



### Model Curriculum

#### Associate- Regulatory Affairs and Intellectual Property

##### Electives

1. Pharma, Cosmetics, Nutraceuticals & AYUSH
2. Biologics
3. Scientific Writing for Research

##### Options:

1. Regulated Business Operations=60 Hours

QP Code: LFS/Q0501

QP Version: 2.0

NSQF Level: 5

Model Curriculum Version: 1.0

Life Sciences Sector Skill Development Council

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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 NCO-2015/1223.0201
<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>	2.0
<b>Model Curriculum Creation Date</b>	17 August 2021
<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=150 Hours

	<p>Practical= 210 Hours Employability Skills= 90 Hours Total Compulsory Notional Hours=450 Hours</p> <p>3 Electives = 180 Hours each Theory= 60 Hours Practical= 120 Hours <b>Minimum Notional Hours with one elective=630 Hours</b></p>
<p><b>Maximum Duration of the Course</b></p>	<p>Compulsory Notional Hours Theory=150 Hours Practical= 210 Hours Employability Skills= 90 Hours Total Compulsory Notional Hours=450 Hours</p> <p>3 Electives = 180 Hours each Theory= 60 Hours Practical= 120 Hours Total Notional Hours with all 3 electives=990 Hours</p> <p>Notional Hours for Optional Module Theory= 30 Hours Practical= 30 Hours Total Notional Hours for Optional Module= 60 Hours</p> <p><b>Max Notional Hours with 3 elective and 1 Option: 1050 Hours</b></p> <p>Apprenticeship Duration=6 months</p> <p>Note: Apprenticeship is exempted for B. Pharma Students</p>

## 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 (Pharma, Cosmetics and Biologics) 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:

NOS/ Module Details	Total Duration Hours	Level	Credit
<b>Compulsory Bridge Module</b> Introduction to life sciences industry and applicable regulations & Fundamentals of Research and Development in Life Sciences Sector	30:00	Level-5	1.00
<b>Compulsory Module</b> LFS/N0512 v2.0: Development of Technical Dossier as per the regulatory guidelines of intended market (India and Global) for Pharmaceutical (including AYUSH), Cosmetics, Nutraceutical and biologics	120:00	Level-5	4.00
<b>Compulsory Module</b> LFS/N0502 v2.0: Submission of Technical Dossier as per the regulatory guidelines	60:00	Level-5	2.00
<b>Compulsory Module</b> LFS/N0571 v1.0: Assist in intellectual property rights management for life sciences products and assets	60:00	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	30:00	Level-5	1.00
<b>Compulsory Module</b> LFS/N0567 v1.0: Coordinate with Manager, team-members, cross-functional teams and auditors	60:00	Level-5	2.00
<b>DGT/VSQ/N0103: Employability Skills</b>	90:00		3.00
<b>Elective 1: Pharma, Cosmetics, Nutraceuticals &amp; AYUSH</b> LFS/N0501 v2.0: Assist in managing the regulatory affairs for Pharmaceutical (including AYUSH), Cosmetics, and Nutraceutical products	180:00	Level-5	6.00
<b>Elective 2: Biologics</b> LFS/N0568 v1.0: Assist in managing the regulatory affairs for Biologics	180:00	Level-5	6.00
<b>Elective 3: Scientific Writing for Research</b> LFS/N0521 v2.0: Author, edit and maintain scientific documents for research purpose	180:00	Level-5	6.00
<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	30:00	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>	<b>Level-5</b>	<b>1.00</b>
<b>Total Duration of Maximum Notional Hours</b>	<b>1050:00</b>		
<b>Mandatory 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.

<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>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 Life Sciences Sector	15:00	00:00	00:00	00:00	15:00
<b>LFS/N0512: Development of Technical Dossier as per the regulatory guidelines of intended market (India and Global) for Pharmaceutical (including AYUSH), Cosmetics, Nutraceutical and biologics NOS Version No. 2 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	30:00	90:00	00:00	00:00	120:00

guidelines for Pharmaceutical (including AYUSH), Cosmetics, Nutraceutical and Biologics					
<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>30:00</b>	<b>00:00</b>	<b>00:00</b>	<b>60:00</b>
Module 4: Submission of Technical Dossier as per the regulatory guidelines	30:00	30:00	00:00	00:00	60:00
<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 5: Managing Intellectual property rights for life sciences	30:00	30:00	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 6: Comply EHS rules at workplace	15:00	15:00	00:00	00:00	30:00
<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,	15:00	45:00	00:00	00:00	60:00

