation development protocols, including selecting appropriate ingredients and dosage forms.
- Perform standardization, optimization, and scale-up of new non-sterile formulation synthesis reactions, adhering to established protocols.

#### Classroom Aids:

Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil

#### Tools, Equipment and Other Requirements

As equipment list mentioned in the annexure 2 and the item No are 1-46

## Module 11: Aseptic product development

Mapped to LFS/N0575, v1

### Terminal Outcomes:

- Explain the methods of New aseptic product development.

<b>Duration: 30:00 hrs</b>	<b>Duration: 30:00 hrs</b>
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Describe the fundamental principles and objectives of Aseptic formulation development in pharmaceuticals.</li> <li>● Explain the regulatory requirements and guidelines governing Aseptic formulation development, including Good Manufacturing Practices (GMP).</li> <li>● Explain the development of exploratory development proposals for innovative product ideas.</li> <li>● Demonstrate the ability to design synthetic processes to produce new Aseptic product, considering efficiency, safety, and scalability.</li> <li>● Discuss the various dosage forms suitable for Aseptic pharmaceutical products and their advantages and limitations.</li> <li>● Explain the process of optimizing Aseptic formulations to achieve desired drug release profiles and stability.</li> </ul>	<ul style="list-style-type: none"> <li>● Demonstrate Aseptic formulation development protocols, including selecting appropriate ingredients and dosage forms.</li> <li>● Perform standardization, optimization, and scale-up of new Aseptic formulation synthesis reactions, adhering to established protocols.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
Colour-coded waste bin bag, colour-coded waste container and as equipment list mentioned in the annexure 2 and the item No are 1-46	

## Module 12: New Biological product development

### Mapped to LFS/N0576, v1

#### Terminal Outcomes:

- Explain the methods of New Biological formulation product development.

<b>Duration:</b> 60:00 hrs	<b>Duration:</b> 90:00 hrs
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Describe the fundamental principles and objectives of biological formulation development in pharmaceuticals.</li> <li>● Explain the regulatory requirements and guidelines governing biological formulation development, including Good Manufacturing Practices (GMP).</li> <li>● Explain the development of exploratory development proposals for innovative product ideas.</li> <li>● Demonstrate the ability to design synthetic processes to produce new biological product, considering efficiency, safety, and scalability.</li> <li>● Discuss the various dosage forms suitable for Biological pharmaceutical products and their advantages and limitations.</li> <li>● Explain the process of optimizing biological formulations to achieve desired drug release profiles and stability.</li> </ul>	<ul style="list-style-type: none"> <li>● Demonstrate Biological formulation development protocols, including selecting appropriate ingredients and dosage forms.</li> <li>● Perform standardization, optimization, and scale-up of new Biological formulation synthesis reactions, adhering to established protocols.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
Colour-coded waste bin bag, colour-coded waste container and As equipment list mentioned in the annexure 2 and the item No are 1-43	

## Module 13: Prepare for technology translation and process development

### Mapped to LFS/N0517, v1

#### Terminal Outcomes:

- Discuss process of technology translation and process development.

<b>Duration: 60:00 hrs</b>	<b>Duration: 90:00 hrs</b>
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Discuss about the QbD approach.</li> <li>● Explain the importance of Qbd.</li> <li>● Discuss the QbD flow in product development.</li> <li>● Discuss about the risk management tools.</li> <li>● Explain in detail about the technology translation process and stages involved in it</li> <li>● Explain the Importance of technology translation.</li> <li>● Discuss about the categories of technology translation.</li> <li>● Discuss about the goals of technology translation.</li> <li>● Discuss about the guidelines for technology translation.</li> <li>● Explain the role and responsibilities of team members of technology translation.</li> </ul>	<ul style="list-style-type: none"> <li>● Discuss how QbD promotes continuous improvement and innovation in pharmaceutical development.</li> <li>● Identify the sequential stages involved in technology translation, from identification to commercialization.</li> <li>● Discuss how technology translation addresses societal challenges and improves the quality of life.</li> <li>● Discuss the specific responsibilities and contributions of each team member to ensure a successful technology translation outcome.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
Sonicator, Hot air oven, Rotary shaker, water bath, Glassware drying oven, Cleaning agents (soap/alconox etc), Centrifuge , Centrifuge tubes, pH meter, conductivity meter, Scale, Magnetic stirrers, Hot plate with magnetic stirrer, LOD bottles, Desiccator, Droppers, Vortex mixer, Lab equipped with Fume Hood and As equipment list mentioned in the annexure 2 and the item No are 1-43	

## Module 14: Prepare for Technology transfer

*Mapped to LFS/N0577, v1*

### Terminal Outcomes:

- Discuss process of technology transfer.

