Qualification Pack

Analyst- Drug Safety/ Pharmacovigilance

QP Code: LFS/Q0701

Version: 2.0

NSQF Level: 5.5

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

Contents

Qualification Pack

LFS/Q0701: Analyst- Drug Safety/ Pharmacovigilance

Brief Job Description

Analyst- Drug Safety/ Pharmacovigilance is responsible for the collection of information on ADR/AE and processing of Individual Case Safety Reports (ICSR). The individual is responsible for preparation and submission of Periodic Safety Reports Like PSUR, PBRER, DUSR etc. The person is also expected to render support in development of Risk Management Plan (RMP) and Pharmacovigilance System Master File (PSMF).The individual is also responsible for Global and local Literature Surveillance using literature databases (e.g. PubMed, Embase).This individual is involved in Processing , maintenance and safety of sensitive personal information in compliance with local regulations and company's Global Pharmacovigilance requirements. The individual is responsible for permanent organized documented records of for all safety reports.

Personal Attributes

The individual should be highly process driven with excellent attention to detail and time management; have good writing, reading and computer skills.

Applicable National Occupational Standards (NOS)

Compulsory NOS:

1. LFS/N0702: Perform collection, processing, medical coding and assessment of Individual Case Study Reports (ICSRs)
2. LFS/N0705: Use relevant software systems for various Pharmacovigilance activities (Case Processing, Aggregate Safety reports, signal management , etc.)
3. LFS/N0706: Prepare and compile Aggregate Safety Reports (PSURs, PBRERs, PADERs, HHE reports), Risk Management Plans & Signal Management Reports
4. LFS/N0703: Ensure regulatory compliance
5. LFS/N0704: Coordinate with relevant internal and external stakeholders
6. LFS/N0119: Ensure environment sustainability and sensitivity towards all genders and people with disability
7. DGT/VSQ/N0102: Employability Skills (60 Hours)

Qualification Pack (QP) Parameters

Qualification Pack

Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research, Biotechnology
Occupation	Pharmacovigilance, Pharmacovigilance
Country	India
NSQF Level	5.5
Credits	18
Aligned to NCO/ISCO/ISIC Code	NCO-2015- 2212.9900
Minimum Educational Qualification & Experience	Graduate (Completed B.Sc (Microbiology) / B. Pharma / B. Tech (Biotech) (Indian / foreign universities)) OR Medical Graduate (Completed MBBS/BDS/BPT/BOT/BAMS/BHMS (in any medical subject)/ (Indian / recognized foreign universities))
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	01/11/2026
NSQC Approval Date	01/11/2023
Version	2.0
Reference code on NQR	QG-5.5-LS-01267-2023-V1-LSSSDC
NQR Version	1

Qualification Pack

LFS/N0702: Perform collection, processing, medical coding and assessment of Individual Case Study Reports (ICSRs)

Description

This NOS gives an overview how a individual working pharmacovigilance Perform collection, processing, medical coding and assessment of Individual Case Study Reports (ICSRs)

Scope

The scope covers the following :

- Data Collection of ICSR's
- Processing of ICSR and Triage
- Data entry of ICSR
- Reporting of ICSR

Elements and Performance Criteria

Data Collection of ICSR's

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

PC1. collect data from solicited sources (Patient registries, Interventional and non-interventional studies, post-approval compassionate use programs, name patient programs (Pre-approval) etc.) and unsolicited sources (Regulatory reports, Literature Reports, Spontaneous Reports from healthcare professional/consumer, Internet/digital media etc.,) to strengthen spontaneous reporting of ADRs

PC2. perform literature monitoring of pharmaceutical products by using electronic literature database or offline literature to identify ICSR and other safety related information in compliance with Company's policies and local Pharmacovigilance requirements for the same

PC3. follow-up regularly to obtain additional information relevant to the case as necessary to provide a complete description of the safety event

PC4. handle the calls as required if deputed in drug safety call centres

Processing of ICSR and Triage

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

PC5. record the date of receipt for each ADR from initial notification to follow-up communication

PC6. record the date first valid (Day Zero/ Clock start date- considered the day on which the minimum criteria like patient information, suspect drug, AE/ADR , reporter details for a reportable ICSR is fulfilled)

PC7. perform duplicate check of ICSR

PC8. check whether the case is medically confirmed

PC9. ensure that the patient's confidentiality and privacy in accordance with local applicable laws and regulations are adhered to and if necessary, performed by redaction of patient

PC10. perform triage prioritization of 15-day cases

Medical coding for ICSR

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

PC11. perform data entry for ICSRs into safety databases and coding of relevant medical terminologies using MedDRA dictionary

PC12. write case narrative in chronological order

PC13. maintain source documents as per Good Pharmacovigilance Practices (GPvP)

Reporting of ICSR

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

PC14. interpret all the validated new information from appropriate sources

PC15. perform ICSR reporting by including essential data elements like patient information, reporter details, suspected reaction and suspected medications

PC16. submit expedited reports within given time frame to meet the regulatory reporting timelines

PC17. classify special population (Pregnancy, Geriatric and Paediatric) cases using pharmaceutical products

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. data collection procedure of company

KU2. ICSR related Standard Operating Procedures (SOPs)