teammates and Auditors and display Sensitivity towards genders and people with disability					
<b>DGT/VSQ/N0103: Employability Skills (90 Hours)</b>					
<b>NOS Version No. 1</b>					
<b>Module 8: 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>990:00</b>	<b>00:00</b>	<b>990:00</b>
<b>Total Duration</b>	<b>240:00</b>	<b>210:00</b>	<b>990:00</b>	<b>00:00</b>	<b>1410:00</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 NOSs of the QP.

#### Elective 1: Pharma, Cosmetics, Nutraceuticals & AYUSH

NOS and Module Details	Theory Duration	Practical Duration	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration
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<b>LFS/N0501: Assist in managing the regulatory affairs for Pharmaceutical (including AYUSH), Cosmetics, and Nutraceutical products NOS Version No. 2 NSQF Level-5</b>	<b>60:00</b>	<b>120:00</b>	<b>00:00</b>	<b>00:00</b>	<b>180:00</b>
Module 9: Managing the regulatory affairs for Pharmaceutical (including AYUSH), Cosmetics, and Nutraceutical products	60:00	120:00	00:00	00:00	180:00
<b>Total Duration</b>	<b>60:00</b>	<b>120:00</b>	<b>00:00</b>	<b>00:00</b>	<b>180:00</b>

### Elective 2: Biologics

<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/N0568: Assist in managing the regulatory affairs for Biologics NOS Version No. 1 NSQF Level-5</b>	<b>60:00</b>	<b>120:00</b>	<b>00:00</b>	<b>00:00</b>	<b>180:00</b>
Module 10: Managing the Regulatory affairs for Biologics	60:00	120:00	00:00	00:00	180:00
<b>Total Duration</b>	<b>60:00</b>	<b>120:00</b>	<b>00:00</b>	<b>00:00</b>	<b>180:00</b>

### Elective 3: Scientific Writing for Research

<b>NOS and Module Details</b>	<b>Theory Duration</b>	<b>Practical Duration</b>	<b>On-the-Job Training Duration</b>	<b>On-the-Job Training Duration</b>	<b>Total Duration</b>
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			(Mandatory)	(Recommended)	
<b>LFS/N0521: Author, edit and maintain scientific documents for research purpose NOS Version No. 2 NSQF Level-5</b>	<b>60:00</b>	<b>120:00</b>	<b>00:00</b>	<b>00:00</b>	<b>180:00</b>
Module 11: Author, edit and maintain scientific documents for research purpose	60:00	120:00	00:00	00:00	180:00
<b>Total Duration</b>	<b>60:00</b>	<b>120:00</b>	<b>00:00</b>	<b>00:00</b>	<b>180:00</b>

### Optional Modules

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

#### Option 1: Regulated Business Operations

NOS and Module Details	Theory Duration	Practical Duration	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration
<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>
Module 12: 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 13: Manage the critical documents for	15:00	15:00	00:00	00:00	30:00

business activities and for statutory and regulatory compliance					
<b>Total Duration</b>	<b>30:00</b>	<b>30:00</b>	<b>00:00</b>	<b>00:00</b>	<b>60:00</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 to Associate-Regulatory Affairs and Intellectual Property (Pharma, Cosmetics and Biologics).
- Discuss the importance of a skilled Associate- Regulatory Affairs and Intellectual Property (Pharma, Cosmetics and Biologics).

Duration: 15:00	Duration: 00:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<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 (Pharma, Cosmetics and Biologics)</li> <li>● Explain the opportunities of entrepreneurship for Associate-Regulatory Affairs and Intellectual Property (Pharma, Cosmetics and Biologics)</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 Life Sciences Sector

### Bridge Module

#### Terminal Outcomes:

- Discuss the fundamental concepts of Research and Development and its various process.

Duration: 15:00	Duration: 00:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<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 dossiers to support appropriate licensing, marketing and legal compliance of products and 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 (Pharma, Cosmetics and Biologics) drug by recalling all the essential concepts of documentation 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	

### Module 3: Development of Technical Dossier guidelines for Pharmaceutical (including AYUSH), Cosmetics, Nutraceutical and biologics products

*Mapped to LFS/N0512, v2*

#### Terminal Outcomes:

- Explain the methods of technical dossier development
- Discuss how to prepare COA, MOA, TDS etc.

