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## Training Parameters

<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceuticals, Bio Pharmaceuticals, Contract Research
<b>Occupation</b>	Research & Development
<b>Country</b>	India
<b>NSQF Level</b>	5
<b>Aligned to NCO/ISCO/ISIC Code</b>	NCO-2015/3359 NCO-2015/2611.1001
<b>Minimum Educational Qualification and Experience</b>	B.Tech Final Year Student (in Relevant Field) OR B. Pharma final year student OR M.Sc (with relevant Subjects) Final Year Student
<b>Pre-Requisite License or Training</b>	NIL
<b>Minimum Job Entry Age</b>	21 Years
<b>Last Reviewed On</b>	28/07/2022
<b>Next Review Date</b>	28/07/2025
<b>NSQC Approval Date</b>	28/07/2022
<b>QP Version</b>	1.0
<b>Model Curriculum Creation Date</b>	31 March 2022
<b>Model Curriculum Valid Up to Date</b>	28 July 2025
<b>Model Curriculum Version</b>	1.0
<b>Minimum Duration of the Course</b>	Compulsory Notional Hours Theory=180 Hours Practical= 330 Hours Employability Skills= 90 Hours Total Compulsory Notional Hours=600 Hours  <b>Minimum Notional Hours =600 Hours</b>

<b>Maximum Duration of the Course</b>	<p>Compulsory Notional Hours Theory=180 Hours Practical= 330 Hours Employability Skills= 90 Hours <b>Total Compulsory Notional Hours=600 Hours</b></p> <p>Notional Hours for Optional Module Theory= 30 Hours Practical=30 Hours <b>Total Notional Hours for Optional Module= 60 Hours</b></p> <p><b>Max Notional Hours with 1 Option: 660 Hours</b></p> <p>Recommended Apprenticeship Duration=6 months</p>
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## Program Overview

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

### Training Outcomes

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

- Discuss performance of Associate- Regulatory Affairs and Intellectual Property (IVD and Medical Devices) in compliance with Good Manufacturing Practices (GMP) and other environmental regulatory guidelines.
- Explain the fundamentals of the manufacturing process and its various components.
- Demonstrate how to manage production activities across the product line in a life science manufacturing facility.
- Discuss how to maintain a healthy, safe and secure working environment in the production and GMP controlled area.
- Demonstrate how to coordinate with supervisor, colleagues and respond to audit queries during GMP/ regulatory audits.
- Demonstrate sensitivity towards genders, cultures and specially-abled persons.
- Demonstrate the methods of reporting and documentation for regulatory compliance.

**Notional Hours Distribution:**

<b>NOS/ Module Details</b>	<b>Total Duration Hours</b>	<b>Level</b>	<b>Credit</b>
<b>Compulsory Bridge Module</b> Introduction to life sciences industry and applicable regulations & Fundamentals of Research and Development in medical devices and In-vitro Diagnostic Devices (IVD)	<b>30:00</b>	Level-5	1.00
<b>Compulsory Module</b> LFS/N0570 v1.0: Development of Technical Dossier as per the regulatory guidelines of intended market (India and Global) for medical devices and In-vitro Diagnostic Devices (IVD)	<b>120:00</b>	Level-5	4.00
<b>Compulsory Module</b> LFS/N0502 v2.0: Submission of Technical Dossier as per the regulatory guidelines	<b>90:00</b>	Level-5	3.00
<b>Compulsory Module</b> LFS/N0569 v1.0: Assist in managing the regulatory affairs for medical devices and In-vitro Diagnostic Devices (IVD)	<b>120:00</b>	Level-5	4.00
<b>Compulsory Module</b> LFS/N0571 v1.0: Assist in intellectual property rights management for life sciences products and assets	<b>60:00</b>	Level-5	2.00
<b>Compulsory Module</b> LFS/N0567 v1.0: Coordinate with Manager, team-members, cross-functional teams and auditors	<b>60:00</b>	Level-5	2.00
<b>Compulsory Module</b> LFS/N0122 v1.0: Ensure adherence to Environment, health and safety guidelines at workplace by self and subordinates	<b>30:00</b>	Level-5	1.00
<b>DGT/VSQ/N0103: Employability Skills</b>	<b>90:00</b>		3.00
<b>Total Duration (A)</b>	<b>600:00</b>		20.00
<b>Option 1: Regulated Business Operations</b> LFS/N0120 v2.0: Establish own enterprise and perform various entrepreneurial activities to run the business operations in Life Sciences Sector	<b>30:00</b>	Level-5	1.00
<b>Option 1: Regulated Business Operations</b> LFS/N0121 v2.0: Maintain the critical business documents as Entrepreneur in Life Sciences Sector	<b>30:00</b>	Level-5	1.00
<b>Total Duration of Maximum Notional Hours</b>	<b>660:00</b>		
<b>Recommended Apprenticeship</b>	<b>6 Months</b>		

