Qualification Pack


# Associate- Regulatory Affairs and Intellectual Property

Pharma, Cosmetics, Nutraceuticals & AYUSH

Regulated Business Operations

QP Code: LFS/Q0501  Instantiated QP Code: LFS/Q0501-SI004

Version: 2.0

NSQF Level: 5

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Life Sciences Sector Skill Development Council || # 14, Rear 2nd Floor, Palam Marg, Vasant Vihar New Delhi-110057 || email:SHIVI.CHAUDHARY@LSSSDC.IN

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# LFS/Q0501-SI004: Associate- Regulatory Affairs and Intellectual Property

## Brief Job Description

Associate- Regulatory Affairs and Intellectual Property, prepares dossiers to support appropriate licensing, marketing and legal compliance of products and ensure products comply with current regulations. The job role holder carries out proper documentation and reporting for dossier preparation and assist in intellectual property management. This job role holder can also set up his own consulting business in regulatory affairs.

## Personal Attributes

Job role holder is expected to have orientation to detail and high level of customer centricity. He/she should have excellent communication and negotiation skills. As this job requires interacting across stakeholder hence good interpersonal skills and planning and organizing skills are needed. The person should have excellent problem solving and decision making skills.

## Applicable National Occupational Standards (NOS)

### Compulsory NOS:

1. 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

2. LFS/N0502: Submission of Technical Dossier as per the regulatory guidelines

3. LFS/N0571: Assist in intellectual property rights management for life sciences products and assets

4. LFS/N0122: Ensure adherence to Environment, health and safety guidelines at the workplace by self and subordinates

5. LFS/N0567: Coordinate with Manager, R&D team, other cross-functional teams, external stakeholders and regulatory agencies to manage regulatory affairs operations

6. DGT/VSQ/N0103: Employability Skills (90 Hours)

### Electives*(mandatory to select at least one):*

Elective : Pharma, Cosmetics, Nutraceuticals & AYUSH

1. LFS/N0501: Assist in managing the regulatory affairs for Pharmaceutical (including AYUSH), Cosmetics, and Nutraceutical products

### Options*(Not mandatory):*

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Option : Regulated Business Operations

1. LFS/N0120: Establish own enterprise and perform various entrepreneurial activities to run the business operations in Life Sciences Sector

2. LFS/N0121: Maintain the critical business documents as Entrepreneur in Life Sciences Sector

## Qualification Pack (QP) Parameters

| | |
|---|---|
| **Sector** | Life Sciences |
| **Sub-Sector** | Pharmaceutical, Bio Pharmaceutical and Contract Research |
| **Occupation** | Research and Development |
| **Country** | India |
| **NSQF Level** | 5 |
| **Credits** | 23 |
| **Aligned to NCO/ISCO/ISIC Code** | NCO-2015/2641.0901 |
| **Minimum Educational Qualification & Experience** | B.Tech (Final Year Student (in Relevant Field))<br>OR<br>B.Pharma (final year student )<br>OR<br>M.Sc ((with relevant Subjects) Final Year Student) |
| **Minimum Level of Education for Training in School** | Not Applicable |
| **Pre-Requisite License or Training** | NA |
| **Minimum Job Entry Age** | 21 Years |
| **Last Reviewed On** | NA |
| **Next Review Date** | 28/07/2025 |
| **NSQC Approval Date** | 28/07/2022 |
| **Version** | 2.0 |
| **Reference code on NQR** | QM -05-LS-00252-2023-V1.1-LSSSDC |
| **NQR Version** | 1 |

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# 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

## Description

This NOS is about a job holder involved in the Development of Technical Dossier as per the regulatory guidelines of intended market (India and Global) for Pharmaceutical (including AYUSH), Cosmetics, Nutraceutical and Biologics

## Scope

The scope covers the following :

- Regulatory Dossier Preparation
- Regulatory compliance for labelling and inserts

## Elements and Performance Criteria

*Regulatory Dossier Preparation*

To be competent, the user/individual on the job must be able to:

**PC1.** collaborate with internal stakeholders (manufacturing, R&D, stability) to compile quality dossiers timely, as per country specific requirements.

**PC2.** collaborate with research team for development of DMF / ASMF as part of Common Technical Document in regulatory dossier for submission of an intended application

**PC3.** facilitate in preparation of certificate of analysis (COA), technical data sheet (TDS), material safety data sheet (MSDS), method of analysis (MOA), Checklist (for central insecticide laboratory (CIL) & central insecticide board (CIB)) for product registration.

**PC4.** maintain locally the database of product registration

*Regulatory compliance for labelling and inserts*

To be competent, the user/individual on the job must be able to:

**PC5.** outline requirements for labelling, storage and packaging as per regulatory requirements

**PC6.** keeping a check on label content and leaflets as per regulatory norms (Label proofing & Artwork)

**PC7.** create and edit Structured Product Labels using software like pharmaready, Xforms or any other

**PC8.** perform label proofing and artwork review with the help of text verification software like TVT or any other.

**PC9.** review and facilitate development of Patient information leaflet (PIL), and package Insert for regulatory dossier of an intended application

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

**KU1.** common technical documents in regulatory dossier for submission of an application

**KU2.** Certificate of analysis (COA),Material safety data sheet (MSDS) ,Method of analysis (MOA), Checklist (for central insecticide laboratory (CIL) & central insecticide board (CIB)) for product registration

**KU3.** organizational coding system and company manual

**KU4.** types of documentation in organization, importance of maintaining the same and different methods of recording information.

**KU5.** PIL (Patient information leaflet) and Package insert for regulatory dossier

**KU6.** clinical trial process and good clinical practices

**KU7.** use of computer/application software

**KU8.** processing of information by compiling, coding, categorizing, auditing or verifying data.

**KU9.** ability to relate individual elements of clinical development programs to specific needs for document preparation and production

**KU10.** different regulatory documents reports, forms, plans associated with product quality and compliance as required by different regulatory agencies

**KU11.** knowledge of regulation requirements and approval processes.

**KU12.** knowledge of pharmaceutical dossiers like the master formula of the product, manufacturing procedure and the equipments list used in the production, the Stability data, preclinical and clinical data, specifications used in testing the final product and other regulatory documents

**KU13.** different quality management systems, good laboratory and manufacturing practices.

## Generic Skills (GS)

User/individual on the job needs to know how to:

**GS1.** use written communication skills to record information accurately in compliance with ALCOA principles as per SOP and regulatory guidelines in the English language

**GS2.** use reading and comprehension skills to read the various coding systems, instructions, prescription, guidelines, procedures, rules, and signage

**GS3.** use listening skills to interpret the instructions, procedures, and alarms

**GS4.** use verbal communication skills to interact with supervisor, teammates, cross-functional teams and customers as applicable

**GS5.** apply problem-solving skills to find solutions for workflow-related difficulties

**GS6.** apply planning and organizing skills to plan and organize tools and material required to fulfil documentation related requirements

**GS7.** apply critical thinking skills to analyse and identify what and when to report an issue/concern to the supervisor/ Clinical research team/ QA team / any other stakeholder

**GS8.** apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations

## Assessment Criteria

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| *Regulatory Dossier Preparation* | **15** | **30** | **10** | **5** |
| **PC1.** collaborate with internal stakeholders (manufacturing, R&D, stability) to compile quality dossiers timely, as per country specific requirements. | - | - | - | - |
| **PC2.** collaborate with research team for development of DMF / ASMF as part of Common Technical Document in regulatory dossier for submission of an intended application | - | - | - | - |
| **PC3.** facilitate in preparation of certificate of analysis (COA), technical data sheet (TDS), material safety data sheet (MSDS), method of analysis (MOA), Checklist (for central insecticide laboratory (CIL) & central insecticide board (CIB)) for product registration. | - | - | - | - |
| **PC4.** maintain locally the database of product registration | - | - | - | - |
| *Regulatory compliance for labelling and inserts* | **10** | **15** | **10** | **5** |
| **PC5.** outline requirements for labelling, storage and packaging as per regulatory requirements | - | - | - | - |
| **PC6.** keeping a check on label content and leaflets as per regulatory norms (Label proofing & Artwork) | - | - | - | - |
| **PC7.** create and edit Structured Product Labels using software like pharmaready, Xforms or any other | - | - | - | - |
| **PC8.** perform label proofing and artwork review with the help of text verification software like TVT or any other. | - | - | - | - |
| **PC9.** review and facilitate development of Patient information leaflet (PIL), and package Insert for regulatory dossier of an intended application | - | - | - | - |
| **NOS Total** | **25** | **45** | **20** | **10** |

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## National Occupational Standards (NOS) Parameters

| | |
|---|---|
| **NOS Code** | LFS/N0512 |
| **NOS Name** | Development of Technical Dossier as per the regulatory guidelines of intended market (India and Global) for Pharmaceutical (including AYUSH), Cosmetics, Nutraceutical and Biologics |
| **Sector** | Life Sciences |
| **Sub-Sector** | Pharmaceutical, Bio Pharmaceutical and Contract Research |
| **Occupation** | Research and Development |
| **NSQF Level** | 5 |
| **Credits** | 4.00 |
| **Version** | 2.0 |
| **Last Reviewed Date** | NA |
| **Next Review Date** | 28/07/2025 |
| **NSQC Clearance Date** | 28/07/2022 |

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# LFS/N0502: Submission of Technical Dossier as per the regulatory guidelines

## Description

This NOS is about a person involved in the Submission of Technical Dossier as per the regulatory guidelines

## Scope

The scope covers the following :

- Operating the Regulatory Systems
- Regulatory Dossier Submission

## Elements and Performance Criteria

*Operating the Regulatory Systems*

To be competent, the user/individual on the job must be able to:

**PC1.** register the organization on SUGAM portal of Indian national regulator.

**PC2.** perform various operations on SUGAM portal related to applications and related Common Technical Document (CTD), query escalation and meeting request with Indian regulatory officers

**PC3.** register the organization on portal of regulator of intended market/ country

**PC4.** perform various operations on international regulator portal/ software (like electronic submission gateway (ESG), Common European Submission Portal (CESP), eSubmission gateway etc.) related to applications, query escalation and supplement/ amendment submissions as well as for tracking the application status

**PC5.** ensure 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.

**PC6.** ensure eCTD Validation Criteria, ICH Study Tagging Files (ICH STF) specifications and Submission Transmission Specifications ae met while submitting the eCTD.