<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>● Explain the collaboration with research team for development of DMF / ASMF as part of Common Technical Document in regulatory dossier for submission of an intended application</li> <li>● Describe how to prepare certificate of analysis (COA), technical data sheet (TDS), material safety data sheet (MSDS), method of analysis (MOA), Checklist (for central insecticide laboratory (CIL) &amp; central insecticide board (CIB)) for product registration.</li> <li>● Describe how to maintain the local database</li> <li>● Discuss how to create and edit Structured Product Labels using software like pharmaready, Xforms or any other</li> <li>● Explain what PIL (Patient information leaflet)</li> </ul>	<ul style="list-style-type: none"> <li>● Demonstrate the use of certificate of analysis (COA), technical data sheet (TDS), material safety data sheet (MSDS), method of analysis (MOA), Checklist (for central insecticide laboratory (CIL) &amp; central insecticide board (CIB)) for product registration.</li> <li>● Demonstrate locally the database of product registration</li> <li>● Demonstrate how to maintain both electronic and manual regulatory dossiers</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>	

Sample dossier

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

*Mapped to LFS/N0502, v2*

### Terminal Outcomes:

- Discuss the technical dossier submissions
- Demonstrate the dossier preparation

<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>● 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 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:</b> 30:00	<b>Duration:</b> 30:00
<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 API/ Formulation and Biological products 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 6: Comply EHS rules at workplace**

*Mapped to LFS/N0122, v1*

**Terminal Outcomes:**

- Explain the health and hygiene protocols to be followed at workplace
- Describe safety, security and emergency procedures at workplace

<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>● 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> </ul>	<ul style="list-style-type: none"> <li>● Create a checklist of energy conservation practices during and post-work.</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>● Demonstrate how to use different types of safety gears by following the procedures to use them.</li> </ul>

- Explain all the emergency procedures for different emergencies.
- Identify evacuation procedures for employees, contract staff and visitors
- 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.
- Discuss the type of safety gears and procedure to use them

**Classroom Aids:**

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

**Tools, Equipment and Other Requirements**

Printouts of WHO guidelines

**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 (Pharma, Cosmetics and Biologics)</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 behavior.</li> <li>● Explain the procedure to report inappropriate behaviour e.g., sexual harassment.</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>

<ul style="list-style-type: none"> <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> <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: 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 the Directorate General of Training (DGT). For further details regarding modules please find at below link.

<https://www.nqr.gov.in/national-skills-qualification-framework>

## Module 9: Managing the regulatory affairs for Pharmaceutical (including AYUSH), Cosmetics, and Nutraceutical products

*Mapped to LFS/N0501, v2*

### Terminal Outcomes:

- Discuss Regulatory facilitation for Licences and Authorization
- Discuss Regulatory facilitation for Miscellaneous Approvals

<b>Duration: 60:00</b>	<b>Duration: 120:00</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 New Drug Application (IND) for regulatory approval</li> <li>● Discuss the submission of Clinical Trial Application (CTA) for regulatory approval.</li> <li>● Explain the regulatory approval for new drug application (NDA)/ New Drug Submission (NDS) for a new pharmaceutical drug product.</li> <li>● Discuss the regulatory approval for abbreviated new drug application (ANDA) / ANDS (Abbreviated New Drug Submission) for a generic drug product.</li> <li>● Explain the regulatory approval for market authorization application (MAA) via centralized procedure (CP) or national procedure (NP) or mutual recognition and decentralized procedure (MRP and DCP)</li> <li>● Describe the regulatory approval for SANDS (Supplement to Abbreviated New Drug Submission) and SNDS (Supplement to a New Drug Submission) for a new brand name drug</li> </ul>	<ul style="list-style-type: none"> <li>● Read the process of submission of Investigational New Drug Application (IND), new drug application (NDA), market authorization application (MAA), abbreviated new drug application (ANDA)</li> <li>● Demonstrate the filing submission with food safety and standards authority of India (FSSAI) for any nutraceutical products, wherever applicable.</li> <li>● Demonstrate compliance checks of current registered information versus manufacturing documentation for licensed medicinal products</li> </ul>