## Details of Modules (Compulsory & Option) and Apprenticeship

### Compulsory Modules

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

NOS and Module Details	Theory Duration	Practical Duration	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration
<b>Bridge Module</b>	<b>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	15:00	00:00	00:00	00:00	15:00
Module 2: Fundamentals of Research and Development in medical devices and In-vitro Diagnostic Devices (IVD)	15:00	00:00	00:00	00:00	15:00
<b>LFS/N0570: Development of Technical Dossier as per the regulatory guidelines of intended market (India and Global) for medical devices and In-vitro Diagnostic Devices (IVD) NOS Version No. 1 NSQF Level-5</b>	<b>30:00</b>	<b>90:00</b>	<b>00:00</b>	<b>00:00</b>	<b>120:00</b>
Module 3: Development of Technical Dossier guidelines for medical devices and In-vitro Diagnostic Devices (IVD)	30:00	90:00	00:00	00:00	120:00
<b>LFS/N0502: Submission of Technical Dossier as per the regulatory guidelines 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: Submission of Technical Dossier as per the regulatory guidelines	30:00	60:00	00:00	00:00	90:00

<b>LFS/N0569: Assist in managing the regulatory affairs for medical devices and In-vitro Diagnostic Devices (IVD) NOS Version No. 1 NSQF Level-5</b>	<b>30:00</b>	<b>90:00</b>	<b>00:00</b>	<b>00:00</b>	<b>120:00</b>
Module 5: Managing the regulatory affairs for medical devices and In-vitro Diagnostic Devices (IVD)	30:00	90:00	00:00	00:00	120:00
<b>LFS/N0571: Assist in intellectual property rights management for life sciences products and assets NOS Version No. 1 NSQF Level-5</b>	<b>30:00</b>	<b>30:00</b>	<b>00:00</b>	<b>00:00</b>	<b>60:00</b>
Module 6: Managing Intellectual property rights for medical devices and In-vitro Diagnostic Devices (IVD)	30:00	30:00	00:00	00:00	60:00
<b>LFS/N0567: Coordinate with Manager, team-members, cross-functional teams and auditors NOS Version No. 1 NSQF Level-5</b>	<b>15:00</b>	<b>45:00</b>	<b>00:00</b>	<b>00:00</b>	<b>60:00</b>
Module 7: Coordination with Manager, teammates and Auditors and display Sensitivity towards genders and people with disability	15:00	45:00	00:00	00:00	60:00
<b>LFS/N0122: Ensure adherence to Environment, health and safety guidelines at workplace by self and subordinates NOS Version No. 1 NSQF Level-5</b>	<b>15:00</b>	<b>15:00</b>	<b>00:00</b>	<b>00:00</b>	<b>30:00</b>
Module 8: Comply EHS rules at workplace	15:00	15:00	00:00	00:00	30:00