**Duration:** 60:00 hrs

#### Theory – Key Learning Outcomes

- Explain in detail about the technology transfer process and stages involved in it.
- Explain the Importance of technology transfer.
- Discuss about the categories of technology transfer.
- Discuss about the goals of technology transfer.
- Discuss about the guidelines for technology transfer.
- Explain the role and responsibilities of team members of technology transfer.
- Discuss in detail about the following Technology transfer documents like R&D reports for Technology transfer, Product specification file (PSF), Technology transfer plan, Technology Transfer Report (TTR)
- Discuss Verification of results of technology transfer and Technology Transfer Dossier (TTD).

**Duration:** 90:00 hrs

#### Practical – Key Learning Outcomes

- Begin by identifying promising technologies within your organization or research institution.
- Evaluate the feasibility and potential of the technology, considering technical, economic, and market factors.
- Detailed records of research, methodologies, and results, forming the basis for the transfer.

#### Classroom Aids:

Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil

#### Tools, Equipment and Other Requirements

As equipment list mentioned in the annexure 2 and the item No are 1-43

## Module 15: Mass Spectrometry analysis

### Mapped to LFS/N0578, v1

#### Terminal Outcomes:

- Prepare the checklist of chemicals and reagents to be used for Mass Spectrometry.
- Perform sample preparation for Mass Spectrometry.

<b>Duration:</b> 60:00 hrs	<b>Duration:</b> 90:00 hrs
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Explain the properties of different chemicals, reagents and reference standards and working standards used for Mass Spectrometry analysis.</li> <li>● Recall the safety measures to be taken while operating the Mass Spectrometry instrument.</li> <li>● Discuss the analytical calculations required in a Mass Spectrometry analysis.</li> <li>● Discuss the procedures of sample preparation for Mass Spectrometry test analysis.</li> <li>● Explain the scientific principles behind the Mass Spectrometry test performed.</li> <li>● Explain the methods of recording and analysis of Mass Spectrometry.</li> <li>● Explain the concepts of Mass Spectrometry data deviations in case of deviations in the results.</li> </ul>	<ul style="list-style-type: none"> <li>● Prepare a checklist of different chemicals, reagents and working standards required for Mass Spectrometry analysis.</li> <li>● Demonstrate safety measures to be taken while handling chemicals, reagents, working standards and reference materials.</li> <li>● Demonstrate how to perform sample preparation for Mass Spectrometry analysis considering stability and storage requirement.</li> <li>● Demonstrate how to perform sample analysis by Mass Spectrometry.</li> <li>● Record the observations of test results and analyse the data.</li> <li>● Identify data deviations in case of deviation in results and raise/log an incident in the system.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
Sonicator, Hot air oven, Rotary shaker, water bath, Glassware drying oven, Cleaning agents (soap/alconox etc), Centrifuge, Centrifuge tubes, pH meter, conductivity meter, Scale, Magnetic stirrers, Hot plate with magnetic stirrer, LOD bottles, Desiccator, Droppers, Vortex mixer, Lab equipped with Fume Hood	

## Module 16: Nuclear Magnetic Resonance analysis

### Mapped to LFS/N0579, v1

#### Terminal Outcomes:

- Prepare the checklist of chemicals and reagents to be used for Nuclear Magnetic Resonance.
- Perform sample preparation for Nuclear Magnetic Resonance analysis.