KU3. SOP on case processing, writing case narratives and MedDRA coding

KU4. procedures for reporting data

KU5. escalation procedures

KU6. quality management SOPs including those for change control, deviations and Corrective Action Preventive Action (CAPA) and Business continuity planning (BCP)

KU7. security, privacy, data protection, IT policies and integrity policies of organization

KU8. general principles of pharmacology

KU9. PVPI, ICH and WHO guidelines for adverse event reporting

KU10. GCP, GPvP guidelines and GVP Modules

KU11. concepts of Pharmacology including Absorption, Distribution, Metabolism, Elimination, and Route of Drug Administration in context of Pharmacovigilance

KU12. understanding of Post Marketing Surveillance (PMS), Pharmacovigilance System Master File (PSMF), Risk Management Planning (RMP) followed by risk/benefit assessment, Periodic Safety Update Reports (PSURs) and Signal detection and Management.

KU13. procedure proportional reporting ratio (PRR) and IC Value calculation

KU14. utilization of MedDRA and WHO drug dictionary

KU15. method of writing case narratives and medical writing

KU16. tools and methods of literature search (e.g. PubMed)

KU17. tools and software for ICSR report generation (e.g. Argus, ArisG)

KU18. functioning of EudraVigilance

KU19. PV guidelines and regulatory requirement of USFDA, EMA, CDSCO, UKMHRA, Health Canada and other international regulators

KU20. changes/new regulations affecting pharmacovigilance activities

KU21. report writing for medication error and lack of efficacy

Generic Skills (GS)

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

GS1. record and communicate details of work done to appropriate people using written/typed report or computer-based record/electronic mail

GS2. use computers, internet, software tools to write the case narratives

GS3. read and interpret the various coding systems as per company norms, GCP, GVP, Volume 9A, Volume 10, CIOMS, ICH E2B, E2C, E2D, E2F, M4, M1 and WHO guidelines

GS4. disclose information only to those who have the right and need to know it and maintain confidentiality

GS5. practice professional telephone etiquette

GS6. practice strong verbal and interpersonal communication skills

GS7. communicate new or changed regulations to relevant members of the department to initiate any change in process

GS8. use verbal communication etiquette to build and maintain good relationships across functional units and company affiliates

GS9. make decisions to write case narratives in compliance to the regulations and guidelines

GS10. practice strong organization and prioritization skills for handling administrative and data entry duties simultaneously

GS11. plan work assigned on a daily basis and provide estimates of time required for each piece of work

GS12. adapt to meet work timelines

GS13. seek clarification on problems from others

GS14. use effective problem-solving techniques

GS15. escalate critical items or any other issue deemed necessary to concerned managers/ clients

GS16. apply, analyse and evaluate information to define action steps

GS17. apply balanced judgments to different approaches

GS18. analyse the depth of the issue and apply a proactive approach

GS19. identify the data points which needs to be queried to reporter or local safety officer

GS20. keep customer guidelines, instructions and the related regulatory requirement in focus while writing ICSR

GS21. liaise effectively and maintain excellent relationship with the internal/ external contacts

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Data Collection of ICSR's	**15**	**15**	**6**	**4**
PC1. collect data from solicited sources (Patient registries, Interventional and non-interventional studies, post-approval compassionate use programs, name patient programs (Pre-approval) etc.) and unsolicited sources (Regulatory reports, Literature Reports, Spontaneous Reports from healthcare professional/consumer, Internet/digital media etc.,) to strengthen spontaneous reporting of ADRs	-	-	-	-
PC2. perform literature monitoring of pharmaceutical products by using electronic literature database or offline literature to identify ICSR and other safety related information in compliance with Company's policies and local Pharmacovigilance requirements for the same	-	-	-	-
PC3. follow-up regularly to obtain additional information relevant to the case as necessary to provide a complete description of the safety event	-	-	-	-
PC4. handle the calls as required if deputed in drug safety call centres	-	-	-	-
Processing of ICSR and Triage	**10**	**10**	**10**	**5**
PC5. record the date of receipt for each ADR from initial notification to follow-up communication	-	-	-	-
PC6. record the date first valid (Day Zero/ Clock start date- considered the day on which the minimum criteria like patient information, suspect drug, AE/ADR , reporter details for a reportable ICSR is fulfilled)	-	-	-	-
PC7. perform duplicate check of ICSR	-	-	-	-
PC8. check whether the case is medically confirmed	-	-	-	-
PC9. ensure that the patient's confidentiality and privacy in accordance with local applicable laws and regulations are adhered to and if necessary, performed by redaction of patient	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC10. perform triage prioritization of 15-day cases	-	-	-	-
Medical coding for ICSR	**-**	**-**	**-**	**-**
PC11. perform data entry for ICSRs into safety databases and coding of relevant medical terminologies using MedDRA dictionary	-	-	-	-
PC12. write case narrative in chronological order	-	-	-	-
PC13. maintain source documents as per Good Pharmacovigilance Practices (GPvP)	-	-	-	-
Reporting of ICSR	**8**	**8**	**5**	**4**
PC14. interpret all the validated new information from appropriate sources	-	-	-	-
PC15. perform ICSR reporting by including essential data elements like patient information, reporter details, suspected reaction and suspected medications	-	-	-	-
PC16. submit expedited reports within given time frame to meet the regulatory reporting timelines	-	-	-	-
PC17. classify special population (Pregnancy, Geriatric and Paediatric) cases using pharmaceutical products	-	-	-	-
NOS Total	**33**	**33**	**21**	**13**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0702
NOS Name	Perform collection, processing, medical coding and assessment of Individual Case Study Reports (ICSRs)
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Pharmacovigilance
NSQF Level	5.5
Credits	4.0
Version	1.0
Last Reviewed Date	01/11/2023
Next Review Date	01/11/2026
NSQC Clearance Date	01/11/2023

LFS/N0705: Use relevant software systems for various Pharmacovigilance activities (Case Processing, Aggregate Safety reports, signal management , etc.)