**PC7.** ensure mitigation of risk in eCTD publishing.

*Regulatory Dossier Submission*

To be competent, the user/individual on the job must be able to:

**PC8.** prepare and submit dossier for ASEAN countries as per ACTD format of respective country

**PC9.** prepare and submit dossier for US, EU, Canada, GCC, Australia, Switzerland, South Africa, Thailand as per eCTD format of respective country

**PC10.** prepare and submit dossier for Australia, New Zealand, EU, Canada, GCC, Bosnia and Herzegovina as per NeeS format of respective country

**PC11.** prepare and submit dossier for Emerging market like LATAM, MENA, APAC, ASEAN, and CIS region as per pCTD format of respective country

**PC12.** prepare and submit dossier for European region as per vNeeS format

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

**KU1.** different quality management systems (ISO-9000, ISO-14001, OHSAS-18000), good laboratory and manufacturing practices

**KU2.** Dossier preparation in eCTD format, NeeS format, ICH-CTD and their respective submission guidelines

**KU3.** guidelines for submission of eCTD on SUGAM portal

**KU4.** use of computer and application Software

**KU5.** Indian regulatory guidelines

**KU6.** ICH study tagging Files (ICH STF), eCTD validation criteria and submission transmission specification

**KU7.** various international regulatory guidelines and their portal

**KU8.** dossier for emerging market like LATAM, MENA, APAC, ASEAN and CIS region

**KU9.** reporting incidents where standard operating procedures are not followed

**KU10.** the importance of complete and accurate documentation

**KU11.** knowledge of pharmaceutical dossiers like the master formula of the product, manufacturing procedure and the equipments list used in the production, the Stability data, preclinical and clinical data, specifications used in testing the final product and other regulatory documents

**KU12.** training in necessary procedures for filing licenses and liaising with regulatory authorities

**KU13.** good Knowledge of GMP, GCP and Safety requirements

## Generic Skills (GS)

User/individual on the job needs to know how to:

**GS1.** use written communication skills to record information accurately in compliance with ALCOA principles as per SOP and regulatory guidelines in the English language

**GS2.** use reading and comprehension skills to read the various coding systems, instructions, guidelines, procedures, rules, and signage

**GS3.** use listening skills to interpret the instructions, procedures, and alarms

**GS4.** use verbal communication skills to interact with supervisor, teammates and cross-functional teams

**GS5.** apply critical thinking skills to analyse and identify what and when to report an issue/concern to the supervisor/ regulatory team/ QA Team / any other stakeholder

**GS6.** apply problem-solving skills to find solutions for workflow-related difficulties

**GS7.** apply planning and organizing skills to plan and organize tools and material required to fulfil documentation related requirements

## Assessment Criteria

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| *Operating the Regulatory Systems* | **20** | **30** | **9** | **-1** |
| **PC1.** register the organization on SUGAM portal of Indian national regulator. | - | - | - | - |
| **PC2.** perform various operations on SUGAM portal related to applications and related Common Technical Document (CTD), query escalation and meeting request with Indian regulatory officers | - | - | - | - |
| **PC3.** register the organization on portal of regulator of intended market/ country | - | - | - | - |
| **PC4.** perform various operations on international regulator portal/ software (like electronic submission gateway (ESG), Common European Submission Portal (CESP), eSubmission gateway etc.) related to applications, query escalation and supplement/ amendment submissions as well as for tracking the application status | - | - | - | - |
| **PC5.** ensure 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. | - | - | - | - |
| **PC6.** ensure eCTD Validation Criteria, ICH Study Tagging Files (ICH STF) specifications and Submission Transmission Specifications ae met while submitting the eCTD. | - | - | - | - |
| **PC7.** ensure mitigation of risk in eCTD publishing. | - | - | - | - |
| *Regulatory Dossier Submission* | **10** | **20** | **3** | **6** |
| **PC8.** prepare and submit dossier for ASEAN countries as per ACTD format of respective country | - | - | - | - |
| **PC9.** prepare and submit dossier for US, EU, Canada, GCC, Australia, Switzerland, South Africa, Thailand as per eCTD format of respective country | - | - | - | - |

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| **PC10.** prepare and submit dossier for Australia, New Zealand, EU, Canada, GCC, Bosnia and Herzegovina as per NeeS format of respective country | - | - | - | - |
| **PC11.** prepare and submit dossier for Emerging market like LATAM, MENA, APAC, ASEAN, and CIS region as per pCTD format of respective country | - | - | - | - |
| **PC12.** prepare and submit dossier for European region as per vNeeS format | - | - | - | - |
| **NOS Total** | **30** | **50** | **12** | **5** |

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## National Occupational Standards (NOS) Parameters

| | |
|---|---|
| **NOS Code** | LFS/N0502 |
| **NOS Name** | Submission of Technical Dossier as per the regulatory guidelines |
| **Sector** | Life Sciences |
| **Sub-Sector** | Pharmaceutical, Bio Pharmaceutical and Contract Research |
| **Occupation** | Research and Development |
| **NSQF Level** | 5 |
| **Credits** | 2.00 |
| **Version** | 2.0 |
| **Last Reviewed Date** | NA |
| **Next Review Date** | 28/07/2025 |
| **NSQC Clearance Date** | 28/07/2022 |

# LFS/N0571: Assist in intellectual property rights management for life sciences products and assets

## Description

This unit is about a person who assists in intellectual property rights management for life sciences products and assets

## Scope

The scope covers the following :

- IPR Management

## Elements and Performance Criteria

*IPR Management*

To be competent, the user/individual on the job must be able to:

**PC1.** develop initial understanding of the invention, creating search strategies, executing search strategies.

**PC2.** conduct comprehensive patent searches of technical and patent information using online database and other information resources.

**PC3.** collect the relevant information on products, probable customers and competitors from API Marketing team, IP or secondary sources (IMS, Scifinder, Newport, IPD Analytics).

**PC4.** perform prior Art Search / Patentability Search by using various paid and freely available databases

**PC5.** perform extracting and evaluating search results, culling, report formation, mapping and result evaluation, rejection summary and visualization through charts

**PC6.** create, update & maintain the required reports with the correct information & naming convention.

**PC7.** perform patent infringement analysis for various jurisdiction.

**PC8.** assist in preliminary evaluation based on sales projection, possible competitors, expert comments for the success of molecule, IP Analysis etc.

**PC9.** assist in preparation of patent landscape report for API/ Formulation/ Biological products/ Medical Devices/ In-vitro diagnostic devices (IVD) as per organizational need.

**PC10.** assist in drafting In-house opinion reports for the Invalidation of patents.

**PC11.** facilitate in providing clearance reports for various markets.

**PC12.** draft patent application for provisional/ non provisional & complete filing.

**PC13.** assist in prosecution of patent application in collaboration with legal department for national and global markets

**PC14.** liaise with multiple organizational functions like legal, regulatory affairs, research& development, medical affairs, marketing team to gather and validate cross-functional inputs required for decision making

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

**KU1.** Intellectual Property Rights and its types- Patents, Copyrights, Trademarks, etc.
**KU2.** intellectual property laws in India and in Global market
**KU3.** procedure for filing the copyright for intellectual assets in India and in Global market
**KU4.** how to operate software tools like IMS, Scifinder, Newport, IPD Analytics
**KU5.** patent infringement analysis and how to defend the IPR in court of law
**KU6.** how to liaising for various IPR related matters with cross functional colleagues like product marketing, QA, Production, R&D, legal etc.
**KU7.** process of obtaining patents and trademarks
**KU8.** various licensing scenarios: cross-licensing, inbound licensing and out-bound licensing
**KU9.** impact of IPR on regulatory affairs

## Generic Skills (GS)

User/individual on the job needs to know how to:

**GS1.** use written communication skills to record information accurately in compliance with ALCOA principles as per SOP and regulatory guidelines in the English language
**GS2.** use reading and comprehension skills to read the various coding systems, instructions, guidelines, procedures, rules, and signage
**GS3.** use listening skills to interpret the instructions, procedures, and alarms
**GS4.** use verbal communication skills to interact with supervisor, teammates, cross-functional teams and customers as applicable
**GS5.** apply problem-solving skills to find solutions for workflow-related difficulties
**GS6.** apply planning and organizing skills to plan and organize tools and material required to fulfil documentation related requirements
**GS7.** apply critical thinking skills to analyse and identify what and when to report an issue/concern to the supervisor/ regulatory team / QA team / any other stakeholder
**GS8.** apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations

## Assessment Criteria

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| *IPR Management* | **30** | **50** | **10** | **10** |
| **PC1.** develop initial understanding of the invention, creating search strategies, executing search strategies. | - | - | - | - |
| **PC2.** conduct comprehensive patent searches of technical and patent information using online database and other information resources. | - | - | - | - |
| **PC3.** collect the relevant information on products, probable customers and competitors from API Marketing team, IP or secondary sources (IMS, Scifinder, Newport, IPD Analytics). | - | - | - | - |
| **PC4.** perform prior Art Search / Patentability Search by using various paid and freely available databases | - | - | - | - |
| **PC5.** perform extracting and evaluating search results, culling, report formation, mapping and result evaluation, rejection summary and visualization through charts | - | - | - | - |
| **PC6.** create, update & maintain the required reports with the correct information & naming convention. | - | - | - | - |
| **PC7.** perform patent infringement analysis for various jurisdiction. | - | - | - | - |
| **PC8.** assist in preliminary evaluation based on sales projection, possible competitors, expert comments for the success of molecule, IP Analysis etc. | - | - | - | - |
| **PC9.** assist in preparation of patent landscape report for API/ Formulation/ Biological products/ Medical Devices/ In-vitro diagnostic devices (IVD) as per organizational need. | - | - | - | - |
| **PC10.** assist in drafting In-house opinion reports for the Invalidation of patents. | - | - | - | - |