<b>Duration:</b> 60:00 hrs	<b>Duration:</b> 90:00 hrs
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Explain the properties of different chemicals, reagents and reference standards and working standards used for Nuclear Magnetic Resonance analysis.</li> <li>● Recall the safety measures to be taken while operating the Nuclear Magnetic Resonance analysis instrument.</li> <li>● Discuss the analytical calculations required in a Nuclear Magnetic Resonance analysis.</li> <li>● Discuss the procedures of sample preparation for Nuclear Magnetic Resonance analysis.</li> <li>● Explain the scientific principles behind the Nuclear Magnetic Resonance analysis test performed.</li> <li>● Explain the methods of recording and analysis of Nuclear Magnetic Resonance analysis.</li> <li>● Explain the concepts of Nuclear Magnetic Resonance analysis data deviations in case of deviations in the results.</li> </ul>	<ul style="list-style-type: none"> <li>● Prepare a checklist of different chemicals, reagents and working standards required for Nuclear Magnetic Resonance analysis.</li> <li>● Demonstrate safety measures to be taken while handling chemicals, reagents, working standards and reference materials.</li> <li>● Demonstrate how to perform sample preparation for Nuclear Magnetic Resonance analysis considering stability and storage requirement.</li> <li>● Demonstrate how to perform sample analysis by Nuclear Magnetic Resonance analysis.</li> <li>● Record the observations of test results and analyse the data.</li> <li>● Identify data deviations in case of deviation in results and raise/log an incident in the system.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
Sonicator, Hot air oven, Rotary shaker, water bath, Glassware drying oven, Cleaning agents (soap/alconox etc), Centrifuge, Centrifuge tubes, pH meter, conductivity meter, Scale, Magnetic stirrers, Hot plate with magnetic stirrer, LOD bottles, Desiccator, Droppers, Vortex mixer, Lab equipped with Fume Hood	

## Module 17: Entrepreneurial activities to start and run the business operations

### Mapped to LFS/N0126, v1

#### Terminal Outcomes:

- Discuss the various steps in setting up a business unit
- Explain the processes and steps to be adopted to run a successful business operation

Duration: 60:00 hrs	Duration: 60:00 hrs
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Discuss the strategies and methodologies to perform a market evaluation to identify a business opportunity</li> <li>● Explain the stages of development of a business proposal and detailed project report.</li> <li>● Discuss various government schemes and non-government funding sources for investment in a business startup and steps to apply for the same</li> <li>● Explain various statutory, legal and regulatory framework applicable in life sciences sector for setting up a business unit</li> <li>● Explain various promotion trends and strategies for promotion of a product or services in life sciences area</li> <li>● Discuss the basic concepts of accounting and taxation rules to be followed by a start up in biotechnology sector</li> <li>● List the elements of a proposal to attract future business opportunities and prospective clients.</li> <li>● Explain how to conduct entrepreneurial programs to identify new business opportunities, generate employment and increase clientele.</li> <li>● Discuss the importance of a quality system like ISO and stages for implementation of ISO system in a start up</li> <li>● Discuss the importance of a carbon credits for environmental sustainability and earning the goodwill and stages for implementation of an environmental sustainability plan in a start up in innovation led enterprises</li> </ul>	<ul style="list-style-type: none"> <li>● Role plays the characteristics of an effective innovation led entrepreneur and leader</li> <li>● Demonstrate on how to identify new business opportunities</li> <li>● Prepare a sample business plan and Detailed Project report (DPR)</li> <li>● Prepare a detailed sample report consisting of information such as future investments, forecasting, business expansion, etc.</li> <li>● Demonstrate the procedure to apply for bank finances</li> <li>● Prepare a sample plan to solve problems and improve productivity at the workplace.</li> <li>● Demonstrate the procedure to operate a computer for digital marketing, e-commerce, branding, etc.</li> <li>● Demonstrate how to sell a product or service on an e-commerce platform with integration of payment gateway</li> <li>● Show how to use services such as NEFT, IMPS, UPI, RTGS for online banking.</li> <li>● Demonstrate the steps to maintain the accounts and ledgers and how to perform reconciliation on an open-source accounting software</li> <li>● Perform a role play for giving presentation about business plan, forecasting, business expansion to seek the investment</li> <li>● Develop a plan to implement a quality system like ISO in a startup.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
As equipment list mentioned in the annexure 2 and the item No are 7,8,9,10,45,46	