<b>DGT/VSQ/N0103 : Employability Skills (90 Hours)</b>					
<b>NOS Version No. 1</b>					
<b>Module 9: Employability Skills</b>					
Introduction to Employability Skills	03:00	00:00	00:00	00:00	01:30
Constitutional values - Citizenship	01:30	00:00	00:00	00:00	01:30
Becoming a Professional in the 21st Century	05:00	00:00	00:00	00:00	02:30
Basic English Skills	10:00	00:00	00:00	00:00	10:00
Career Development & Goal Setting	04:00	00:00	00:00	00:00	02:00
Communication Skills	10:00	00:00	00:00	00:00	05:00
Diversity and Inclusion	02:30	00:00	00:00	00:00	02:30
Financial and Legal Literacy	10:00	00:00	00:00	00:00	05:00
Essential Digital Skills	20:00	00:00	00:00	00:00	10:00
Entrepreneurship	07:00	00:00	00:00	00:00	07:00
Customer Service	09:00	00:00	00:00	00:00	05:00
Getting ready for apprenticeship & Jobs	08:00	00:00	00:00	00:00	08:00
<b>Apprenticeship Training</b>	<b>00:00</b>	<b>00:00</b>	<b>00:00</b>	<b>990:00</b>	<b>990:00</b>
<b>Total Duration</b>	<b>270:00</b>	<b>330:00</b>	<b>00:00</b>	<b>990:00</b>	<b>1560:00</b>

### Optional Modules

The table lists the modules and their duration corresponding to the optional NOSs of the QP.

#### Option 1 : Regulated Business Operations

<b>NOS and Module Details</b>	<b>Theory Duration</b>	<b>Practical Duration</b>	<b>On-the-Job Training Duration (Mandatory )</b>	<b>On-the-Job Training Duration (Recommended)</b>	<b>Total Duration</b>
<b>LFS/N0120 v2.0: Establish own enterprise and perform various entrepreneurial activities to run the business operations in Life Sciences Sector</b>	<b>15:00</b>	<b>15:00</b>	<b>00:00</b>	<b>00:00</b>	<b>30:00</b>

Associate- Regulatory Affairs and Intellectual Property (IVD and Medical Devices)

Module 10: Entrepreneurial activities to start and run the business operations	15:00	15:00	00:00	00:00	30:00
<b>LFS/N0121 v2.0: Maintain the critical business documents as Entrepreneur in Life Sciences Sector</b>	<b>15:00</b>	<b>15:00</b>	<b>00:00</b>	<b>00:00</b>	<b>30:00</b>
Module 11: Manage the critical documents for business activities and for statutory and regulatory compliance	15:00	15:00	00:00	00:00	30:00
<b>Total Duration</b>	<b>30:00</b>	<b>30:00</b>	<b>00:00</b>	<b>00:00</b>	<b>60:00</b>

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

## 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 to Associate- Regulatory Affairs and Intellectual Property (IVD and Medical Devices).
- Discuss the importance of a skilled Associate- Regulatory Affairs and Intellectual Property (IVD and Medical Devices).

<b>Duration:</b> 15:00	<b>Duration:</b> 00:00
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Discuss the Life Sciences industry in Indian and global context.</li> <li>● Discuss the regulatory authorities, regulations, legislation, and good practices (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 Associate- Regulatory Affairs and Intellectual Property (IVD and Medical Devices)</li> <li>● Explain the opportunities of entrepreneurship for Associate-Regulatory Affairs and Intellectual Property (IVD and Medical Devices)</li> </ul>	
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector/ screen, Scanner, Computer speakers, Pencil	
<b>Tools, Equipment and Other Requirements</b>	
N/A	

**Module 2: Fundamentals of Research and Development in medical devices and In-vitro Diagnostic Devices (IVD)**

*Bridge Module*

**Terminal Outcomes:**

- Discuss the fundamental concepts of Research and Development and its various process in case of medical devices and In-vitro Diagnostic Devices (IVD)