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| **PC11.** facilitate in providing clearance reports for various markets. | - | - | - | - |
| **PC12.** draft patent application for provisional/ non provisional & complete filing. | - | - | - | - |
| **PC13.** assist in prosecution of patent application in collaboration with legal department for national and global markets | - | - | - | - |
| **PC14.** liaise with multiple organizational functions like legal, regulatory affairs, research& development, medical affairs, marketing team to gather and validate cross-functional inputs required for decision making | - | - | - | - |
| **NOS Total** | **30** | **50** | **10** | **10** |

## National Occupational Standards (NOS) Parameters

| | |
|---|---|
| **NOS Code** | LFS/N0571 |
| **NOS Name** | Assist in intellectual property rights management for life sciences products and assets |
| **Sector** | Life Sciences |
| **Sub-Sector** | Pharmaceutical, Bio Pharmaceutical, Contract Research |
| **Occupation** | Research and Development |
| **NSQF Level** | 5 |
| **Credits** | 2.00 |
| **Version** | 1.0 |
| **Last Reviewed Date** | NA |
| **Next Review Date** | 28/07/2025 |
| **NSQC Clearance Date** | 28/07/2022 |

# LFS/N0122: Ensure adherence to Environment, health and safety guidelines at the workplace by self and subordinates

## Description

This NOS is about a person who Ensure adherence to Environment, health and safety guidelines at the workplace by self and subordinates

## Scope

The scope covers the following :

- Adhere to health and hygiene protocols
- Adhere to safety and security procedures
- Adhere to emergency procedures
- Environment Sustainability

## Elements and Performance Criteria

*Adhere to health and hygiene protocols*

To be competent, the user/individual on the job must be able to:

**PC1.** comply with health and personal hygiene-related protocols as per WHO standards and ICH GMP guidelines

**PC2.** sanitize your hands and follow cleanroom protocol, if applicable before entering in laboratory and production area and ensure the adherence of same by subordinates

**PC3.** report any allergy, sickness or any other environment-related breach before or after entering the work premises to the designated person

**PC4.** take preventive actions on the report of any allergy, sickness or any other environment-related breach reported by subordinates

*Adhere to safety and security procedures*

To be competent, the user/individual on the job must be able to:

**PC5.** observe compliance by self and subordinates with safety and security policies and procedures

**PC6.** ensure the use of appropriate safety gears like headgear, masks, gloves and other accessories as mentioned in the guidelines, by self and subordinates while working or visiting the manufacturing or laboratory area

**PC7.** take preventive and corrective actions on the report of any identified breaches in safety and security policies and procedures by subordinates and team mates

**PC8.** ensure proper material segregation and labelling at workplace

**PC9.** comply with material handling, segregation and storage as per 5S system at workplace

*Adhere to emergency procedures*

To be competent, the user/individual on the job must be able to:

**PC10.** report any hazards that he/she is not competent to deal with the relevant EHS personnel and warn other people who may be affected

**PC11.** raise the alarm and inform the concerned person immediately for action in the cases of spill, fall, injury, toxic inhale, fire or explosion

**PC12.** follow emergency protocols for any alarms and ensure the safety of subordinates in the area under supervision

**PC13.** follow emergency procedures efficiently

**PC14.** ensure injured employees are provided appropriate first aid and medical aid

*Environment Sustainability*

To be competent, the user/individual on the job must be able to:

**PC15.** ensure energy conservation by switching off the machine (including laptops etc.) and equipment post operations

**PC16.** identify ways to optimize the usage of electricity/energy in various tasks/activities/processes

**PC17.** ensure energy conservation by optimizing the machine (including laptop etc) / equipment performance

**PC18.** identify recyclable and non-recyclable, and hazardous waste generated

**PC19.** segregate waste into different categories to achieve minimum pollution of land and water

**PC20.** Ensure no water leakage in work area and take corrective actions, if any

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

**KU1.** the WHO guidelines and ICH-cGMP rules for health and personal hygiene

**KU2.** • individual's role and responsibilities in maintaining healthy, hygienic, safe and secure
• working environment

**KU3.** company's procedures and protocols for the environment, health and safety

**KU4.** relevant legislative requirements as per local laws

**KU5.** implications that any non-compliance with health, safety and security may have on individuals and the organization

**KU6.** limits of individual responsibility for dealing with hazards

**KU7.** the organization's emergency procedures for different emergency situations and the importance of following these

**KU8.** evacuation procedures for employees, contract staff and visitors

**KU9.** importance of material segregation and 5S system

**KU10.** types of safety gears and procedure to use them

**KU11.** different types of breaches in the environment, health, safety and security and how and when to report these

**KU12.** procedure to summon medical assistance and the emergency services, where necessary

**KU13.** the guidelines related to environmental sustainability

**KU14.** methods to conserve energy, water and methods to minimize pollution

**KU15.** WHO guidelines and ICH-cGMP rules for waste disposal and waste management

## Generic Skills (GS)

User/individual on the job needs to know how to:

**GS1.** use reading and comprehension skills to understand the various coding systems and to read instructions, guidelines, procedures, rules, and signages to understand the procedure to be followed

**GS2.** use listening skills to follow the instructions and procedures during emergency alarms

**GS3.** use written communication skills to accurately record every information required to be reported as per SOP and GCP guidelines in the prescribed language

**GS4.** apply planning and organizing skills to plan and organize tools and material required for work to fulfil environment, health, safety and security requirements

**GS5.** use critical thinking skills to take relevant actions on the accidents and breach in compliance with EHS protocols

**GS6.** apply decision-making skills to make balanced judgments within the authority while dealing with hazards and breaches

**GS7.** apply problem-solving skills to find solutions for workflow-related difficulties

**GS8.** use verbal communication skills to communicate with supervisor/ manager/ EHS Incharge or any other concerned authority clearly for escalating any emergency or hazard

## Assessment Criteria

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| *Adhere to health and hygiene protocols* | **10** | **10** | **3** | **2** |
| **PC1.** comply with health and personal hygiene-related protocols as per WHO standards and ICH GMP guidelines | - | - | - | - |
| **PC2.** sanitize your hands and follow cleanroom protocol, if applicable before entering in laboratory and production area and ensure the adherence of same by subordinates | - | - | - | - |
| **PC3.** report any allergy, sickness or any other environment-related breach before or after entering the work premises to the designated person | - | - | - | - |
| **PC4.** take preventive actions on the report of any allergy, sickness or any other environment-related breach reported by subordinates | - | - | - | - |
| *Adhere to safety and security procedures* | **10** | **10** | **2** | **2** |
| **PC5.** observe compliance by self and subordinates with safety and security policies and procedures | - | - | - | - |
| **PC6.** ensure the use of appropriate safety gears like headgear, masks, gloves and other accessories as mentioned in the guidelines, by self and subordinates while working or visiting the manufacturing or laboratory area | - | - | - | - |
| **PC7.** take preventive and corrective actions on the report of any identified breaches in safety and security policies and procedures by subordinates and team mates | - | - | - | - |
| **PC8.** ensure proper material segregation and labelling at workplace | - | - | - | - |
| **PC9.** comply with material handling, segregation and storage as per 5S system at workplace | - | - | - | - |
| *Adhere to emergency procedures* | **10** | **10** | **3** | **3** |

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| **PC10.** report any hazards that he/she is not competent to deal with the relevant EHS personnel and warn other people who may be affected | - | - | - | - |
| **PC11.** raise the alarm and inform the concerned person immediately for action in the cases of spill, fall, injury, toxic inhale, fire or explosion | - | - | - | - |
| **PC12.** follow emergency protocols for any alarms and ensure the safety of subordinates in the area under supervision | - | - | - | - |
| **PC13.** follow emergency procedures efficiently | - | - | - | - |
| **PC14.** ensure injured employees are provided appropriate first aid and medical aid | - | - | - | - |
| *Environment Sustainability* | **10** | **10** | **2** | **3** |
| **PC15.** ensure energy conservation by switching off the machine (including laptops etc.) and equipment post operations | - | - | - | - |
| **PC16.** identify ways to optimize the usage of electricity/energy in various tasks/activities/processes | - | - | - | - |
| **PC17.** ensure energy conservation by optimizing the machine (including laptop etc) / equipment performance | - | - | - | - |
| **PC18.** identify recyclable and non-recyclable, and hazardous waste generated | - | - | - | - |
| **PC19.** segregate waste into different categories to achieve minimum pollution of land and water | - | - | - | - |
| **PC20.** Ensure no water leakage in work area and take corrective actions, if any | - | - | - | - |
| **NOS Total** | **40** | **40** | **10** | **10** |

## National Occupational Standards (NOS) Parameters

| | |
|---|---|
| **NOS Code** | LFS/N0122 |
| **NOS Name** | Ensure adherence to Environment, health and safety guidelines at the workplace by self and subordinates |
| **Sector** | Life Sciences |
| **Sub-Sector** | Pharmaceutical, Bio Pharmaceutical, Contract Research |
| **Occupation** | Generic |
| **NSQF Level** | 5 |
| **Credits** | 1.00 |
| **Version** | 1.0 |
| **Last Reviewed Date** | NA |
| **Next Review Date** | 28/07/2025 |
| **NSQC Clearance Date** | 28/07/2022 |

# LFS/N0567: Coordinate with Manager, R&D team, other cross-functional teams, external stakeholders and regulatory agencies to manage regulatory affairs operations

## Description

This NOS is about a person who Coordinate with Manager, R&D team, other cross-functional teams, external stakeholders and regulatory agencies to manage regulatory affairs operations

## Scope

The scope covers the following :

- Coordination with Manager
- Coordination with R&D Team
- Coordination with cross-functional teams
- Coordination with External Stakeholders and Regulatory Agencies
- Sensitivity towards all genders and people with disability

## Elements and Performance Criteria

*Coordination with Manager*

To be competent, the user/individual on the job must be able to:

**PC1.** effectively communicate and collaborate with manager in order to develop regulatory strategies

**PC2.** provide local regulation intelligence to manager for efficient regulatory affairs management

**PC3.** maintain protocol-related documents and get them reviewed and approved by manager

**PC4.** identify problems arising within the process, resulting from change management or due to change in vendors, or human error, and escalate the same by following the proper escalation matrix

*Coordination with R&D Team*

To be competent, the user/individual on the job must be able to:

**PC5.** coordinate with various technical professionals to gather, organize and compile information on new products or processes and maintain confidentiality

**PC6.** work effectively with other staff in clinical operations (e.g., biostatistics, data management, clinical monitoring), regulatory affairs and others in team.