Description

This NOS gives an overview about the Use relevant software systems for various Pharmacovigilance activities (Case Processing, Aggregate Safety reports, signal management , etc.)

Scope

The scope covers the following :

- Coding using MedDRA Dictionary, WHO Drug Dictionary and Medical terminologies
- Study of Drug Safety Databases like Argus, ArisGlobal, Safety Easy (AB Cube)
- Working with Pharmacovigilance Databases

Elements and Performance Criteria

Coding using MedDRA Dictionary, WHO Drug Dictionary and Medical terminologies

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

PC1. use MedDRA software tools

PC2. conduct medical coding of adverse events by using appropriate MedDRA code to ensure accuracy of label AE assessments

PC3. utilize MedDRA coding according to ICH (International Conference on Harmonization) guidelines while coding an adverse event

PC4. deliver outcomes using MedDRA in Clinical trial databases, Investigator’s Brochures, Core Safety Information, Safety summaries, Clinical Study Reports, ICSRs, PSURs and product labelling

PC5. generate line listing and summary tabulation

Study of Drug Safety Databases like Argus, ArisGlobal, Safety Easy (AB Cube)

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

PC6. use relevant software tools to support the entry, classification, coding and assessment of adverse event reports, in accordance with international standards and guidelines

PC7. manage reports from all potential sources, including spontaneous, literature and clinical trial safety reports, to support blinded clinical trials and other specific business processes and SOPs

PC8. facilitate compliance with domestic and global safety reporting obligations for drugs, vaccines, biologics, devices and combination products

PC9. assist in delivering automated global case processing, periodic reporting, E2B intake and submission, comprehensive reporting, detailed analytics and safety operations from within a single system

PC10. assist in specific actions and monitor response timeframes for all key activities such as data entry, assessment, coding and reporting for full compliance

PC11. explain wide range ICSR reports including expedited (serious reports, at risk reports), non-expedited reports and aggregate reports to aid in global adverse event reporting, including the national and other international adverse reporting forms and aggregate report templates

PC12. develop matrix of continuous flow and submission of cases

Working with Pharmacovigilance Databases

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

PC13. check for software tools' validation (IQ, OQ & PQ) before using the software tool or databases and perform labelling of ADRs against the approved company labels

PC14. perform manual data entry from ADR paper forms with support from integrated international terminologies (latest versions) such as WHO Drug and MedDRA

PC15. comply with the international ICH E2B standard and support quality review of cases processed and report scheduling

PC16. support the domestic collection and processing of individual case safety report (ICSR) data, and its sharing of reports

PC17. perform post marketing surveillance at the sponsor site, CRO site, hospitals, AMCs (Adverse Drug Reaction Monitoring Centres) to store the safety profile and adverse event reports of the drug

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. IT policies of company

KU2. data integrity related SOPs

KU3. SOP for accessing the computer systems and emails

KU4. procedures for reporting data, escalation procedures

KU5. quality management SOPs including those for change control, deviations and CAPAs and BCP

KU6. operating procedure of software like MedDRA, WHO Drug dictionary, SAS, various Drug Safety Database like Argus and ArisGlobal, Safety Easy (AB Cube), EudraVigilance and ADR reporting software like VigiFlow and VigiBase

KU7. GCP guidelines and ICH E2B standard

KU8. how to improve the typing speed

KU9. method of writing case narratives and medical writing

KU10. tools and methods of literature search

KU11. process flow and forms of ADR reporting reports

KU12. artificial intelligence future software validation tools (IQ, OQ & PQ) as well as about artificial intelligence

KU13. changes/new regulations affecting pharmacovigilance activities

KU14. assessment of Vaccine Adverse Event Reporting System (VAERS)

KU15. recall International Classification of Diseases (ICD) codes for drugs

Generic Skills (GS)

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

GS1. draft letters pertaining to AEs and write detailed reports for pharmacovigilance reporting

GS2. record and communicate details of work done to appropriate people using written/typed report or computer-based record/electronic mail

GS3. use computers, internet, software tools for pharmacovigilance related work

GS4. read and interpret various coding systems, medical terminology as per company norms, GCP, PVPI and WHO guidelines

GS5. read notes/comments from supervisors

GS6. disclose information only to those who have the right and need to know it

GS7. maintain confidentiality of sensitive information

GS8. communicate new or changed regulations to relevant members of the department to initiate any change in process

GS9. build and maintain good relationships across functional units and company affiliates