<b>Duration:</b> 15:00	<b>Duration:</b> 00:00
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Discuss the basic concepts of biological engineering and biotechnology in the field of medical devices and In-vitro Diagnostic Devices (IVD)</li> <li>● Discuss fundamental science in production of medical devices and In-vitro Diagnostic Devices (IVD)</li> <li>● Explain the role of dossiers to support appropriate licensing, marketing and legal compliance of medical devices and In-vitro Diagnostic Devices (IVD) products and to ensure products comply with current regulations</li> <li>● Explain the proper documentation and reporting for dossier preparation</li> <li>● Demonstrate how to perform job activities of Associate- Regulatory Affairs and Intellectual Property (IVD and Medical Devices) drugs by recalling all the essential concepts of documentation in life sciences manufacturing facilities.</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	

**Module 3: Development of Technical Dossier guidelines for medical devices and In-vitro Diagnostic Devices (IVD)**  
**Mapped to LFS/N0570, v1**

**Terminal Outcomes:**

- Discuss how to develop Technical Dossier guidelines for medical devices and In-vitro Diagnostic Devices (IVD)
- Perform label proofing and artwork review

<b>Duration: 30:00</b>	<b>Duration: 90:00</b>
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Discuss how to Prepare a Design Dossier, ensuring compliance with regulatory and quality framework as per country specific regulatory authority, for CE Marking application or other market authorization applications</li> <li>● Discuss how to Prepare a Clinical Evaluation Report (CER) and performance evaluation report according to regulatory and quality framework as per country specific regulatory authority</li> <li>● Describe the Clinical Evaluation Report (CER) and performance evaluation report according to regulatory and quality framework as per country specific regulatory authority</li> <li>● Explain the basic of Declaration of Conformity (DoC)</li> <li>● Discuss how to create and edit Structured Product Labels using software like pharmaready, Xforms or any other.</li> <li>● Explain label proofing and artwork review with the help of text verification software like TVT or any other.</li> <li>● Discuss how to review and facilitate development of Patient information leaflet (PIL), and package Insert for regulatory dossier of an intended application.</li> </ul>	<ul style="list-style-type: none"> <li>● Identify and prepare Technical Dossier that provides detailed information on your medical device/ in-vitro diagnostic device (IVD) ensuring compliance with regulatory and quality framework as per country specific regulatory authority</li> <li>● Demonstrate label proofing and artwork review with the help of text verification software like TVT or any other.</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>	

## Module 4: Submission of Technical Dossier as per the regulatory guidelines

*Mapped to LFS/N0502, v2*

### Terminal Outcomes:

- Discuss the technical dossier preparation and submissions
- Demonstrate the dossier preparation

<b>Duration: 30:00</b>	<b>Duration: 60:00</b>
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Describe SUGAM portal related to applications and related Common Technical Document (CTD), query escalation and meeting request with Indian regulatory officers</li> <li>● Explain efficient operations of international regulator portal/ software for Submission Management, DLP, SLP and Submission Dispatch, Archival and Troubleshooting during the electronic Common Technical Document (eCTD) filing</li> <li>● Discuss the preparation and submission of dossier for ASEAN countries as per ACTD format of respective country</li> <li>● Explain dossier for US, EU, Canada, GCC, Australia, Switzerland, South Africa, Thailand as per eCTD format of respective country</li> <li>● Explain the dossier format for European region as per vNeeS format</li> </ul>	<ul style="list-style-type: none"> <li>● Read dossier for US, EU, Canada, GCC, Australia, Switzerland, South Africa, Thailand as per eCTD format of respective country</li> <li>● Prepare a dummy dossier as per ASEAN countries</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>	

**Module 5: Managing the regulatory affairs for medical devices and In-vitro Diagnostic Devices (IVD)**

*Mapped to LFS/N0569, v1*

**Terminal Outcomes:**

- Discuss the regulatory affairs for medical devices and In-vitro Diagnostic Devices