- Discuss how to obtain the certificate of good manufacturing practices from the Indian drug regulatory authority (CDSCO).
- Explain the 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**

Various application forms sample, CDSCO guidelines, SUGAM Portal demo

## Module 10: Managing the Regulatory affairs for Biologics

*Mapped to LFS/N0568, v1*

### Terminal Outcomes:

- Discuss Regulatory facilitation for Licenses and Authorization
- Discuss Regulatory facilitation for Miscellaneous Approvals

<b>Duration: 60:00</b>	<b>Duration: 120:00</b>
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Discuss the process of submission of Investigational New Drug Application (IND) for regulatory approval</li> <li>● Discuss the submission of Clinical Trial Application (CTA) for regulatory approval.</li> <li>● Explain the regulatory approval for biologics license application (BLA) for a new biological drug product.</li> <li>● Discuss the regulatory approval for market authorization application (MAA) via Gulf Cooperation Council procedure (GCC)</li> <li>● Explain regulatory approval for New Drug Submission (NDS) / for a new brand name drug</li> <li>● Describe the regulatory approval for SANDS (Supplement to Abbreviated New Drug Submission) and SNDS (Supplement to a New Drug Submission) for a new brand name drug</li> <li>● Explain CMC assessments for gap</li> <li>● Discuss control review and management while implementation of vendor changes, change in plant machineries, pharmacopeia updates or any process changes etc.</li> <li>● Discuss Development Safety Update Reports (DSURs), Periodic Benefit Risk Evaluation</li> </ul>	<ul style="list-style-type: none"> <li>● Perform dummy CMC assessments for gap</li> <li>● Perform dummy compliance checks of current registered information versus manufacturing documentation for licensed biologics</li> <li>● Read Development Safety Update Reports (DSURs), Periodic Benefit Risk Evaluation Reports (PBRERs) and Risk Management Plans (RMPs) available on internet</li> </ul>

Reports (PBRERs) and Risk Management Plans (RMPs)	
<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>	
Various application forms sample, CDSCO guidelines, SUGAM Portal demo	

## Module 11: Author, edit and maintain scientific documents for research purpose

*Mapped to LFS/N0521, v2*

### Terminal Outcomes:

- Discuss how to author, edit and maintain scientific documents for research purpose
- Perform medical writing activities

<b>Duration: 60:00</b>	<b>Duration: 120:00</b>
<b>Theory – Key Learning Outcomes</b>	<b>Practical – Key Learning Outcomes</b>
<ul style="list-style-type: none"> <li>● Discuss how to author and maintain documents that regulatory agencies require in the approval process for drugs, devices and biologics.</li> <li>● Discuss assisting in drafting the investigator's brochure and updates once clinical strategy is finalized.</li> <li>● Explain the development of clinical trial protocols.</li> <li>● Discuss how to author and edit clinical study reports for phase 1-4 trials, including full study reports and abbreviated reports</li> <li>● Explain the medical writing activities on the assigned project in a timely and efficient manner.</li> <li>● Explain the medical writing activities using manuscripts of ancient Vedic literature while working on the AYUSH medical writing projects</li> <li>● Discuss governmental regulations and company sops for document preparation</li> <li>● Explain marketing authorization submissions accurately and consistently</li> </ul>	<ul style="list-style-type: none"> <li>● Demonstrate the medical writing activities on the assigned project in a timely and efficient manner.</li> <li>● Read medical journal/articles/programs as per the scientific journal standards for nurses, physicians and pharmacists for continuing medical education (CME).</li> <li>● coordinate with various technical professionals to gather, organize and compile information on new products or processes</li> </ul>

present key clinical messages in accordance with program goals and regulatory requirements	
<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>	
Sample Clinical Trials report	

## Module 12: Entrepreneurial activities to start and run the business operations

*Mapped to LFS/N0120, 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

<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 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</li> </ul>	<ul style="list-style-type: none"> <li>● Role plays 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</li> </ul>

<p>opportunities, generate employment and increase clientele.</p> <ul style="list-style-type: none"> <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 a environmental sustainability plan in a start up in life sciences sector</li> </ul>	<p>perform reconciliation on an open source accounting software</p> <ul style="list-style-type: none"> <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>	
NA	

