



Qualification Pack



Associate- Regulatory Affairs and Intellectual Property

Biologics

QP Code: LFS/Q0501 Instantiated QP Code: LFS/Q0501-SI002

Version: 2.0

NSQF Level: 5

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LFS/Q0501-SI002: 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 : Biologics

1. [LFS/N0568: Assist in managing the regulatory affairs for Biologics](#)

Qualification Pack (QP) Parameters



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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.Pharm (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:



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- 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



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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Regulatory Dossier Preparation</i>	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	-	-	-	-
<i>Regulatory compliance for labelling and inserts</i>	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 are 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



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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

Qualification Pack

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Operating the Regulatory Systems</i>	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 are met while submitting the eCTD.	-	-	-	-
PC7. ensure mitigation of risk in eCTD publishing.	-	-	-	-
<i>Regulatory Dossier Submission</i>	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



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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



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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)



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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

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>IPR Management</i>	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.	-	-	-	-



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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



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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



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- 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)



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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

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Adhere to health and hygiene protocols</i>	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	-	-	-	-
<i>Adhere to safety and security procedures</i>	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	-	-	-	-
<i>Adhere to emergency procedures</i>	10	10	3	3

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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	-	-	-	-
<i>Environment Sustainability</i>	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



Qualification Pack

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 Trial 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

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- 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 distributors 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



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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

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Coordination with Manager</i>	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	-	-	-	-
<i>Coordination with R&D Team</i>	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	-	-	-	-
<i>Coordination with cross-functional teams</i>	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 Trial 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	-	-	-	-

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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	-	-	-	-
<i>Coordination with External Stakeholders and Regulatory Agencies</i>	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 distributors as per regulatory laws if any	-	-	-	-
PC17. collaborate with the local Regulatory liaison agent for smooth execution & liasoning	-	-	-	-
<i>Sensitivity towards all genders and people with disability</i>	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



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- 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

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- 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



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- 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

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Introduction to Employability Skills</i>	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	-	-	-	-
<i>Constitutional values – Citizenship</i>	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	-	-	-	-
<i>Becoming a Professional in the 21st Century</i>	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	-	-	-	-
<i>Basic English Skills</i>	3	4	-	-
PC9. use basic English for everyday conversation in different contexts, in person and over the telephone	-	-	-	-

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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	-	-	-	-
<i>Career Development & Goal Setting</i>	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	-	-	-	-
<i>Communication Skills</i>	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	-	-	-	-
<i>Diversity & Inclusion</i>	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	-	-	-	-
<i>Financial and Legal Literacy</i>	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	-	-	-	-

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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	-	-	-	-
<i>Essential Digital Skills</i>	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	-	-	-	-
<i>Entrepreneurship</i>	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	-	-	-	-
<i>Customer Service</i>	1	2	-	-
PC33. identify different types of customers and ways to communicate with them	-	-	-	-



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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	-	-	-	-
<i>Getting ready for apprenticeship & Jobs</i>	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



Qualification Pack

LFS/N0568: Assist in managing the regulatory affairs for Biologics

Description

The NOS is about a person who Assist in managing the regulatory affairs for Biologics

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.** Conduct IBSC (Institutional Biosafety committee) review meeting at regular intervals.
- PC4.** submit information to RCGM (Review committee on Genetic manipulation) in prescribed formats to carry out research and development involving Hazardous Microorganisms (HMOs), Genetically Modified Organisms (GMOs)/ Living Modified Organisms (LMOs) for healthcare and industrial use.
- PC5.** facilitate for submission to RCGM in prescribed formats to conduct preclinical and/or safety studies of similar biologic developed using GMOs/ LMOs for healthcare and industrial use for Biosimilars
- PC6.** facilitate for submission of the application to RCGM in prescribed formats for Import and Export of HMOs, GMOs/LMOs and Product(S) for research & development purpose
- PC7.** facilitate for submission of Toxicology report to RCGM in prescribed formats, post completion of the Toxicology studies for biosimilars
- PC8.** facilitate the domestic and international tendering process, audits and inspections and submission of various applications to state drug control administration and zonal office of national regulatory agency (i.e. CDSCO ZO) as part of the life cycle management and tender support
- PC9.** 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)
- PC10.** facilitate for regulatory approval for market authorization application (MAA) via Gulf Cooperation Council procedure (GCC)
- PC11.** facilitate for regulatory approval for New Drug Submission (NDS) / for a new brand name drug



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- PC12.** 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:

- PC13.** facilitate in obtaining certificate of suitability (CEP/ COS) from drug regulatory authority.
- PC14.** facilitate in obtaining certificate of pharmaceutical product (COPP) and certificate of good manufacturing practices from Indian drug regulatory authority (CDSCO).
- PC15.** facilitate in obtaining the free sale and commerce certificate (FSC)/ certificate for export from Indian Drug Regulatory authority (CDSCO).
- PC16.** facilitate in liasoning and filing submission with national pharmaceutical pricing authority (NPPA)
- PC17.** facilitate in liasoning and filing submission with central insecticide lab (CIL) and central insecticide board (CIB)