GS10. analyse data and information for preparing reports

GS11. pay attention to detail

GS12. identify anomalies in data

GS13. suggest improvements (if any) in process/formats for reports/documentation based on experience and observation

GS14. use available data and computer software to create required documentation

GS15. make decisions on a suitable course of action or response

GS16. make decisions to write case narratives in compliance to the regulations and guidelines

GS17. plan and organize assigned work in order to achieve specified deadlines

GS18. multi-task and adapt to meet work timelines

GS19. effectively interact with the various stakeholders to complete assigned tasks

GS20. evaluate the drafted reports in line to data integrity rules

GS21. critically assess the terms/ medical codes for preparing the report

GS22. take help of IT team in case of any login related issues

GS23. escalate critical items or any other issue deemed necessary to concerned managers/ clients

GS24. keep customer guidelines, instructions and the relevant regulatory guidelines in focus while reporting the ADR

GS25. ensure data integrity and confidentiality while entering information

GS26. liaise effectively and maintain excellent relationship with the internal/external contacts

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Coding using MedDRA Dictionary, WHO Drug Dictionary and Medical terminologies	**12**	**12**	**7**	**4**
PC1. use MedDRA software tools	-	-	-	-
PC2. conduct medical coding of adverse events by using appropriate MedDRA code to ensure accuracy of label AE assessments	-	-	-	-
PC3. utilize MedDRA coding according to ICH (International Conference on Harmonization) guidelines while coding an adverse event	-	-	-	-
PC4. deliver outcomes using MedDRA in Clinical trial databases, Investigator's Brochures, Core Safety Information, Safety summaries, Clinical Study Reports, ICSRs, PSURs and product labelling	-	-	-	-
PC5. generate line listing and summary tabulation	-	-	-	-
Study of Drug Safety Databases like Argus, ArisGlobal, Safety Easy (AB Cube)	**12**	**12**	**7**	**4**
PC6. use relevant software tools to support the entry, classification, coding and assessment of adverse event reports, in accordance with international standards and guidelines	-	-	-	-
PC7. manage reports from all potential sources, including spontaneous, literature and clinical trial safety reports, to support blinded clinical trials and other specific business processes and SOPs	-	-	-	-
PC8. facilitate compliance with domestic and global safety reporting obligations for drugs, vaccines, biologics, devices and combination products	-	-	-	-
PC9. assist in delivering automated global case processing, periodic reporting, E2B intake and submission, comprehensive reporting, detailed analytics and safety operations from within a single system	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC10. assist in specific actions and monitor response timeframes for all key activities such as data entry, assessment, coding and reporting for full compliance	-	-	-	-
PC11. explain wide range ICSR reports including expedited (serious reports, at risk reports), non-expedited reports and aggregate reports to aid in global adverse event reporting, including the national and other international adverse reporting forms and aggregate report templates	-	-	-	-
PC12. develop matrix of continuous flow and submission of cases	-	-	-	-
Working with Pharmacovigilance Databases	**10**	**10**	**6**	**4**
PC13. check for software tools' validation (IQ, OQ & PQ) before using the software tool or databases and perform labelling of ADRs against the approved company labels	-	-	-	-
PC14. perform manual data entry from ADR paper forms with support from integrated international terminologies (latest versions) such as WHO Drug and MedDRA	-	-	-	-
PC15. comply with the international ICH E2B standard and support quality review of cases processed and report scheduling	-	-	-	-
PC16. support the domestic collection and processing of individual case safety report (ICSR) data, and its sharing of reports	-	-	-	-
PC17. perform post marketing surveillance at the sponsor site, CRO site, hospitals, AMCs (Adverse Drug Reaction Monitoring Centres) to store the safety profile and adverse event reports of the drug	-	-	-	-
NOS Total	**34**	**34**	**20**	**12**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0705
NOS Name	Use relevant software systems for various Pharmacovigilance activities (Case Processing, Aggregate Safety reports, signal management , etc.)
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Pharmacovigilance
NSQF Level	5.5
Credits	3.0
Version	1.0
Last Reviewed Date	01/11/2023
Next Review Date	01/11/2026
NSQC Clearance Date	01/11/2023

Qualification Pack

LFS/N0706: Prepare and compile Aggregate Safety Reports (PSURs, PBRERs, PADERs, HHE reports), Risk Management Plans & Signal Management Reports

Description

This NOS gives an overview about how to Prepare and compile Aggregate Safety Reports (PSURs, PBRERs, PADERs, HHE reports), Risk Management Plans & Signal Management Reports

Scope

The scope covers the following :

- Aggregate Safety Reports
- Risk Management Plans (RMPs)
- Signal Management Reports

Elements and Performance Criteria

Aggregate Safety Reports

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

PC1. compiles and prepares Aggregate Safety Reports (e.g., PSURs, PBRERs, PADERs, HHE reports) with accuracy and adherence to regulatory timelines.

PC2. ensures that all Aggregate Safety Reports are compliant with relevant regulatory guidelines, such as ICH E2E, ICH E2C, and local regulatory requirements.

PC3. conducts robust benefit-risk assessments for products and communicates findings effectively in Aggregate Safety Reports.

PC4. submits Aggregate Safety Reports with a high degree of accuracy and adherence to regulatory requirements, avoiding critical errors or omissions.