**PC7.** maintain protocol-related documents by obtaining approval from required departments and review staff

*Coordination with cross-functional teams*

To be competent, the user/individual on the job must be able to:

**PC8.** coordinate with the quality and production team for required facilitation in various activities for regulatory compliance

**PC9.** coordinate with BA/BE and Clinical Trail Team for seeking the status of project and for filing the IND supplements and other reports

**PC10.** coordinate with pharmacovigilance team for periodic product safety reporting

**PC11.** coordinate with the product development team for development of CMC related documents

**PC12.** support the Regulatory prices related decision making in collaboration with commercial department

*Coordination with External Stakeholders and Regulatory Agencies*

To be competent, the user/individual on the job must be able to:

**PC13.** collaborate with the local Regulatory liaison agent for smooth execution & liasoning

**PC14.** participate in Ethics Committee Meetings as and when required

**PC15.** maintain cordial relationship with the national and state level regulatory authorities for keeping self and organization updated and abreast with latest changes in regulations as well as status of applications

**PC16.** obtaining market permissions and approvals for company distributers as per regulatory laws if any

**PC17.** collaborate with the local Regulatory liaison agent for smooth execution & liasoning

*Sensitivity towards all genders and people with disability*

To be competent, the user/individual on the job must be able to:

**PC18.** respect all genders, religions, and caste

**PC19.** empathize with people with disability

**PC20.** offer support or help to a person with disability only when asked

**PC21.** ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act

**PC22.** report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

**KU1.** company's policies on preferred language of communication, reporting and escalation policy, quality delivery standards, and personnel management

**KU2.** the reporting structure of the organization

**KU3.** the required regulatory and statutory compliance related documentation

**KU4.** the guidelines for data integrity, ethics, and compliance in the life sciences industry

**KU5.** the guidelines laid on Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act

**KU6.** the methods of workplace communication

**KU7.** the methods of team coordination

**KU8.** the types of possible disabilities among people with disability (PWD)

**KU9.** the importance of awareness for gender sensitization and prevention of sexual harassment (POSH) act

**KU10.** the importance of respect for all the religions, caste, and cultures

**KU11.** the right way to use the laws acts, and provisions defined for PwD by the statutory bodies

**KU12.** various approach to define key performance indicators and methods to evaluate performance at work

**KU13.** time management strategies

**KU14.** how to develop a collaborative culture for cross-culture and gender-inclusive team

## Generic Skills (GS)

User/individual on the job needs to know how to:

**GS1.** use written communication skills to record information accurately in compliance with ALCOA principles as per SOP and regulatory guidelines in the English language

**GS2.** use reading and comprehension skills to read the various coding systems, instructions, guidelines, procedures, rules, and signage

**GS3.** use listening skills to interpret the instructions, procedures, and alarms

**GS4.** use verbal communication skills to interact with supervisor, teammates, cross-functional teams and customers as applicable

**GS5.** apply problem-solving skills to find solutions for workflow-related difficulties

**GS6.** apply planning and organizing skills to plan and organize tools and material required to fulfil documentation related requirements

**GS7.** apply critical thinking skills to analyse and identify what and when to report an issue/concern to the supervisor/ QA team/ audit team / any other stakeholder

**GS8.** apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations

## Assessment Criteria

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| *Coordination with Manager* | **5** | **10** | **3** | **2** |
| **PC1.** effectively communicate and collaborate with manager in order to develop regulatory strategies | - | - | - | - |
| **PC2.** provide local regulation intelligence to manager for efficient regulatory affairs management | - | - | - | - |
| **PC3.** maintain protocol-related documents and get them reviewed and approved by manager | - | - | - | - |
| **PC4.** identify problems arising within the process, resulting from change management or due to change in vendors, or human error, and escalate the same by following the proper escalation matrix | - | - | - | - |
| *Coordination with R&D Team* | **5** | **10** | **3** | **2** |
| **PC5.** coordinate with various technical professionals to gather, organize and compile information on new products or processes and maintain confidentiality | - | - | - | - |
| **PC6.** work effectively with other staff in clinical operations (e.g., biostatistics, data management, clinical monitoring), regulatory affairs and others in team. | - | - | - | - |
| **PC7.** maintain protocol-related documents by obtaining approval from required departments and review staff | - | - | - | - |
| *Coordination with cross-functional teams* | **5** | **10** | **3** | **2** |
| **PC8.** coordinate with the quality and production team for required facilitation in various activities for regulatory compliance | - | - | - | - |
| **PC9.** coordinate with BA/BE and Clinical Trail Team for seeking the status of project and for filing the IND supplements and other reports | - | - | - | - |
| **PC10.** coordinate with pharmacovigilance team for periodic product safety reporting | - | - | - | - |

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| **PC11.** coordinate with the product development team for development of CMC related documents | - | - | - | - |
| **PC12.** support the Regulatory prices related decision making in collaboration with commercial department | - | - | - | - |
| *Coordination with External Stakeholders and Regulatory Agencies* | **5** | **10** | **5** | **5** |
| **PC13.** collaborate with the local Regulatory liaison agent for smooth execution & liasoning | - | - | - | - |
| **PC14.** participate in Ethics Committee Meetings as and when required | - | - | - | - |
| **PC15.** maintain cordial relationship with the national and state level regulatory authorities for keeping self and organization updated and abreast with latest changes in regulations as well as status of applications | - | - | - | - |
| **PC16.** obtaining market permissions and approvals for company distributers as per regulatory laws if any | - | - | - | - |
| **PC17.** collaborate with the local Regulatory liaison agent for smooth execution & liasoning | - | - | - | - |
| *Sensitivity towards all genders and people with disability* | **5** | **5** | **3** | **2** |
| **PC18.** respect all genders, religions, and caste | - | - | - | - |
| **PC19.** empathize with people with disability | - | - | - | - |
| **PC20.** offer support or help to a person with disability only when asked | - | - | - | - |
| **PC21.** ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act | - | - | - | - |
| **PC22.** report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee | - | - | - | - |
| **NOS Total** | **25** | **45** | **17** | **13** |

Qualification Pack

## National Occupational Standards (NOS) Parameters

| | |
|---|---|
| **NOS Code** | LFS/N0567 |
| **NOS Name** | Coordinate with Manager, R&D team, other cross-functional teams, external stakeholders and regulatory agencies to manage regulatory affairs operations |
| **Sector** | Life Sciences |
| **Sub-Sector** | Pharmaceutical, Bio Pharmaceutical, Contract Research |
| **Occupation** | Research and Development |
| **NSQF Level** | 5 |
| **Credits** | 2.00 |
| **Version** | 1.0 |
| **Last Reviewed Date** | NA |
| **Next Review Date** | 28/07/2025 |
| **NSQC Clearance Date** | 28/07/2022 |

Qualification Pack

# DGT/VSQ/N0103: Employability Skills (90 Hours)

## Description

This unit is about employability skills, Constitutional values, becoming a professional in the 21st Century, digital, financial, and legal literacy, diversity and Inclusion, English and communication skills, customer service, entrepreneurship, and apprenticeship, getting ready for jobs and career development.

## Scope

The scope covers the following :

- Introduction to Employability Skills
- Constitutional values - Citizenship
- Becoming a Professional in the 21st Century
- Basic English Skills
- Career Development & Goal Setting
- Communication Skills
- Diversity & Inclusion
- Financial and Legal Literacy
- Essential Digital Skills
- Entrepreneurship
- Customer Service
- Getting ready for Apprenticeship & Jobs

## Elements and Performance Criteria

*Introduction to Employability Skills*

To be competent, the user/individual on the job must be able to:

**PC1.** understand the significance of employability skills in meeting the current job market requirement and future of work

**PC2.** identify and explore learning and employability relevant portals

**PC3.** research about the different industries, job market trends, latest skills required and the available opportunities

*Constitutional values – Citizenship*

To be competent, the user/individual on the job must be able to:

**PC4.** recognize the significance of constitutional values, including civic rights and duties, citizenship, responsibility towards society etc. and personal values and ethics such as honesty, integrity, caring and respecting others, etc.

**PC5.** follow environmentally sustainable practices

*Becoming a Professional in the 21st Century*

To be competent, the user/individual on the job must be able to:

**PC6.** recognize the significance of 21st Century Skills for employment

**PC7.** practice the 21st Century Skills such as Self-Awareness, Behaviour Skills, time management, critical and adaptive thinking, problem-solving, creative thinking, social and cultural awareness, emotional awareness, learning to learn for continuous learning etc. in personal and professional life

**PC8.** adopt a continuous learning mindset for personal and professional development

*Basic English Skills*

To be competent, the user/individual on the job must be able to:

**PC9.** use basic English for everyday conversation in different contexts, in person and over the telephone

**PC10.** read and understand routine information, notes, instructions, mails, letters etc. written in English

**PC11.** write short messages, notes, letters, e-mails etc. in English

*Career Development & Goal Setting*

To be competent, the user/individual on the job must be able to:

**PC12.** identify career goals based on the skills, interests, knowledge, and personal attributes

**PC13.** prepare a career development plan with short- and long-term goals

*Communication Skills*

To be competent, the user/individual on the job must be able to:

**PC14.** follow verbal and non-verbal communication etiquette while communicating in professional and public settings

**PC15.** use active listening techniques for effective communication

**PC16.** communicate in writing using appropriate style and format based on formal or informal requirements

**PC17.** work collaboratively with others in a team

*Diversity & Inclusion*

To be competent, the user/individual on the job must be able to:

**PC18.** communicate and behave appropriately with all genders and PwD

**PC19.** escalate any issues related to sexual harassment at workplace according to POSH Act

*Financial and Legal Literacy*

To be competent, the user/individual on the job must be able to:

**PC20.** identify and select reliable institutions for various financial products and services such as bank account, debit and credit cards, loans, insurance etc.