## Module 18: Manage the critical documents for business activities and for statutory and regulatory compliance

*Mapped to LFS/N127, v1*

Duration: 10:00 hrs	Duration: 20:00 hrs
<p><b>Theory – Key Learning Outcomes</b></p> <ul style="list-style-type: none"> <li>● Discuss system of documentation as per ISO/ good documentation practices and method of implementation</li> <li>● Explain scoring, grading and accreditation system of affiliating bodies and clients</li> <li>● Explain the guidelines for facing audits and best practices for making organization audit ready</li> <li>● List various types of documents and records to be maintained in the work process</li> <li>● Discuss software and latest information technology tools for documentation and record maintenance</li> <li>● Discuss the use of statistical tools for analysis and monitoring</li> <li>● Elaborate various recording and documentation needs in managing sales, marketing, supply chain etc.</li> <li>● Explain the need for and importance of engineering drawing and architectural layouts</li> <li>● Explain best practices in engineering and maintenance in biotechnology sub sector</li> <li>● Explain accounting standards and regulations</li> <li>● Discuss the standard procedure for reporting and documentation pertaining to production facility / a laboratory/ a trading organization</li> <li>● Discuss the methods of material inspection and vendor audit</li> <li>● Discuss various supply chain management strategies</li> <li>● Discuss the importance of cold chain management and environmental condition control and monitoring for products and services in biotechnology sub sector</li> <li>● Discuss the ways to develop team and leadership always ready for audits and inspection</li> <li>● Discuss the importance of compliance with Statutory, legal and regulatory framework and importance of documentation for each</li> </ul>	<p><b>Practical – Key Learning Outcomes</b></p> <ul style="list-style-type: none"> <li>● Show how to update all the relevant document for future reference</li> <li>● Show how to maintain various material records and other documents such as equipment manuals, manufacturers’ instructions, etc.</li> <li>● Demonstrate the documentation for sales and marketing management for a start up</li> <li>● Demonstrate the documentation for financial management for a start up</li> <li>● Demonstrate the documentation for efficient supply chain and logistics management for a start up</li> <li>● Demonstrate the documentation for sales and marketing management for a start up</li> <li>● Demonstrate through the role play the inspection methods to check and verify the quality of materials received from the vendors as per standards</li> <li>● Employ a situation on how to report and document the safety and non-compliance issues as per the company standards</li> <li>● Perform the simulated role play and sample documentation for compliance with Statutory, legal and regulatory framework applicable in life sciences sector</li> <li>● Demonstrate through role play a simulated audit / inspection by client or regulatory body</li> <li>● Develop an audit response for a sample client inspection report</li> </ul>

inspection and communication with authorities	
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
As equipment list mentioned in the annexure 2 and the item No are 7,8,9,10,11,45,46	

## Module 19: Product commercialization and Intellectual Property Rights Management

*Mapped to LFS/N0128, v1*

<i>Duration: 20:00 hrs</i>	<i>Duration: 100:00 hrs</i>
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Understand the theoretical frameworks of market analysis, pricing strategies, and sales forecasting.</li> <li>● Analyze theoretical models of product life cycles to inform product launch strategies.</li> <li>● Discuss theoretical frameworks in IP management to align IP assets with organizational goals.</li> <li>● Explain concepts of budgeting, financial planning, and resource allocation.</li> <li>● Discuss Theoretical models of market research methodologies, data collection, and analysis.</li> <li>● Discuss concepts of risk identification, assessment, and mitigation.</li> </ul>	<ul style="list-style-type: none"> <li>● Develop a product launch plan that includes market analysis, target audience identification, pricing strategies, and sales forecasts.</li> <li>● Demonstrate, develop and oversee budgets for product development, IP protection, and related activities.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
As equipment list mentioned in the annexure 2 and the item No are 7,8,9,10,45,46,	

## Module 20 : Apprenticeship Training

*Mapped to: Research Associate- Pharma and Biological Products*

**Mandatory Duration:** 00:00 hrs

**Recommended Duration:** 990:00 hrs

**Module Name:** Apprenticeship Training

**Location:** On-Site

### Terminal Outcomes

- Demonstrate proficiency in assisting with the development of biological products, including API synthesis and medicinal chemistry-based research.
- Apply theoretical knowledge and practical skills to actively contribute to the research and development process.
- Execute experiments and protocols with precision and accuracy to support product development.
- Assist in technology transfer and process development activities from research to large-scale manufacturing.
- Contribute to the smooth transition of products from laboratory settings to commercial production.