Risk Management Plans (RMPs)

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

PC5. develops and maintains comprehensive Risk Management Plans (RMPs) that effectively address product safety concerns and meet regulatory requirements.

PC6. identifies potential safety concerns and recommends risk mitigation strategies within RMPs, contributing to product safety and patient well-being.

PC7. Report and document to ensure seamless integration of safety information into RMPs.

Signal Management Reports

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

PC8. efficiently detects and evaluates potential safety signals using appropriate methodologies, ensuring timely signal detection and assessment

PC9. generates and maintains Signal Management Reports that clearly summarize signal detection activities, risk assessments, and management strategies

PC10. effectively prioritizes safety signals based on their potential impact and seriousness, ensuring that critical signals are addressed promptly.

PC11. ensure to respond effectively to safety crises or urgent safety issues, including the preparation of rapid response plans and communications.

PC12. effectively incorporates adverse event case data into Signal Management Reports, ensuring the comprehensive assessment of product safety.

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. IT policies of company

KU2. data integrity related SOPs

KU3. SOP for accessing the computer systems and emails

KU4. procedures for reporting data, escalation procedures

KU5. quality management SOPs including those for change control, deviations and CAPAs and BCP

KU6. basic of PSUR,PBRER,PADER,HHE reports

KU7. operating procedure of software like MedDRA, WHO Drug dictionary, SAS, various Drug Safety Database like Argus and ArisGlobal, Safety Easy (AB Cube), EudraVigilance and ADR reporting software like VigiFlow and VigiBase

KU8. GCP guidelines and ICH E2B standard

KU9. how to improve the typing speed

KU10. method of writing case narratives and medical writing

KU11. tools and methods of literature search

KU12. process flow and forms of ADR reporting reports

KU13. artificial intelligence future software validation tools (IQ, OQ & PQ) as well as about artificial intelligence

KU14. changes/new regulations affecting pharmacovigilance activities

KU15. assessment of Vaccine Adverse Event Reporting System (VAERS)

KU16. recall International Classification of Diseases (ICD) codes for drugs

Generic Skills (GS)

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

GS1. draft letters pertaining to AEs and write detailed reports for pharmacovigilance reporting

GS2. record and communicate details of work done to appropriate people using written/typed report or computer-based record/electronic mail

GS3. use computers, internet, software tools for pharmacovigilance related work

GS4. read and interpret various coding systems, medical terminology as per company norms, GCP, PVPI and WHO guidelines

GS5. read notes/comments from supervisors

GS6. disclose information only to those who have the right and need to know it

GS7. maintain confidentiality of sensitive information

GS8. communicate new or changed regulations to relevant members of the department to initiate any change in process

GS9. build and maintain good relationships across functional units and company affiliates

GS10. analyse data and information for preparing reports

GS11. pay attention to detail

GS12. identify anomalies in data

GS13. suggest improvements (if any) in process/formats for reports/documentation based on experience and observation

GS14. use available data and computer software to create required documentation

GS15. make decisions on a suitable course of action or response

GS16. make decisions to write case narratives in compliance to the regulations and guidelines

GS17. plan and organize assigned work in order to achieve specified deadlines

GS18. multi-task and adapt to meet work timelines

GS19. effectively interact with the various stakeholders to complete assigned tasks

GS20. evaluate the drafted reports in line to data integrity rules

GS21. critically assess the terms/ medical codes for preparing the report

GS22. take help of IT team in case of any login related issues

GS23. escalate critical items or any other issue deemed necessary to concerned managers/ clients

GS24. keep customer guidelines, instructions and the relevant regulatory guidelines in focus while reporting the ADR

GS25. ensure data integrity and confidentiality while entering information

GS26. liaise effectively and maintain excellent relationship with the internal/external contacts

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Aggregate Safety Reports	**12**	**12**	**7**	**4**
PC1. compiles and prepares Aggregate Safety Reports (e.g., PSURs, PBRERs, PADERs, HHE reports) with accuracy and adherence to regulatory timelines.	-	-	-	-
PC2. ensures that all Aggregate Safety Reports are compliant with relevant regulatory guidelines, such as ICH E2E, ICH E2C, and local regulatory requirements.	-	-	-	-
PC3. conducts robust benefit-risk assessments for products and communicates findings effectively in Aggregate Safety Reports.	-	-	-	-
PC4. submits Aggregate Safety Reports with a high degree of accuracy and adherence to regulatory requirements, avoiding critical errors or omissions.	-	-	-	-
Risk Management Plans (RMPs)	**12**	**12**	**7**	**4**
PC5. develops and maintains comprehensive Risk Management Plans (RMPs) that effectively address product safety concerns and meet regulatory requirements.	-	-	-	-
PC6. identifies potential safety concerns and recommends risk mitigation strategies within RMPs, contributing to product safety and patient well-being.	-	-	-	-
PC7. Report and document to ensure seamless integration of safety information into RMPs.	-	-	-	-
Signal Management Reports	**10**	**10**	**6**	**4**
PC8. efficiently detects and evaluates potential safety signals using appropriate methodologies, ensuring timely signal detection and assessment	-	-	-	-
PC9. generates and maintains Signal Management Reports that clearly summarize signal detection activities, risk assessments, and management strategies	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC10. effectively prioritizes safety signals based on their potential impact and seriousness, ensuring that critical signals are addressed promptly.	-	-	-	-
PC11. ensure to respond effectively to safety crises or urgent safety issues, including the preparation of rapid response plans and communications.	-	-	-	-
PC12. effectively incorporates adverse event case data into Signal Management Reports, ensuring the comprehensive assessment of product safety.	-	-	-	-
NOS Total	**34**	**34**	**20**	**12**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0706
NOS Name	Prepare and compile Aggregate Safety Reports (PSURs, PBRERs, PADERs, HHE reports), Risk Management Plans & Signal Management Reports
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Pharmacovigilance
NSQF Level	5.5
Credits	2.0
Version	1.0
Last Reviewed Date	01/11/2023
Next Review Date	01/11/2026
NSQC Clearance Date	01/11/2023