**PC21.** carry out offline and online financial transactions, safely and securely, using various methods and check the entries in the passbook

**PC22.** identify common components of salary and compute income, expenses, taxes, investments etc

**PC23.** identify relevant rights and laws and use legal aids to fight against legal exploitation

*Essential Digital Skills*

To be competent, the user/individual on the job must be able to:

**PC24.** operate digital devices and use their features and applications securely and safely

**PC25.** carry out basic internet operations by connecting to the internet safely and securely, using the mobile data or other available networks through Bluetooth, Wi-Fi, etc.

**PC26.** display responsible online behaviour while using various social media platforms

**PC27.** create a personal email account, send and process received messages as per requirement

**PC28.** carry out basic procedures in documents, spreadsheets and presentations using respective and appropriate applications

**PC29.** utilize virtual collaboration tools to work effectively

*Entrepreneurship*

To be competent, the user/individual on the job must be able to:

**PC30.** identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research

**PC31.** develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion

**PC32.** identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity

*Customer Service*

To be competent, the user/individual on the job must be able to:

**PC33.** identify different types of customers and ways to communicate with them

**PC34.** identify and respond to customer requests and needs in a professional manner

**PC35.** use appropriate tools to collect customer feedback

**PC36.** follow appropriate hygiene and grooming standards

*Getting ready for apprenticeship & Jobs*

To be competent, the user/individual on the job must be able to:

**PC37.** create a professional Curriculum vitae (Résumé)

**PC38.** search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively

**PC39.** apply to identified job openings using offline /online methods as per requirement

**PC40.** answer questions politely, with clarity and confidence, during recruitment and selection

**PC41.** identify apprenticeship opportunities and register for it as per guidelines and requirements

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

**KU1.** need for employability skills and different learning and employability related portals

**KU2.** various constitutional and personal values

**KU3.** different environmentally sustainable practices and their importance

**KU4.** Twenty first (21st) century skills and their importance

**KU5.** how to use English language for effective verbal (face to face and telephonic) and written communication in formal and informal set up

**KU6.** importance of career development and setting long- and short-term goals

**KU7.** about effective communication

**KU8.** POSH Act

**KU9.** Gender sensitivity and inclusivity

**KU10.** different types of financial institutes, products, and services

**KU11.** components of salary and how to compute income and expenditure
**KU12.** importance of maintaining safety and security in offline and online financial transactions
**KU13.** different legal rights and laws
**KU14.** different types of digital devices and the procedure to operate them safely and securely
**KU15.** how to create and operate an e- mail account
**KU16.** use applications such as word processors, spreadsheets etc.
**KU17.** how to identify business opportunities
**KU18.** types and needs of customers
**KU19.** how to apply for a job and prepare for an interview
**KU20.** apprenticeship scheme and the process of registering on apprenticeship portal

## Generic Skills (GS)

User/individual on the job needs to know how to:

**GS1.** read and write different types of documents/instructions/correspondence in English and other languages
**GS2.** communicate effectively using appropriate language in formal and informal settings
**GS3.** behave politely and appropriately with all to maintain effective work relationship
**GS4.** how to work in a virtual mode, using various technological platforms
**GS5.** perform calculations efficiently
**GS6.** solve problems effectively
**GS7.** pay attention to details
**GS8.** manage time efficiently
**GS9.** maintain hygiene and sanitization to avoid infection

## Assessment Criteria

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| *Introduction to Employability Skills* | **1** | **1** | **-** | **-** |
| **PC1.** understand the significance of employability skills in meeting the current job market requirement and future of work | - | - | - | - |
| **PC2.** identify and explore learning and employability relevant portals | - | - | - | - |
| **PC3.** research about the different industries, job market trends, latest skills required and the available opportunities | - | - | - | - |
| *Constitutional values – Citizenship* | **1** | **1** | **-** | **-** |
| **PC4.** recognize the significance of constitutional values, including civic rights and duties, citizenship, responsibility towards society etc. and personal values and ethics such as honesty, integrity, caring and respecting others, etc. | - | - | - | - |
| **PC5.** follow environmentally sustainable practices | - | - | - | - |
| *Becoming a Professional in the 21st Century* | **1** | **3** | **-** | **-** |
| **PC6.** recognize the significance of 21st Century Skills for employment | - | - | - | - |
| **PC7.** practice the 21st Century Skills such as Self-Awareness, Behaviour Skills, time management, critical and adaptive thinking, problem-solving, creative thinking, social and cultural awareness, emotional awareness, learning to learn for continuous learning etc. in personal and professional life | - | - | - | - |
| **PC8.** adopt a continuous learning mindset for personal and professional development | - | - | - | - |
| *Basic English Skills* | **3** | **4** | **-** | **-** |
| **PC9.** use basic English for everyday conversation in different contexts, in person and over the telephone | - | - | - | - |

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| **PC10.** read and understand routine information, notes, instructions, mails, letters etc. written in English | - | - | - | - |
| **PC11.** write short messages, notes, letters, e-mails etc. in English | - | - | - | - |
| *Career Development & Goal Setting* | **1** | **2** | **-** | **-** |
| **PC12.** identify career goals based on the skills, interests, knowledge, and personal attributes | - | - | - | - |
| **PC13.** prepare a career development plan with short- and long-term goals | - | - | - | - |
| *Communication Skills* | **2** | **2** | **-** | **-** |
| **PC14.** follow verbal and non-verbal communication etiquette while communicating in professional and public settings | - | - | - | - |
| **PC15.** use active listening techniques for effective communication | - | - | - | - |
| **PC16.** communicate in writing using appropriate style and format based on formal or informal requirements | - | - | - | - |
| **PC17.** work collaboratively with others in a team | - | - | - | - |
| *Diversity & Inclusion* | **1** | **1** | **-** | **-** |
| **PC18.** communicate and behave appropriately with all genders and PwD | - | - | - | - |
| **PC19.** escalate any issues related to sexual harassment at workplace according to POSH Act | - | - | - | - |
| *Financial and Legal Literacy* | **2** | **3** | **-** | **-** |
| **PC20.** identify and select reliable institutions for various financial products and services such as bank account, debit and credit cards, loans, insurance etc. | - | - | - | - |
| **PC21.** carry out offline and online financial transactions, safely and securely, using various methods and check the entries in the passbook | - | - | - | - |

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| **PC22.** identify common components of salary and compute income, expenses, taxes, investments etc | - | - | - | - |
| **PC23.** identify relevant rights and laws and use legal aids to fight against legal exploitation | - | - | - | - |
| *Essential Digital Skills* | **3** | **5** | **-** | **-** |
| **PC24.** operate digital devices and use their features and applications securely and safely | - | - | - | - |
| **PC25.** carry out basic internet operations by connecting to the internet safely and securely, using the mobile data or other available networks through Bluetooth, Wi-Fi, etc. | - | - | - | - |
| **PC26.** display responsible online behaviour while using various social media platforms | - | - | - | - |
| **PC27.** create a personal email account, send and process received messages as per requirement | - | - | - | - |
| **PC28.** carry out basic procedures in documents, spreadsheets and presentations using respective and appropriate applications | - | - | - | - |
| **PC29.** utilize virtual collaboration tools to work effectively | - | - | - | - |
| *Entrepreneurship* | **2** | **3** | **-** | **-** |
| **PC30.** identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research | - | - | - | - |
| **PC31.** develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion | - | - | - | - |
| **PC32.** identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity | - | - | - | - |
| *Customer Service* | **1** | **2** | **-** | **-** |
| **PC33.** identify different types of customers and ways to communicate with them | - | - | - | - |

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| **PC34.** identify and respond to customer requests and needs in a professional manner | - | - | - | - |
| **PC35.** use appropriate tools to collect customer feedback | - | - | - | - |
| **PC36.** follow appropriate hygiene and grooming standards | - | - | - | - |
| *Getting ready for apprenticeship & Jobs* | **2** | **3** | **-** | **-** |
| **PC37.** create a professional Curriculum vitae (Résumé) | - | - | - | - |
| **PC38.** search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively | - | - | - | - |
| **PC39.** apply to identified job openings using offline /online methods as per requirement | - | - | - | - |
| **PC40.** answer questions politely, with clarity and confidence, during recruitment and selection | - | - | - | - |
| **PC41.** identify apprenticeship opportunities and register for it as per guidelines and requirements | - | - | - | - |
| **NOS Total** | **20** | **30** | **-** | **-** |

**Qualification Pack**

## National Occupational Standards (NOS) Parameters

| | |
|---|---|
| **NOS Code** | DGT/VSQ/N0103 |
| **NOS Name** | Employability Skills (90 Hours) |
| **Sector** | Cross Sectoral |
| **Sub-Sector** | Professional Skills |
| **Occupation** | Employability |
| **NSQF Level** | 5 |
| **Credits** | 3 |
| **Version** | 1.0 |
| **Last Reviewed Date** | 30/05/2024 |
| **Next Review Date** | 30/05/2027 |
| **NSQC Clearance Date** | 30/05/2024 |

# LFS/N0501: Assist in managing the regulatory affairs for Pharmaceutical (including AYUSH), Cosmetics, and Nutraceutical products

## Description

This NOS is about a job holder Assist in managing the regulatory affairs for Pharmaceutical (including AYUSH), Cosmetics, and Nutraceutical product

## Scope

The scope covers the following :

- Regulatory facilitation for Licences and Authorization
- Regulatory facilitation for Miscellaneous Approvals
- Regulatory facilitation for Post Approval Changes

## Elements and Performance Criteria

*Regulatory facilitation for Licences and Authorization*

To be competent, the user/individual on the job must be able to:

**PC1.** facilitate for submission of Investigational New Drug Application (IND) for regulatory approval and ensure submission of amendments and supplements with regulator throughout the clinical trials.