<b>Duration: 30:00</b>	<b>Duration: 90:00</b>
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Discuss the submission of investigational device exemption (IDE) for regulatory approval.</li> <li>● Describe the submission of clinical trial applications (CTA) for regulatory approval</li> <li>● Explain the submission of Premarket notification (PMN) application or 510(k) application for class 2 and class 3 devices for regulatory approval</li> <li>● Discuss the submission of De Novo application for novel medical devices without a predicate for regulatory approval.</li> <li>● Discuss the submission of Humanitarian Device Exemption (HDE) application for regulatory approval</li> <li>● Explain the submission of investigational device (medical device/ IVD) application / clinical study approval for regulatory approval for the EU market.</li> <li>● Discuss the submission of the application for manufacturing license for medical device/ In Vitro Diagnostic Device (IVD) from state or national regulatory authority in India as per applicable classification</li> <li>● Describe medical device/ In Vitro Diagnostic Device (IVD) with regulator and get Unique Identification number (UID) either country specific or global as per requirement</li> </ul>	<ul style="list-style-type: none"> <li>● Demonstrate gap assessments for post approval compliance for the data available</li> <li>● Demonstrate compliance checks of current registered information versus manufacturing documentation for licensed medical device/ In Vitro Diagnostic Device (IVD)</li> <li>● Demonstrate the submission of clinical trial applications (CTA) for regulatory approval</li> </ul>

- Discuss Institutional review board (IRB)/ ethics committee approval for clinical trials
- Explain liasoning and filing submission with national pharmaceutical pricing authority (NPPA)

**Classroom Aids:**

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

**Tools, Equipment and Other Requirements**

## Module 6: Managing Intellectual property rights for life sciences

Mapped to LFS/N00571, v1

### Terminal Outcomes:

- Discuss the importance of intellectual property rights
- Demonstrate the IPR management for life sciences products and asset

<b>Duration: 30:00</b>	<b>Duration: 30:00</b>
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Explain the initial understanding of the invention, creating search strategies, executing search strategies.</li> <li>● Explain data collection on products, probable customers and competitors from API Marketing team, IP or secondary sources (IMS, Scifinder, Newport, IPD Analytics).</li> <li>● Describe extracting and evaluating search results, culling, report formation, mapping and result evaluation, rejection summary and visualization through charts</li> <li>● Discuss how to create, update &amp; maintain the required reports with the correct information &amp; naming convention.</li> <li>● Explain the preparation of patent landscape report for Medical Devices/ In-vitro diagnostic devices (IVD) as per organizational need.</li> <li>● Describe the drafting In-house opinion reports for the Invalidation of patents.</li> <li>● Explain drafting patent application for provisional/ non-provisional &amp; complete filing.</li> </ul>	<ul style="list-style-type: none"> <li>● Demonstrate how to collect the relevant information on products, probable customers and competitors from API Marketing team, IP or secondary sources (IMS, Scifinder, Newport, IPD Analytics).</li> <li>● Demonstrate prior Art Search / Patentability Search</li> <li>● Draft patent application for provisional/ non-provisional &amp; complete filing.</li> </ul>
<b>Classroom Aids:</b>	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector/ screen, Computer speakers, Pencil	
<b>Tools, Equipment and Other Requirements</b>	

**Module 7: Coordination with Manager, teammates and Auditors and display Sensitivity towards genders and people with disability**

*Mapped to LFS/N0567, v1*

**Terminal Outcomes:**

- Demonstrate the effective coordination and collaboration with manager, cross-functional teams.
- Describe the prevention of sexual harassment (POSH) rules at the workplace.
- Demonstrate how to respect all genders and cultures at the workplace.