LFS/N0703: Ensure regulatory compliance

Description

This NOS unit discusses about the procedures followed by Pharmacovigilance analyst for ensuring regulatory compliance

Scope

The scope covers the following :

- Compile and review the regulatory compliance of ICSRs
- Identifying and resolving any issues hampering the regulatory compliance
- Improving regulatory compliance

Elements and Performance Criteria

Compile and review the regulatory compliance of ICSRs

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

PC1. ensure timely submission of ICSRs, PSUR, RMP, Signal reports and aggregate reports as per the respective Regulatory Authority submission timeline

PC2. ensure appropriate processes are in place to comply with the respective Regulatory Authority requirement (GVP, PVPI, FDA, PMDA, Eudravigilance & regulatory guidelines from major markets including but not limited to ANVIA, ANMAT, COFEPRIS, Russian Federation, CIS countries, China, Malaysia, Indonesia, Vietnam, Singapore, Sri Lanka Bangladesh, China, South Korea)

PC3. review the accuracy of reports on a regular basis to comply with the existing Regulatory requirements and perform the receipt and evaluation of safety data exchange agreements (as applicable)

PC4. ensure that the reports are submitted to regulatory authorities within timelines

Identifying and resolving any issues hampering the regulatory compliance

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

PC5. take corrective action in response to non-compliance of reports

PC6. initiate investigation for the deviations

PC7. identify the root cause of the deviation, take corrective and preventive actions and provide adequate trainings. (if required)

PC8. ensure appropriate documentation of these corrective and preventive actions

Improving regulatory compliance

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

PC9. maintain awareness about current regulatory trends and practices.

PC10. ensure adherence to Pharmacovigilance Quality Management System (PQMS)

PC11. incorporate continuous improvements into Pharmacovigilance processes and policies based on existing Global and Local Regulatory Pharmacovigilance requirements

PC12. participate in regulatory inspection/ internal and client audit

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. IT rules and policies of company
KU2. data integrity related SOPs
KU3. SOP for accessing the computer systems and emails
KU4. procedures for reporting of faulty system or software problems
KU5. escalation procedures
KU6. quality management SOPs including those for change control, deviations and CAPAs and BCP
KU7. operating procedure of software like MedDRA, WHO Drug dictionary, SAS, Drug Study Database like Argus and ArisGlobal, ADR reporting software like VigiFlow, VigiBase
KU8. GCP guidelines and ICH E2B standard
KU9. computer handling (MS Word, Excel, Power Point Presentation, Outlook and Skype)
KU10. software validation procedures
KU11. changes/new regulations affecting pharmacovigilance activities

Generic Skills (GS)

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

GS1. complete accurate and well written work with attention to detail
GS2. record and communicate details of work done to appropriate people using written/typed report or computer-based record/electronic mail
GS3. use computers, internet, software tools ONLY for pharmacovigilance related work
GS4. read instructions, guidelines, procedures, rules and service level agreements
GS5. understand the various coding systems, software terminology as per company norms, GCP, GVP, PVPI and WHO guidelines
GS6. communicate with IT infrastructure and QA team
GS7. disclose information only to those who have the right and need to know it and maintain confidentiality
GS8. communicate new or changed regulations to relevant members of the department to initiate any change in process
GS9. build and maintain good relationships across functional units and company affiliates
GS10. make decisions on suitable courses of action
GS11. make decisions to use the software which are in compliance to the regulations and guidelines
GS12. plan and organize your work to meet timelines and work requirement and regulatory standards
GS13. apply problem solving approaches in different situations
GS14. take help of IT team in case of any computer infrastructure and software related issues
GS15. analyse data and activities
GS16. analyse the regulatory requirement of the relevant country before compiling the report

GS17. apply balanced judgments to different situations
GS18. ensure data integrity and confidentiality
GS19. keep the relevant regulatory guidelines in mind while using computer systems
GS20. liaise effectively and maintain excellent relationship with the internal/external contacts