## Module 13: Manage the critical documents for business activities and for statutory and regulatory compliance

*Mapped to LFS/N0121, v1*

Duration: 15:00	Duration: 15:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<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 life sciences sector</li> <li>● Explain accounting standards and regulations</li> <li>● Discuss the standard procedure for reporting and documentation pertaining to</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> </ul>

<p>production facility / a laboratory/ a trading organization</p> <ul style="list-style-type: none"> <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 life sciences 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 inspection and communication with authorities</li> </ul>	<ul style="list-style-type: none"> <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>
<p><b>Classroom Aids:</b></p>	
<p>Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil</p>	
<p><b>Tools, Equipment and Other Requirements</b></p>	
<p>NA</p>	

## Module 14: Apprenticeship Training

*Mapped to Associate- Regulatory Affairs and Intellectual Property*

<b>Mandatory Duration: 990:00 (6 months)</b>	<b>Recommended Duration: 00:00</b>
<b>Module Name: On the Job Training</b>	
<b>Location: On-Site</b>	
<b>Terminal Outcomes</b>	
<ul style="list-style-type: none"><li>● Explain 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><li>● Manage regulatory affairs guidelines for either one of following:<ol style="list-style-type: none"><li>1. Regulatory Affairs for Pharma, Cosmetics and Nutraceuticals (including AYUSH)</li><li>2. Regulatory Affairs for Biologics</li><li>3. Scientific Writing for Research</li></ol></li></ul>	



## Annexure - 1

### 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 Pharma, Cosmetics and Biologics products	2	On the job assessment/ Training experience/ Vocational assessment/ Academic assessment	
Postgraduate	M. Pharma OR M. Sc (Chemistry) OR M.E./M. Tech (with relevant subjects)	4	Regulatory Affairs and Intellectual Property Management for Pharma, Cosmetics and Biologics products	2	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” in any one 1. Pharma, Cosmetics, Nutraceuticals & AYUSH 2. Biologics 3. Scientific Writing for Research: “LFS/Q0501, v2.0” 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, v1.0” 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 Pharma, Cosmetics and Biologics products	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 Pharma, Cosmetics and Biologics products	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” in any one 1. Pharma, Cosmetics, Nutraceuticals & AYUSH 2. Biologics 3. Scientific Writing for Research: “LFS/Q0501, v2.0” 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, v1.0” with minimum score of 80%.			

## Assessment Strategy

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

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

### Assessment Process:

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

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

The assessment body/agency is selected based on

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

#### 1.2 Assessment tool for Training:

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

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

**Scope** – Is used to test the knowledge component of the QP.

**Tools** –computer or tab based online or offline.

**Method** – objective type questions, match the columns, fill in the blanks, tick the odd man out, choose the correct option, choose the best answer, True or false, Identify the object, tool or machinery, arrange in proper sequence, case study, scenario-based responses.

**Analysis** – Question paper is divided into sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section-wise calculation of marks gives a clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.

### 2.2.2 Digital Written test for skill assessment:

**Scope** – Is used to test primarily the Skill component of the QP. Trainee’s expertise in handling and managing the situation is tested.

**Tools** – computer or tab based online or offline questions

**Method** – A situation is narrated or created in the question posed to the trainee and he is asked objective type questions to select the correct reaction to the situation. The selected situations are based on real situations.

**Analysis** – Question paper is divided into sections. Each Section intends to assess a particular skill field of the trainee. Thus, section-wise calculation of marks gives a clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.

### 2.3 Steps for assessment development:

- The selection of assessment tool(s) is done as per the assessment criteria prescribed in Qualification Pack.
- For Associate- Regulatory Affairs and Intellectual Property (Pharma, Cosmetics and Biologics) 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, end the desired outcome of the assessment.

## 2.4 Execution of Training Assessment:

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

### 2.4.1 Tab based assessment using physical proctoring

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

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

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

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

- All trainees due for assessments are registered on an assessment tool application using their unique mobile number and e-mail ID along with a Govt. ID issued proof.
- An assessment link is sent to the mail ID of each trainee with a defined expiry date of the link.

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

## Annexure -2

### Model Curriculum for Employability Skills

#### 1. Employability Skills (60 hours)

Learning outcomes, assessment criteria, syllabus and Tool List of Employability Skills which is common for all sectors, provided separately in

<https://www.nqr.gov.in/national-skills-qualification-framework>

## 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