Regulatory facilitation for Post Approval Changes

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

- PC18.** perform CMC assessments for gap
- PC19.** perform compliance checks of current registered information versus manufacturing documentation for licensed biologics
- PC20.** perform change control review and management while implementation of vendor changes, change in plant machineries, pharmacopoeia updates or any process changes etc.
- PC21.** prepare and facilitate submission of variations to the regulators to close the identified 'compliance gaps'
- PC22.** 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.
- PC23.** 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.** excellent knowledge of HMOs, GMOs and LMOs in R&D
- KU2.** related Indian drug regulatory authority like CDSCO, IBSC and RCGM
- KU3.** IND, NDS, SANDS and SNDS regulatory approval procedures
- KU4.** different certificate CEP/COS, COPP, FSC from national authority
- KU5.** how to liaising for various product submission with NPPA, CIL, CIB
- KU6.** different procedure like (CP, NP, MRP and DCP) for approval of Market authorization application (MAA)
- KU7.** broad knowledge of Regulatory Affairs and specific working knowledge of current regulations and guidance
- KU8.** preparation of various document like DSUR, PBRER and RMPs



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- KU9.** 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
- KU10.** various management changing techniques according change in process
- KU11.** associated experience in Quality Assurance and Document Control is required in certain cases
- KU12.** training in necessary procedures for filing licenses and liaising with regulatory authorities of different countries
- KU13.** good knowledge of GMP, GLP and Safety requirements
- KU14.** national/international standard test methods for different compounds
- KU15.** 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

Qualification Pack

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Regulatory facilitation for Licences and Authorization</i>	10	20	5	3
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. Conduct IBSC (Institutional Biosafety committee) review meeting at regular intervals.	-	-	-	-
PC4. submit information to RCGM (Review committee on Genetic manipulation) in prescribed formats to carry out research and development involving Hazardous Microorganisms (HMOs), Genetically Modified Organisms (GMOs)/ Living Modified Organisms (LMOs) for healthcare and industrial use.	-	-	-	-
PC5. facilitate for submission to RCGM in prescribed formats to conduct preclinical and/or safety studies of similar biologic developed using GMOs/ LMOs for healthcare and industrial use for Biosimilars	-	-	-	-
PC6. facilitate for submission of the application to RCGM in prescribed formats for Import and Export of HMOs, GMOs/LMOs and Product(S) for research & development purpose	-	-	-	-
PC7. facilitate for submission of Toxicology report to RCGM in prescribed formats, post completion of the Toxicology studies for biosimilars	-	-	-	-
PC8. facilitate the domestic and international tendering process, audits and inspections and submission of various applications to state drug control administration and zonal office of national regulatory agency (i.e. CDSCO ZO) as part of the life cycle management and tender support	-	-	-	-

Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC9. 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)	-	-	-	-
PC10. facilitate for regulatory approval for market authorization application (MAA) via Gulf Cooperation Council procedure (GCC)	-	-	-	-
PC11. facilitate for regulatory approval for New Drug Submission (NDS) / for a new brand name drug	-	-	-	-
PC12. 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	-	-	-	-
<i>Regulatory facilitation for Miscellaneous Approvals</i>	10	20	5	2
PC13. facilitate in obtaining certificate of suitability (CEP/ COS) from drug regulatory authority.	-	-	-	-
PC14. facilitate in obtaining certificate of pharmaceutical product (COPP) and certificate of good manufacturing practices from Indian drug regulatory authority (CDSCO).	-	-	-	-
PC15. facilitate in obtaining the free sale and commerce certificate (FSC)/ certificate for export from Indian Drug Regulatory authority (CDSCO).	-	-	-	-
PC16. facilitate in liasoning and filing submission with national pharmaceutical pricing authority (NPPA)	-	-	-	-
PC17. facilitate in liasoning and filing submission with central insecticide lab (CIL) and central insecticide board (CIB)	-	-	-	-
<i>Regulatory facilitation for Post Approval Changes</i>	5	10	5	5
PC18. perform CMC assessments for gap	-	-	-	-
PC19. perform compliance checks of current registered information versus manufacturing documentation for licensed biologics	-	-	-	-



Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC20. perform change control review and management while implementation of vendor changes, change in plant machineries, pharmacopoeia updates or any process changes etc.	-	-	-	-
PC21. prepare and facilitate submission of variations to the regulators to close the identified 'compliance gaps'	-	-	-	-
PC22. 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.	-	-	-	-
PC23. 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	50	15	10



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0568
NOS Name	Assist in managing the regulatory affairs for Biologics
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Research and Development
NSQF Level	5
Credits	6.00
Version	1.0
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 viva 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



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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



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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 Biologics

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0568.Assist in managing the regulatory affairs for Biologics	25	50	15	10	100	40
Total	25	50	15	10	100	40