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Compile and review the regulatory compliance of ICSRs	**15**	**15**	**10**	**5**
PC1. ensure timely submission of ICSRs, PSUR, RMP, Signal reports and aggregate reports as per the respective Regulatory Authority submission timeline	-	-	-	-
PC2. ensure appropriate processes are in place to comply with the respective Regulatory Authority requirement (GVP, PVPI, FDA, PMDA, Eudravigilance & regulatory guidelines from major markets including but not limited to ANVIA, ANMAT, COFEPRIS, Russian Federation, CIS countries, China, Malaysia, Indonesia, Vietnam, Singapore, Sri Lanka Bangladesh, China, South Korea)	-	-	-	-
PC3. review the accuracy of reports on a regular basis to comply with the existing Regulatory requirements and perform the receipt and evaluation of safety data exchange agreements (as applicable)	-	-	-	-
PC4. ensure that the reports are submitted to regulatory authorities within timelines	-	-	-	-
Identifying and resolving any issues hampering the regulatory compliance	**10**	**10**	**7**	**3**
PC5. take corrective action in response to non-compliance of reports	-	-	-	-
PC6. initiate investigation for the deviations	-	-	-	-
PC7. identify the root cause of the deviation, take corrective and preventive actions and provide adequate trainings. (if required)	-	-	-	-
PC8. ensure appropriate documentation of these corrective and preventive actions	-	-	-	-
Improving regulatory compliance	**8**	**8**	**5**	**4**
PC9. maintain awareness about current regulatory trends and practices.	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC10. ensure adherence to Pharmacovigilance Quality Management System (PQMS)	-	-	-	-
PC11. incorporate continuous improvements into Pharmacovigilance processes and policies based on existing Global and Local Regulatory Pharmacovigilance requirements	-	-	-	-
PC12. participate in regulatory inspection/ internal and client audit	-	-	-	-
NOS Total	**33**	**33**	**22**	**12**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0703
NOS Name	Ensure regulatory compliance
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Pharmacovigilance
NSQF Level	5.5
Credits	4.0
Version	1.0
Last Reviewed Date	01/11/2023
Next Review Date	01/11/2026
NSQC Clearance Date	01/11/2023

LFS/N0704: Coordinate with relevant internal and external stakeholders

Description

This NOS unit gives an overview how a Pharmacovigilance analyst coordinates with relevant internal and external stakeholders

Scope

The scope covers the following :

- Coordination with internal team members
- Coordination with Cross- Functional Team
- Respond to audit queries

Elements and Performance Criteria

Coordination with internal team members

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

PC1. ask queries to the relevant team members to understand the work output requirements

PC2. perform a self-run quality check for the cases in coordination with team members, while routing it to the medical reviewer for next workflow

PC3. co-ordinate with various stakeholders in the team for resolution of queries while ensuring the completeness and accuracy of the information entered into the database for all the cases, especially while working on Suspected Unexpected Serious Adverse Reaction or fatal cases for smooth workflow

PC4. inform supervisor on issues requiring intervention

PC5. deliver quality work on time and report any anticipated reasons for delays in the timelines to the concern teams and stakeholders

PC6. seek the information from the supervisor relevant to escalated issues and their solutions

PC7. ensure compliance with company policies and rule

PC8. provide support to Pharmacovigilance scientist/in-charge or supervisor in establishment /upgradation of pharmacovigilance system as and when required related to communication escalations for any co-ordination related activity

Coordination with Cross- Functional Team

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

PC9. coordinate with medical affairs team to maintain Medical Information System (MEDINFO)

PC10. impart training to team members/cross-function team members

PC11. coordinate with medical review team for a smooth workflow

PC12. support patient support program associate/ data assistant in mining spontaneous reports submitted to national surveillance systems

Respond to audit queries

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

PC13. interact with auditors in a language he/she is comfortable with

PC14. explain the query clearly and provide response to the auditor
PC15. produce the documented records for activities performed
PC16. maintain data integrity while responding to auditors

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. organizational SOPs and policies on preferred language of communication, reporting and escalation policy, quality delivery standards, and personnel management clinical research team reporting structure
KU2. employment rules and data integrity rules
KU3. reporting structure and escalation matrix
KU4. types of audits
KU5. quality management SOPs including those for change control, deviations and CAPAs and BCP
KU6. compliance related documentation
KU7. ADR reporting procedures
KU8. SOP for use of various software for pharmacovigilance work
KU9. job role boundaries of pharmacovigilance associate
KU10. GMP, GCP, PVPI, WHO guidelines
KU11. ways of communication and interpersonal skills
KU12. development of technical procedures
KU13. installation/validation of database or other tools
KU14. development of PSMF
KU15. Quality Management System (QMS)
KU16. felicitation in registering QPPV/PvOI
KU17. MEDINFO system
KU18. Service Level Agreement (SLA)
KU19. GVP, GCP, PVPI, ICH, CIOMS guidelines
KU20. changes /new regulations affecting pharmacovigilance activities

Generic Skills (GS)

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

GS1. write mails, monitoring reports and documents, letters in English language with sensitivity towards cross cultural differences
GS2. record and communicate details of work done to appropriate people using written/typed report or computer-based record/electronic mail
GS3. read notes/comments from the supervisor
GS4. read and understand the various coding systems as per company norms
GS5. communicate with departmental and cross functional teams including auditors

GS6. effective communication in Pharmacovigilance

GS7. listen effectively and be sensitive to cross cultural differences

GS8. disclose information only to those who have the right and need to know it

GS9. communicate new or changed regulations to relevant members of the department to initiate any change in processes

GS10. use verbal communication etiquette build and maintain good relationships across functional units and company affiliates