**PC2.** facilitate for submission of Clinical Trial Application (CTA) for regulatory approval.

**PC3.** facilitate for regulatory approval for new drug application (NDA)/ New Drug Submission (NDS) for a new pharmaceutical drug product.

**PC4.** facilitate for regulatory approval for abbreviated new drug application (ANDA) / ANDS (Abbreviated New Drug Submission) for a generic drug product.

**PC5.** facilitate for regulatory approval for market authorization application (MAA) via centralized procedure (CP) or national procedure (NP) or mutual recognition and decentralized procedure (MRP and DCP)

**PC6.** facilitate for regulatory approval for market authorization application (MAA) via Gulf Cooperation Council procedure (GCC)

**PC7.** facilitate for regulatory approval for New Drug Submission (NDS) / for a new brand name drug

**PC8.** facilitate for regulatory approval for SANDS (Supplement to Abbreviated New Drug Submission) and SNDS (Supplement to a New Drug Submission) for a new brand name drug

*Regulatory facilitation for Miscellaneous Approvals*

To be competent, the user/individual on the job must be able to:

**PC9.** facilitate in obtaining certificate of suitability (CEP/ COS) from drug regulatory authority.

**PC10.** facilitate in obtaining certificate of pharmaceutical product (COPP) and certificate of good manufacturing practices from Indian drug regulatory authority (CDSCO).

**PC11.** facilitate in obtaining certificate of quality compliance/ standardization mark (like Agmark, AYUSHMark, CE) from concern national authority, wherever applicable.

**PC12.** facilitate in obtaining the free sale and commerce certificate (FSC)/ certificate for export from Indian Drug Regulatory authority (CDSCO).

**PC13.** facilitate in liasoning and filing submission with national pharmaceutical pricing authority (NPPA)

**PC14.** facilitate in liasoning and filing submission with food safety and standards authority of India (FSSAI) for any nutraceutical products, wherever applicable.

*Regulatory facilitation for Post Approval Changes*

To be competent, the user/individual on the job must be able to:

**PC15.** facilitate in liasoning and filing submission with central insecticide lab (CIL) and central insecticide board (CIB)

**PC16.** perform CMC assessments for gap

**PC17.** perform compliance checks of current registered information versus manufacturing documentation for licensed medicinal products

**PC18.** perform change control review and management while implementation of vendor changes, lubricant changes in machines, and change in plant machineries, pharmacopoeial updates or any process changes etc.

**PC19.** prepare and facilitate submission of variations to the regulators to close the identified 'compliance gaps'

**PC20.** prepare Development Safety Update Reports (DSURs), Periodic Benefit Risk Evaluation Reports (PBRERs) and Risk Management Plans (RMPs), ensuring that they are of the highest possible quality and in line with internal/external guidelines and requirements.

**PC21.** provide strategic support to internal management / clients (in case providing services) in advising on the appropriate processes and procedures to ensure sustainable compliance

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

**KU1.** different quality management systems (ISO-9000, ISO-14001, OHSAS-18000), good laboratory and manufacturing practices

**KU2.** Indian drug regulatory authority like CDSCO

**KU3.** IND, CTA, ANDA and NDA regulatory approval procedures

**KU4.** regulatory approval procedure for NDS, SANDS and SNDS

**KU5.** different procedure like ( CP, NP, MRP and DCP) for approval of Market authorization application (MAA)

**KU6.** different certificate CEP/COS, COPP, FSC from national authority

**KU7.** how to liaising for various product submission with FSSAI, CIL, CIB

**KU8.** standardization mark like Agmark, AYUSHMark, CE from concern national authority

**KU9.** the correct method for carrying out corrective actions outlined for each problem

**KU10.** broad knowledge of Regulatory Affairs and specific working knowledge of current regulations and guidance

**KU11.** preparation of various document like DSUR, PBRER and RMPs

**KU12.** knowledge of regulatory authorities like MHRA, MCC, USFDA, TGA, Malaysia, European Union etc in concurrence with the regulations promulgated by a whole range of agencies like the Environmental Protection Agency, Federal Trade Commission, Occupational Safety & Health Administration and Drug Enforcement Administration

**KU13.** associated experience in Quality Assurance and Document Control is required in certain cases

**KU14.** knowledge of pharmaceutical dossiers like the master formula of the product, manufacturing procedure and the equipments list used in the production, the Stability data, preclinical and clinical data, specifications used in testing the final product and other regulatory documents

**KU15.** training in necessary procedures for filing licenses and liaising with regulatory authorities of different countries

**KU16.** good knowledge of GMP, GLP and Safety requirements

**KU17.** national/international standard test methods for different compounds

**KU18.** factors that adversely affect integrity of the sample

## Generic Skills (GS)

User/individual on the job needs to know how to:

**GS1.** use written communication skills to record information accurately in compliance with ALCOA principles as per SOP and regulatory guidelines in the English language

**GS2.** use reading and comprehension skills to read the various coding systems, instructions, guidelines, procedures, rules, and signage

**GS3.** use listening skills to interpret the instructions, procedures, and alarms

**GS4.** use verbal communication skills to interact with supervisor, teammates, cross-functional teams and customers as applicable

**GS5.** apply problem-solving skills to find solutions for workflow-related difficulties

**GS6.** apply planning and organizing skills to plan and organize tools and material required to fulfil documentation related requirements

**GS7.** apply critical thinking skills to analyse and identify what and when to report an issue/concern to the supervisor/ regulatory team / QA team / any other stakeholder

**GS8.** apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations

## Assessment Criteria

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| *Regulatory facilitation for Licences and Authorization* | **10** | **15** | **5** | **5** |
| **PC1.** facilitate for submission of Investigational New Drug Application (IND) for regulatory approval and ensure submission of amendments and supplements with regulator throughout the clinical trials. | - | - | - | - |
| **PC2.** facilitate for submission of Clinical Trial Application (CTA) for regulatory approval. | - | - | - | - |
| **PC3.** facilitate for regulatory approval for new drug application (NDA)/ New Drug Submission (NDS) for a new pharmaceutical drug product. | - | - | - | - |
| **PC4.** facilitate for regulatory approval for abbreviated new drug application (ANDA) / ANDS (Abbreviated New Drug Submission) for a generic drug product. | - | - | - | - |
| **PC5.** facilitate for regulatory approval for market authorization application (MAA) via centralized procedure (CP) or national procedure (NP) or mutual recognition and decentralized procedure (MRP and DCP) | - | - | - | - |
| **PC6.** facilitate for regulatory approval for market authorization application (MAA) via Gulf Cooperation Council procedure (GCC) | - | - | - | - |
| **PC7.** facilitate for regulatory approval for New Drug Submission (NDS) / for a new brand name drug | - | - | - | - |
| **PC8.** facilitate for regulatory approval for SANDS (Supplement to Abbreviated New Drug Submission) and SNDS (Supplement to a New Drug Submission) for a new brand name drug | - | - | - | - |
| *Regulatory facilitation for Miscellaneous Approvals* | **10** | **15** | **5** | **5** |
| **PC9.** facilitate in obtaining certificate of suitability (CEP/ COS) from drug regulatory authority. | - | - | - | - |

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| **PC10.** facilitate in obtaining certificate of pharmaceutical product (COPP) and certificate of good manufacturing practices from Indian drug regulatory authority (CDSCO). | - | - | - | - |
| **PC11.** facilitate in obtaining certificate of quality compliance/ standardization mark (like Agmark, AYUSHMark, CE) from concern national authority, wherever applicable. | - | - | - | - |
| **PC12.** facilitate in obtaining the free sale and commerce certificate (FSC)/ certificate for export from Indian Drug Regulatory authority (CDSCO). | - | - | - | - |
| **PC13.** facilitate in liasoning and filing submission with national pharmaceutical pricing authority (NPPA) | - | - | - | - |
| **PC14.** facilitate in liasoning and filing submission with food safety and standards authority of India (FSSAI) for any nutraceutical products, wherever applicable. | - | - | - | - |
| *Regulatory facilitation for Post Approval Changes* | **5** | **15** | **5** | **5** |
| **PC15.** facilitate in liasoning and filing submission with central insecticide lab (CIL) and central insecticide board (CIB) | - | - | - | - |
| **PC16.** perform CMC assessments for gap | - | - | - | - |
| **PC17.** perform compliance checks of current registered information versus manufacturing documentation for licensed medicinal products | - | - | - | - |
| **PC18.** perform change control review and management while implementation of vendor changes, lubricant changes in machines, and change in plant machineries, pharmacopoeial updates or any process changes etc. | - | - | - | - |
| **PC19.** prepare and facilitate submission of variations to the regulators to close the identified 'compliance gaps' | - | - | - | - |

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| **PC20.** prepare Development Safety Update Reports (DSURs), Periodic Benefit Risk Evaluation Reports (PBRERs) and Risk Management Plans (RMPs), ensuring that they are of the highest possible quality and in line with internal/external guidelines and requirements. | - | - | - | - |
| **PC21.** provide strategic support to internal management / clients (in case providing services) in advising on the appropriate processes and procedures to ensure sustainable compliance | - | - | - | - |
| **NOS Total** | **25** | **45** | **15** | **15** |

Qualification Pack

## National Occupational Standards (NOS) Parameters

| | |
|---|---|
| **NOS Code** | LFS/N0501 |
| **NOS Name** | Assist in managing the regulatory affairs for Pharmaceutical (including AYUSH), Cosmetics, and Nutraceutical products |
| **Sector** | Life Sciences |
| **Sub-Sector** | Pharmaceutical, Bio Pharmaceutical and Contract Research |
| **Occupation** | Research and Development |
| **NSQF Level** | 5 |
| **Credits** | 6.00 |
| **Version** | 2.0 |
| **Last Reviewed Date** | NA |
| **Next Review Date** | 28/07/2025 |
| **NSQC Clearance Date** | 28/07/2022 |

