Qualification Pack

Associate- Regulatory Affairs and Intellectual Property

Pharma, Cosmetics, Nutraceuticals & AYUSH

QP Code: LFS/Q0501 Instantiated QP Code: LFS/Q0501-SI001

Version: 2.0

NSQF Level: 5

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LFS/Q0501-SI001: 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

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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	21
Aligned to NCO/ISCO/ISIC Code	NCO-2015/2641.0901
Minimum Educational Qualification & Experience	B.Tech (Final Year Student (in Relevant Field)) OR B.Pharma (final year student) OR 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	-	-	-	-

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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**

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**

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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**

Qualification Pack

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

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**	**-**	**-**

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

Qualification Pack

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**

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

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	10
LFS/N0502.Submission of Technical Dossier as per the regulatory guidelines	30	50	12	5	97	10
LFS/N0571.Assist in intellectual property rights management for life sciences products and assets	30	50	10	10	100	10
LFS/N0122.Ensure adherence to Environment, health and safety guidelines at the workplace by self and subordinates	40	40	10	10	100	10

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	10
DGT/VSQ/N0103.Employability Skills (90 Hours)	20	30	-	-	50	10
Total	**170**	**260**	**69**	**48**	**547**	**60**

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	40
Total	**25**	**45**	**15**	**15**	**100**	**40**