<b>Duration: 15:00</b>	<b>Duration: 45:00</b>
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● List the functional and cross-functional stakeholders for Associate- Regulatory Affairs and Intellectual Property (IVD and Medical Devices)</li> <li>● Discuss various ways for conflict resolution.</li> <li>● Explain the best strategies of collaborating with others.</li> <li>● Describe the problem-solving techniques for routine work-related issues.</li> <li>● Explain the type of audits in the life sciences sector for the 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</li> </ul>	<ul style="list-style-type: none"> <li>● Demonstrate how to effectively communicate and collaborate with various stakeholders (e.g. manager, groups etc.) in a simulated environment for multiple scenarios.</li> <li>● 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>

<p>people with disabilities in compliance with the legal framework.</p> <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>	
N/A	

## Module 8: Comply EHS rules in production and GMP controlled area

Mapped to LFS/N0122, v1

### Terminal Outcomes:

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

Duration: 15:00	Duration: 15:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<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>● Explain the concept and importance of energy conservation</li> <li>● Describe the possible actions to optimize energy consumption and minimize energy wastage.</li> <li>● Explain the concept of environmental pollution and its impact on the health of self, community, and planet.</li> <li>● Describe the possible actions to be taken to minimize environmental pollution at work</li> <li>● Explain various guidelines to be followed for hazardous waste management and disposal of waste.</li> <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> </ul>	<ul style="list-style-type: none"> <li>● Create a checklist of energy conservation practices during and post-work.</li> <li>● Classify waste into recyclable, non-recyclable, and hazardous.</li> <li>● Demonstrate the sustainable waste disposal- process.</li> <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>

<ul style="list-style-type: none"><li>• Discuss the type of safety gears and procedure 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	

## Module 9 : Employability Skills (90 Hours)

Mapped to DGT/VSQ/N0103 – v1.0

**Mandatory Duration: 90:00**

**Module Name: Employability Skills**

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

<https://www.nqr.gov.in/nsqf>

## Module 10: Entrepreneurial activities to start and run the business operations

Mapped to LFS/N0120, v2

### 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: 15:00	Duration: 15:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<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 life sciences 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 startup</li> <li>● Discuss the importance of a carbon credits for environmental sustainability</li> </ul>	<ul style="list-style-type: none"> <li>● Role play the characteristics of an effective 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>

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and earning the goodwill and stages for implementation of a environmental sustainability plan in a start up in life sciences sector	
<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>	

**Module 11: Manage the critical documents for business activities and for statutory and regulatory compliance**

*Mapped to LFS/N0121, v2*

<b>Duration: 15:00</b>	<b>Duration: 15:00</b>
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<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 and importance of engineering drawing and architectural layouts</li> <li>● Explain best practices in engineering and maintenance in life sciences 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</li> </ul>	<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>

condition control and monitoring for products and services in life sciences sector

- Discuss the ways to develop team and leadership always ready for audits and inspection
- Discuss the importance of compliance with Statutory, legal and regulatory framework and importance of documentation for each inspection and communication with authorities

**Classroom Aids:**

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

**Tools, Equipment and Other Requirements**

## Module 12: Apprenticeship Training

*Mapped to Associate- Regulatory Affairs and Intellectual Property (IVD and Medical Devices)*

<b>Mandatory Duration:</b> 00:00	<b>Recommended Duration:</b> 990:00 (6 months)
<b>Module Name:</b> On the Job Training	
<b>Location:</b> On-Site	
<b>Terminal Outcomes</b> <ul style="list-style-type: none"><li>● Monitor the production process in compliance with GMP and other regulatory guidelines.</li><li>● Maintain a healthy, safe and secure working environment in a production facility and GMP controlled area.</li><li>● Coordinate and communicate with Manager, teammates and cross functional teams and auditors.</li><li>● Perform documentation and reported data review for regulatory compliance.</li></ul>	