# Annexure-1

## Trainer Requirements

### Trainer Prerequisites

Minimum Educational Qualification	Specialization	Relevant Industry Experience		Training Experience		Remarks
		Years	Specialization	Years	Specialization	
Postgraduate	M. Sc.	5	Research Associate- Pharma and Biological Products specification	2	on the job assessment/ Training experience/ Vocational assessment/ Academic assessment	
Postgraduate	M.Pharma (with Pharmacognosy Subject) OR M.Tech in (Relevant Field)	7	Research Associate-Pharma and Biological Products Specification	2	on the job assessment/ Training experience/ Vocational assessment/ Academic assessment	
Certificate	NSQF level 5	3	Research Associate-Pharma and Biological Products Specification	1	on the job assessment/ Training experience/ Vocational assessment/ Academic assessment	

### Trainer Certification

Domain Certification	Platform Certification
Certified for job role: “Research Associate-Pharma and Biological Products” mapped to Qualification Pack: “LFS/Q0514, V1.0” 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	
Postgraduate	M.Pharma	6	Research Associate- Pharma and Biological Products specification	2	On the job assessment/ Training experience/ Vocational assessment/ Academic assessment	
Postgraduate	M. Sc. /M.Tech	8	Research Associate- Pharma and Biological Products specification	2	On the job assessment/ Training experience/ Vocational assessment/ Academic assessment	
Certificate	NSQF Level 5	2	Research Associate- Pharma and Biological Products specification	1	On the job assessment/ Training experience/ Vocational assessment/ Academic assessment	

Assessor Certification	
Domain Certification	Platform Certification
Research Associate- Pharma and Biological Products specification mapped to the Qualification Pack: "LFS/Q0514, v1.0" with minimum accepted score of 80%.	Recommended that the Assessor is certified for the Job Role: "Assessor (VET and Skills)", mapped to the Qualification Pack: "MEP/Q2701, v2.0" with minimum score of 80%.

## Assessment Strategy

This section includes the processes involved in identifying, gathering, and interpreting information to evaluate the learner on the required competencies of the program.

The assessment for the Training will be conducted toward the end of the training duration.

### Assessment Process:

For Execution of the assessment for training, LSSSDC will be engaging more than one assessment agency/ body.

#### 1.1 Criteria of selection of assessment body/agency:

The assessment body/agency is selected based on

- Prior experience and understanding of Life Sciences or similar sector.
- Experience in conducting assessments for similar job roles.
- Manpower and Technical capabilities.
- Geographical reach
- Existing Network in the Life Sciences Sector
- Agencies internal policies to maintain standards, quality & professional Integrity
- Agencies policy in assessor management

#### 1.2 Assessment tool for Training:

For the Training assessment, the assessment instrument development is done by the selected assessment body with close monitoring and support of LSSSDC at every stage.

##### 1.2.1 Digital Written test for knowledge assessment:

**Scope** – Is used to test the knowledge component of the Qualification/NOS/Micro credentials.

**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.

##### 1.2.2 Digital Written test for skill assessment:

**Scope** – Is used to test primarily the Skill component of the

Qualification/NOS/Micro credentials. 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.

### **1.3 Steps for assessment development:**

- The selection of assessment tool(s) is done as per the assessment criteria prescribed in Qualification Pack.
- For Research Associate- Pharma and Biological Products 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 Qualification/NOS/Micro credentials 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, and the desired outcome of the assessment.