# LFS/N0120: Establish own enterprise and perform various entrepreneurial activities to run the business operations in Life Sciences Sector

## Description

This NOS is about an entrepreneur setting up his/her own enterprise and performing various entrepreneurial activities to run the business operations in Life Sciences Sector

## Scope

The scope covers the following :

- Set up enterprise and perform entrepreneurial activities
- Maintenance of accounts and ledgers
- Comply with legal, regulatory and statutory standards

## Elements and Performance Criteria

*Set up enterprise and perform entrepreneurial activities*

To be competent, the user/individual on the job must be able to:

**PC1.** perform a survey in the identified area for business activities to identify prospective customers and business opportunity

**PC2.** identify products and/ or services and it's sources, that match the business opportunity

**PC3.** develop business proposal with objective and identified business area for registering the proposed business as independent entity with competent authorities

**PC4.** submit business proposals and feasibility plans for securing the required funding from govt. schemes for MSMEs like MUDRA etc. as and when needed

**PC5.** present the business proposal to investors and stakeholders to gain their confidence and trust for possible funding

**PC6.** ensure setting up the infrastructure and resources for business as per approved plan and investors/ shareholders agreement

**PC7.** enrol into various government schemes and programs for MSME and avail the benefits

**PC8.** promote the product/ services through various means including digital promotions in line to regulations for promotion and sale as per land of law

**PC9.** develop the supply chain and distribution network

**PC10.** maintain updated information regarding new market trends to provide service to customers and constantly upskill self and employees for futuristic technologies, innovations and methodologies

*Maintenance of accounts and ledgers*

To be competent, the user/individual on the job must be able to:

**PC11.** ensure to generate a final invoice for the services rendered/ or products sold

**PC12.** collect payment either in cash (as per RBI guidelines)/ cheque/ demand draft or through online transactions via RTGS/NEFT/UPI etc.

**PC13.** ensure accounts and ledgers are maintained for the material supplied, payables and receivables, loan ledgers, taxes collected and paid into government treasury as well for wages paid and statutory benefits like PF, ESI contribution deposited with authorities

**PC14.** ensure maintenance and reconciliation of a monthly account as well as movable and immovable assets and stock to keep track of profit/ loss as well as periodic audit as per legal requirements

*Comply with legal, regulatory and statutory standards*

To be competent, the user/individual on the job must be able to:

**PC15.** comply with workplace health and safety rules stipulated by local authorities

**PC16.** comply with rules related to taxes and licensing regulations

**PC17.** comply with prevalent labour laws and keep records for employee's qualifications, employment as well as trainings

**PC18.** comply with regulations and protocols related to maintenance of product/ service license including the pre conditions (if any)

**PC19.** comply with quality system like ISO/GMP/GLP etc and any other rule mandated by appropriate regulatory authorities

**PC20.** comply with pollution norms as per land of law and ensure near zero pollution for a sustainable environment and to earn carbon credits

**PC21.** ensure that business facility and employees are always prepared and ready for any surprise inspection/ audit from clients/ regulatory/ statutory authorities

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

**KU1.** business administration, financial and planning activities

**KU2.** data analysis techniques for continuous improvement and identifying new business opportunities

**KU3.** maintaining confidentiality for information about finances, business secrets and information shared by clients/ stakeholders

**KU4.** procedures for funding approvals, and presenting new business idea/ opportunity for license or stakeholder approvals

**KU5.** prevailing and possible environmental issues and expected quality standards

**KU6.** license, patent and copyright laws

**KU7.** applicable tax, duties and labour laws

**KU8.** fundamentals of costing, pricing and profit

**KU9.** accounting principles and use of accounting software and government software/ portals for taxes and returns

**KU10.** Good Practices (GxP), ISO and other quality systems

**KU11.** talent management and resource planning

**KU12.** Awareness of applicable engineering concepts

**KU13.** audits and regulations in Life Sciences sector applicable for chosen business area

**KU14.** market promotion, globally trending strategies and distribution network

**KU15.** concept of innovation and jugaad principle

## Generic Skills (GS)

User/individual on the job needs to know how to:

**GS1.** note the information to be communicated
**GS2.** fill relevant applications where required
**GS3.** write clear communications to government officials, funding partners, team members, etc
**GS4.** discuss task lists, schedules and activities with customers, peers, partners, vendors etc.
**GS5.** effectively communicate with teams
**GS6.** interact with successful local entrepreneurs, and enterprises in a similar field for best practices and expertise
**GS7.** ask questions in order to understand problems and clarify queries
**GS8.** multi-task and adapt to meet work timelines
**GS9.** apply emotional intelligence while dealing with other genders and people with disability

## Assessment Criteria

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| *Set up enterprise and perform entrepreneurial activities* | **20** | **30** | **6** | **3** |
| **PC1.** perform a survey in the identified area for business activities to identify prospective customers and business opportunity | - | - | - | - |
| **PC2.** identify products and/ or services and it's sources, that match the business opportunity | - | - | - | - |
| **PC3.** develop business proposal with objective and identified business area for registering the proposed business as independent entity with competent authorities | - | - | - | - |
| **PC4.** submit business proposals and feasibility plans for securing the required funding from govt. schemes for MSMEs like MUDRA etc. as and when needed | - | - | - | - |
| **PC5.** present the business proposal to investors and stakeholders to gain their confidence and trust for possible funding | - | - | - | - |
| **PC6.** ensure setting up the infrastructure and resources for business as per approved plan and investors/ shareholders agreement | - | - | - | - |
| **PC7.** enrol into various government schemes and programs for MSME and avail the benefits | - | - | - | - |
| **PC8.** promote the product/ services through various means including digital promotions in line to regulations for promotion and sale as per land of law | - | - | - | - |
| **PC9.** develop the supply chain and distribution network | - | - | - | - |
| **PC10.** maintain updated information regarding new market trends to provide service to customers and constantly upskill self and employees for futuristic technologies, innovations and methodologies | - | - | - | - |
| *Maintenance of accounts and ledgers* | **10** | **20** | **6** | **5** |

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| **PC11.** ensure to generate a final invoice for the services rendered/ or products sold | - | - | - | - |
| **PC12.** collect payment either in cash (as per RBI guidelines)/ cheque/ demand draft or through online transactions via RTGS/NEFT/UPI etc. | - | - | - | - |
| **PC13.** ensure accounts and ledgers are maintained for the material supplied, payables and receivables, loan ledgers, taxes collected and paid into government treasury as well for wages paid and statutory benefits like PF, ESI contribution deposited with authorities | - | - | - | - |
| **PC14.** ensure maintenance and reconciliation of a monthly account as well as movable and immovable assets and stock to keep track of profit/ loss as well as periodic audit as per legal requirements | - | - | - | - |
| *Comply with legal, regulatory and statutory standards* | - | - | - | - |
| **PC15.** comply with workplace health and safety rules stipulated by local authorities | - | - | - | - |
| **PC16.** comply with rules related to taxes and licensing regulations | - | - | - | - |
| **PC17.** comply with prevalent labour laws and keep records for employee's qualifications, employment as well as trainings | - | - | - | - |
| **PC18.** comply with regulations and protocols related to maintenance of product/ service license including the pre conditions (if any) | - | - | - | - |
| **PC19.** comply with quality system like ISO/GMP/GLP etc and any other rule mandated by appropriate regulatory authorities | - | - | - | - |
| **PC20.** comply with pollution norms as per land of law and ensure near zero pollution for a sustainable environment and to earn carbon credits | - | - | - | - |
| **PC21.** ensure that business facility and employees are always prepared and ready for any surprise inspection/ audit from clients/ regulatory/ statutory authorities | - | - | - | - |

**Qualification Pack**

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| **NOS Total** | **30** | **50** | **12** | **8** |

Qualification Pack

## National Occupational Standards (NOS) Parameters

| | |
|---|---|
| **NOS Code** | LFS/N0120 |
| **NOS Name** | Establish own enterprise and perform various entrepreneurial activities to run the business operations in Life Sciences Sector |
| **Sector** | Life Sciences |
| **Sub-Sector** | Pharmaceutical, Bio Pharmaceutical, Contract Research |
| **Occupation** | Generic |
| **NSQF Level** | 6 |
| **Credits** | 1.00 |
| **Version** | 2.0 |
| **Last Reviewed Date** | 29/09/2023 |
| **Next Review Date** | 29/09/2026 |
| **NSQC Clearance Date** | 29/09/2023 |

# LFS/N0121: Maintain the critical business documents as Entrepreneur in Life Sciences Sector

## Description

This NOS is about an entrepreneur maintaining the critical business documents for its business in life sciences sector.

## Scope

The scope covers the following :

- Infrastructure related documentation
- Supply Chain related documentation
- Documentation for sales & marketing
- Quality audit and client/regulatory inspections related documentation

## Elements and Performance Criteria

*Infrastructure related documentation*

To be competent, the user/individual on the job must be able to:

**PC1.** ensure documentation and maintenance of records for architectural building layout like blueprint of plant/lab, electric circuit and plumbing layouts and safety equipment layout, infrastructure and asset insurance and lease/rent contracts/ sale deed (if owned facility)

**PC2.** ensure documentation and maintenance of records for all machineries, equipment and tools installed/used in the plant/ lab unit, with supplier/manufacturer details, manuals of all machineries / equipment, installation and qualification records and annual maintenance details etc

**PC3.** ensure documentation and maintenance of records for engineering and maintenance of each machinery/equipment, machine utilization, machine performance, breakdown details, corrective actions, spares changed, machine/equipment condition etc

*Supply Chain related documentation*

To be competent, the user/individual on the job must be able to:

**PC4.** ensure documentation and maintenance of records for all raw materials, ingredients and packaging materials handled, like name of the supplier, batch details, quantity supplied and quality of the materials supplies etc as well as

**PC5.** ensure documentation and maintenance of records for each supplier quality report on raw materials, ingredients, packaging materials, internal and external quality report on finished products, consumer and customer complaints , corrective actions, legal documents (if any)

**PC6.** ensure documentation and maintenance of records for storage facility, like condition of storage facility, storage parameters if any like temperature, humidity, pressure (as applicable), space utilised, stacking procedure etc

**PC7.** ensure documentation and maintenance of records for distribution details like transport details, quality, hygiene and cleanliness of vehicle, quantity loaded in the vehicle, distribution routes , outlet details, customer/ consumer details, distribution quantity, quantity returned etc.