## Annexure

### Trainer Requirements

Trainer Prerequisites						
Minimum Educational Qualification	Specialization	Relevant Industry Experience		Training Experience		Remarks
		Year s	Specialization	Year s	Specialization	
Graduate	B.Pharma OR B.E./B.Tech (with relevant subjects)	6	Regulatory Affairs and Intellectual Property management for IVD and Medical Devices	1	On the job assessment/ Training experience/ Vocational assessment/ Academic assessment	
Post Graduate	M.Pharma OR M.Sc (Chemistry) OR M.E./M.Tech (with relevant subjects)	4	Regulatory Affairs and Intellectual Property management for IVD and Medical Devices	1	On the job assessment/ Training experience/ Vocational assessment/ Academic assessment	
Trainer Certification						
Domain Certification			Platform Certification			
Certified for Job Role: “Associate-Regulatory Affairs and Intellectual Property (IVD and Medical Devices)” in “LFS/Q0513, 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/2601, v2.0” with minimum score of 80%.			

## Assessor Requirements

Assessor Prerequisites						
Minimum Educational Qualification	Specialization	Relevant Industry Experience		Training/Assessment Experience		Remarks
		Years	Specialization	Years	Specialization	
Graduate	B.Pharma OR B.E./B.Tech (with relevant subjects)	6	Regulatory Affairs and Intellectual Property management for IVD and Medical Devices	2	On the job assessment/ Training experience/ Vocational assessment/ Academic assessment	
Post Graduate	M.Pharma OR M.Sc (Chemistry) OR M.E./M.Tech (with relevant subjects)	4	Regulatory Affairs and Intellectual Property management for IVD and Medical Devices	2	On the job assessment/ Training experience/ Vocational assessment/ Academic assessment	
Assessor Certification						
Domain Certification			Platform Certification			
Certified for Job Role: “Associate-Regulatory Affairs and Intellectual Property (IVD and Medical Devices)” in “LFS/Q0513, 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 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.

##### 1.2.2 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.

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**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 Associate- Regulatory Affairs and Intellectual Property (IVD and Medical Devices) assessment a blueprint of the question paper is part of the assessment tool for training.
- Development of layout of Question paper is such that the entire PCs (Performance Criteria) of that QP are covered.
- Score per question maps with the weightage given to that PC, in the assessment criteria, and the level of difficulty of the question.
- An expert from industry is selected who is called “Subject Matter Expert” (SME). This SME must have over 13-15 years of experience in the industry in pharma R&D occupation.
- SME is screened and approved by LSSSDC. He is oriented by both LSSSDC and Assessment agency on – creating question Bank, level of questions, and the desired outcome of the assessment.

### **2.4 Execution of Training Assessment:**

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

2.4.1 Tab based assessment using physical proctoring

2.4.2 Smartphone-based assessment using e-proctoring

#### **2.4.1 Tab-based assessment using physical proctoring**

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- A representative from the Assessment agency is present on the day of assessment to executing the assessment at the venue in case of physical proctoring.
- The assessment agency representative carries an identity card and letter from the council authorizing to conduct the assessment.
- Assessment agency representative ensures the authenticity of Trainee's identity by verifying the documents (any document issued by GOI, such as Ration card, Aadhaar Card, Driving Licence, Passport, Election card, etc)
- The assessment agency representative maintains the records of attendance, verified documents, and tablet instruments used in the assessment.
- Assessment agency representative collects evidence of the assessment in the best possible way (videos, pictures, voice recordings, etc)
- Assessment agency representative transfers the assessment scores from tab to assessment agency server, using a secure, encrypted web-based program.
- The assessment agency after processing the results and putting them in standard format hands over to LSSSDC within 7 days of assessment.

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

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

## References

## Glossary

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

## Acronyms and Abbreviations

Term	Description
QP	Qualification Pack
NSQF	National Skills Qualification Framework
NSQC	National Skills Qualification Committee
NOS	National Occupational Standards
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
WHO	World Health Organization
SOP	Standard Operating Procedure
MSDS	Material Safety Datasheets
GDP	Good Documentation Practices
EHS	Environment Health Safety
PPE	Personal Protective Equipment