### **1.4 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:

1.4.1 Tab based assessment using physical proctoring

1.4.2 Smartphone-based assessment using e-proctoring

#### **1.4.1 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.

#### **1.4.2 Smartphone-based assessment using e-proctoring**

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

## References

### Glossary

Term	Description
<b>Declarative Knowledge</b>	Declarative knowledge refers to facts, concepts, and principles that need to be known and/or understood to accomplish a task or to solve a problem.
<b>Key Learning Outcome</b>	The key learning outcome is the statement of what a learner needs to know, understand, and be able to do to achieve the terminal outcomes. A set of key learning outcomes will make up the training outcomes. Training outcome is specified in terms of knowledge, understanding (theory), and skills (practical application).
<b>OJT (M)</b>	On-the-job training (Mandatory); trainees are mandated to complete specified hours of training on-site
<b>Procedural Knowledge</b>	Procedural knowledge addresses how to do something, or how to perform a task. It is the ability to work or produce a tangible work output by applying cognitive, affective, or psychomotor skills.
<b>Training Outcome</b>	Training outcome is a statement of what a learner will know, understand, and be able to do upon the completion of the training.
<b>Terminal Outcome</b>	The terminal outcome is a statement of what a learner will know, understand, and be able to do upon the completion of a module. A set of terminal outcomes helps to achieve the training outcome.

### Acronyms and Abbreviations

Acronym	Description
<b>AA</b>	Assessment Agency
<b>AB</b>	Awarding Body
<b>ISCO</b>	International Standard Classification of Occupations
<b>QP</b>	Qualification Pack
<b>NCO</b>	National Classification of Occupations
<b>NCrF</b>	National Credit Framework
<b>NSQF</b>	National Skills Qualification Framework
<b>NSQC</b>	National Skills Qualification Committee
<b>NOS</b>	National Occupational Standards
<b>AYUSH</b>	Ayurveda, Yoga, Naturopathy, Unani
<b>PPE</b>	Personal Protective Equipment
<b>hrs</b>	Hours

## Annexure -2

S. No.	Tool / Equipment Name	Specification	Quantity for specified Batch size
1	Autoclave	Unit = PC	1
2	Laboratory Microscopes(40X and 100X)	Unit = PC	10
3	pH meter	Unit = PC	1
4	Hot plate with magnetic stirrer	Unit = PC	2
5	analytical balance with printer (sensitivity 0.001 mg, 0.01 mg,0.1 mg,1 mg sensitivity)	Unit = PC	4
6	water bath	Unit = PC	2
7	Computer work desk with LAN	Unit = PC	5
8	LCD Projector	Unit = PC	1
9	White Screen	Unit = PC	1
10	White Board	Unit = PC	1
11	Lab Management Information System (Demonstration)	Demo Version	1
12	Vortex Mixer	Unit = PC	2
13	Micropipette (20 to 200 microlitre)	Unit = PC	2
14	Micropipette (100 to 1000 microlitre)	Unit = PC	2
15	Micropipette (0.5 ml to 5 ml)	Unit = PC	2
16	Biosafety Cabinet	Unit = PC	2
17	Laminar air flow (Vertical)	Unit = PC	2
18	Dry Heat Air Oven	Unit = PC	1
19	Depyrogenation oven	Unit = PC	1
20	Refrigerator	Unit = PC	1
21	Deep freezer	Unit = PC	1
22	CO2 Incubator	Unit = PC	1
23	Laboratory incubator for different temperature range	Unit = PC	1
24	Shaker incubator	Unit = PC	1
25	Garment cubicle	Unit = PC	2
26	Needle burner	Unit = PC	1
27	Hygrometer	Unit = PC	1
28	Heat sealing machine	Unit = PC	1
29	Glass slides	PxT 100	10
30	Half Face Mask	Unit = PC	4
31	Full Face Mask	Unit = PC	4
32	Various Cartridges	1 pcs each type	4
33	Safety Goggles	Unit = PC	30
34	Safety Shoes	Unit = PC	4
35	Gum Boots	Unit = PC	1
36	Chemical Absorbent Roll	Unit = PC	2
37	Self Contained Breathing Apparatus	Unit = PC	2
38	PVC Apron	Unit = PC	2
39	Gloves(Nitrile)	Unit = PC	2
40	Gloves({Heat, acid, chemical} resistant)	Unit = PC	2
41	Gloves(washing)	Unit = PC	2
42	Lab Coat	Unit = PC	30
43	Non sterile Surgical Gloves (in Microbiology)	Unit = PC	2
44	Eye washer with sprinkler	Unit = PC	2
45	Co2 type Fire Extinguisher	Unit = PC	2
46	ABC Type Fire Extinguisher	Unit = PC	2