*Documentation for sales & marketing*

To be competent, the user/individual on the job must be able to:

**PC8.** ensure documentation and maintenance of records for long term and short term business plans, feasibility reports, investor/shareholder agreements and disbursement and payment records for loan/grant/equity etc.

**PC9.** ensure documentation and maintenance of records for sale like customer details, customer type, location, quantity purchased by each stockist/consumer, frequency of purchase, sale details like quantity of products/brand sold in each territory

*Quality audit and client/regulatory inspections related documentation*

To be competent, the user/individual on the job must be able to:

**PC10.** ensure documentation and maintenance of records for internal/ external audits with its observations, notices/ feedback, action reports and final submission of audit action reports

**PC11.** ensure documentation and maintenance of records for every communication sent to or received from regulatory/ licensing authorities

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

**KU1.** system of documentation as per ISO/ good documentation practices and method of implementation

**KU2.** scoring, grading and accreditation system of affiliating bodies and clients

**KU3.** guidelines for facing audits and best practices for making organization audit ready

**KU4.** software and latest information technology tools for documentation and record maintenance

**KU5.** statistical tools for analysis and monitoring

**KU6.** various recording and documentation formats applicable in sales, marketing, supply chain etc

**KU7.** basic awareness of engineering drawing and architectural layouts

**KU8.** best practices in engineering and maintenance in sector

**KU9.** accounting standards and regulations

## Generic Skills (GS)

User/individual on the job needs to know how to:

**GS1.** record and communicate details of work done to appropriate people using written/typed report

**GS2.** interact effectively with team members

**GS3.** communicate with team members for data/ information/support/ advice needed

**GS4.** communicate with people in a form and manner and using language that is open and respectful

**GS5.** apply balanced judgement to different situations

**GS6.** plan and organize assigned work in order to drive collaboration with team members

**GS7.** effectively interact with the various stakeholders to complete assigned tasks

**GS8.** resolve any difficulties in relationships with colleagues , or get help from an appropriate person, in a way that preserves goodwill and trust

**GS9.** use team-building skills during the interaction with teammates while managing the difficult/stressful or emotional situations at work

**GS10.** apply emotional intelligence while dealing with other genders and people with disability

## Assessment Criteria

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| *Infrastructure related documentation* | **5** | **20** | **5** | **2** |
| **PC1.** ensure documentation and maintenance of records for architectural building layout like blueprint of plant/lab, electric circuit and plumbing layouts and safety equipment layout, infrastructure and asset insurance and lease/rent contracts/ sale deed (if owned facility) | - | - | - | - |
| **PC2.** ensure documentation and maintenance of records for all machineries, equipment and tools installed/used in the plant/ lab unit, with supplier/manufacturer details, manuals of all machineries / equipment, installation and qualification records and annual maintenance details etc | - | - | - | - |
| **PC3.** ensure documentation and maintenance of records for engineering and maintenance of each machinery/equipment, machine utilization, machine performance, breakdown details, corrective actions, spares changed, machine/equipment condition etc | - | - | - | - |
| *Supply Chain related documentation* | **5** | **20** | **5** | **3** |
| **PC4.** ensure documentation and maintenance of records for all raw materials, ingredients and packaging materials handled, like name of the supplier, batch details, quantity supplied and quality of the materials supplies etc as well as | - | - | - | - |
| **PC5.** ensure documentation and maintenance of records for each supplier quality report on raw materials, ingredients, packaging materials, internal and external quality report on finished products, consumer and customer complaints , corrective actions, legal documents (if any) | - | - | - | - |
| **PC6.** ensure documentation and maintenance of records for storage facility, like condition of storage facility, storage parameters if any like temperature, humidity, pressure (as applicable), space utilised, stacking procedure etc | - | - | - | - |

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| **PC7.** ensure documentation and maintenance of records for distribution details like transport details, quality, hygiene and cleanliness of vehicle, quantity loaded in the vehicle, distribution routes , outlet details, customer/ consumer details, distribution quantity, quantity returned etc. | - | - | - | - |
| *Documentation for sales & marketing* | **5** | **10** | **3** | **3** |
| **PC8.** ensure documentation and maintenance of records for long term and short term business plans, feasibility reports, investor/shareholder agreements and disbursement and payment records for loan/grant/equity etc. | - | - | - | - |
| **PC9.** ensure documentation and maintenance of records for sale like customer details, customer type, location, quantity purchased by each stockist/consumer, frequency of purchase, sale details like quantity of products/brand sold in each territory | - | - | - | - |
| *Quality audit and client/regulatory inspections related documentation* | **5** | **5** | **2** | **2** |
| **PC10.** ensure documentation and maintenance of records for internal/ external audits with its observations, notices/ feedback, action reports and final submission of audit action reports | - | - | - | - |
| **PC11.** ensure documentation and maintenance of records for every communication sent to or received from regulatory/ licensing authorities | - | - | - | - |
| **NOS Total** | **20** | **55** | **15** | **10** |

### National Occupational Standards (NOS) Parameters

| | |
|---|---|
| **NOS Code** | LFS/N0121 |
| **NOS Name** | Maintain the critical business documents as Entrepreneur in Life Sciences Sector |
| **Sector** | Life Sciences |
| **Sub-Sector** | Pharmaceutical, Bio Pharmaceutical, Contract Research |
| **Occupation** | Generic |
| **NSQF Level** | 6 |
| **Credits** | 1.00 |
| **Version** | 2.0 |
| **Last Reviewed Date** | 29/09/2023 |
| **Next Review Date** | 29/09/2026 |
| **NSQC Clearance Date** | 29/09/2023 |

## Assessment Guidelines and Assessment Weightage

### Assessment Guidelines

1. Criteria for assessment for each Qualification Pack will be created by Life Sciences Sector Skill Development Council (LSSSDC)

2. Each Element will be assigned marks proportional to its importance in NOS. LSSSDC will also lay down the proportion of marks for Theory, Practical, Project, and Viva for each Element.

3. The assessment for the theory part will be based on the knowledge bank of questions created by the LSSSDC.

4. Assessment will be conducted for all compulsory NOS, and where applicable, on the selected elective/option NOS/set of NOS.

5. LSSSDC as assessment and awarding body will create unique evaluations for each assessment component i.e. theory, practical, project and via for every student at each examination/training center based on this criterion.

6. Wherever any assessment component is not applicable/ feasible, the balance assessment components will be used to assess the candidate and accordingly the total marks will be calculated only for the applied

assessment component.

7. To pass the Qualification Pack, every trainee should score a minimum of 50%-70% of marks in each NOS (depending on NSQF Level) to successfully clear the assessment. In the case of a Govt funded program, the program guidelines will be overarching on the pass percentage rules.

8. In case of unsuccessful completion, the trainee may seek re-assessment on the Qualification Pack.

**Minimum Aggregate Passing % at QP Level : 70**

(**Please note**: Every Trainee should score a minimum aggregate passing percentage as specified above, to successfully clear the Qualification Pack assessment.)

**Minimum Passing % at NOS Level: 70**

(**Please note**: A Trainee must score the minimum percentage for each NOS separately as well as on the QP as a whole.)

## Assessment Weightage

Compulsory NOS

| National Occupational Standards | Theory Marks | Practical Marks | Project Marks | Viva Marks | Total Marks | Weightage |
|---|---|---|---|---|---|---|
| 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 | 25 | 45 | 20 | 10 | 100 | 6.25 |
| LFS/N0502.Submission of Technical Dossier as per the regulatory guidelines | 30 | 50 | 12 | 5 | 97 | 6.25 |
| LFS/N0571.Assist in intellectual property rights management for life sciences products and assets | 30 | 50 | 10 | 10 | 100 | 6.25 |
| LFS/N0122.Ensure adherence to Environment, health and safety guidelines at the workplace by self and subordinates | 40 | 40 | 10 | 10 | 100 | 6.25 |

| National Occupational Standards | Theory Marks | Practical Marks | Project Marks | Viva Marks | Total Marks | Weightage |
|---|---|---|---|---|---|---|
| LFS/N0567.Coordinate with Manager, R&D team, other cross-functional teams, external stakeholders and regulatory agencies to manage regulatory affairs operations | 25 | 45 | 17 | 13 | 100 | 6.25 |
| DGT/VSQ/N0103.Employability Skills (90 Hours) | 20 | 30 | - | - | 50 | 6.25 |
| **Total** | **170** | **260** | **69** | **48** | **547** | **37.5** |

Elective: 1 Pharma, Cosmetics, Nutraceuticals & AYUSH

| National Occupational Standards | Theory Marks | Practical Marks | Project Marks | Viva Marks | Total Marks | Weightage |
|---|---|---|---|---|---|---|
| LFS/N0501.Assist in managing the regulatory affairs for Pharmaceutical (including AYUSH), Cosmetics, and Nutraceutical products | 25 | 45 | 15 | 15 | 100 | 25 |
| **Total** | **25** | **45** | **15** | **15** | **100** | **25** |

Optional: 1 Regulated Business Operations

| National Occupational Standards | Theory Marks | Practical Marks | Project Marks | Viva Marks | Total Marks | Weightage |
|---|---|---|---|---|---|---|
| LFS/N0120.Establish own enterprise and perform various entrepreneurial activities to run the business operations in Life Sciences Sector | 30 | 50 | 12 | 8 | 100 | 18.75 |
| LFS/N0121.Maintain the critical business documents as Entrepreneur in Life Sciences Sector | 20 | 55 | 15 | 10 | 100 | 18.75 |
| **Total** | **50** | **105** | **27** | **18** | **200** | **37.5** |