GS11. make decisions on a suitable course of action or response

GS12. appropriately use the escalation matrix for complex decisions

GS13. to make decisions related to mode of communication and involvement of stakeholders for any co-ordination purpose

GS14. manage relationship at work by practicing emotional control and high degree of interpersonal skills

GS15. plan and organize assigned work in order to effectively interact with the various stakeholders

GS16. multi-task and adapt to meet timelines

GS17. improve processes by interacting with others and adopting best practices

GS18. identify communication delays and address them with appropriate solutions

GS19. analyse the various operational steps and resources to make informed decisions as per SOP

GS20. analyse any situation which needs an immediate escalation

GS21. critically evaluate his/her actions and words in light to ethical, legal and global impact

GS22. spot process disruptions and delays and report and communicate with solutions

GS23. discuss any suggestions based on experience

GS24. consider impact on human health and drug safety in every activity

GS25. liaise effectively and maintain excellent relationship with the internal/external contacts

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Coordination with internal team members	**15**	**10**	**5**	**5**
PC1. ask queries to the relevant team members to understand the work output requirements	-	-	-	-
PC2. perform a self-run quality check for the cases in coordination with team members, while routing it to the medical reviewer for next workflow	-	-	-	-
PC3. co-ordinate with various stakeholders in the team for resolution of queries while ensuring the completeness and accuracy of the information entered into the database for all the cases, especially while working on Suspected Unexpected Serious Adverse Reaction or fatal cases for smooth workflow	-	-	-	-
PC4. inform supervisor on issues requiring intervention	-	-	-	-
PC5. deliver quality work on time and report any anticipated reasons for delays in the timelines to the concern teams and stakeholders	-	-	-	-
PC6. seek the information from the supervisor relevant to escalated issues and their solutions	-	-	-	-
PC7. ensure compliance with company policies and rule	-	-	-	-
PC8. provide support to Pharmacovigilance scientist/in-charge or supervisor in establishment /upgradation of pharmacovigilance system as and when required related to communication escalations for any co-ordination related activity	-	-	-	-
Coordination with Cross- Functional Team	**15**	**10**	**5**	**5**
PC9. coordinate with medical affairs team to maintain Medical Information System (MEDINFO)	-	-	-	-
PC10. impart training to team members/cross-function team members	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC11. coordinate with medical review team for a smooth workflow	-	-	-	-
PC12. support patient support program associate/ data assistant in mining spontaneous reports submitted to national surveillance systems	-	-	-	-
Respond to audit queries	**10**	**9**	**5**	**6**
PC13. interact with auditors in a language he/she is comfortable with	-	-	-	-
PC14. explain the query clearly and provide response to the auditor	-	-	-	-
PC15. produce the documented records for activities performed	-	-	-	-
PC16. maintain data integrity while responding to auditors	-	-	-	-
NOS Total	**40**	**29**	**15**	**16**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0704
NOS Name	Coordinate with relevant internal and external stakeholders
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Pharmacovigilance
NSQF Level	5.5
Credits	1.0
Version	1.0
Last Reviewed Date	01/11/2023
Next Review Date	01/11/2026
NSQC Clearance Date	01/11/2023

LFS/N0119: Ensure environment sustainability and sensitivity towards all genders and people with disability

Description

This NOS unit is about role holder ensuring environment sustainability and sensitivity towards gender, and people with disabilities at the workplace

Scope

The scope covers the following :

- Environment sustainability
- Sensitivity towards all genders and people with disability

Elements and Performance Criteria

Environment sustainability

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

PC1. ensure energy conservation by switching off the machine and equipment post operations

PC2. identify ways to optimize the usage of electricity/energy in various tasks/activities/processes

PC3. ensure energy conservation by optimizing the machine/ equipment performance

PC4. identify recyclable and non-recyclable, and hazardous waste generated

PC5. segregate waste into different categories to achieve minimum pollution of land and water

PC6. check for water leakage in plant/ work area and take corrective actions

Sensitivity towards all genders and people with disability

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

PC7. respect all genders, religions, and caste

PC8. empathize with the people with disability

PC9. offer support or help to a person with a disability only when asked

PC10. ensure to adhere to the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act

PC11. 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. the guidelines laid on Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act

KU2. the methods of workplace communication

KU3. the methods of team coordination

KU4. the types of possible disabilities among people with disability (PWD)

KU5. the challenges faced by PWD

KU6. importance of displaying empathy towards PWD

KU7. the right way to use the laws, acts, and provisions defined for PwD by the statutory bodies

KU8. the importance of awareness for gender sensitization and prevention of sexual harassment (POSH) act

KU9. the guidelines related to environmental sustainability

KU10. the 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 gauge the relevant information manuals, SOPs, health and safety instructions, memos, reports, job cards, and notes/comments

GS2. use written communication skills to record and communicate details of work done to appropriate stakeholders by using written or computer-based record/electronic mail

GS3. use verbal communication skills to communicate confidential and sensitive information discretely to the authorized person while interacting with teammates

GS4. use team-building skills while dealing with teammates to manage the difficult/stressful or emotional situations at work

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

GS6. apply critical thinking skills to analyze and identify when to report an issue/concern to the supervisor and to deal with a colleague individually, depending on the type of concern

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Environment sustainability	**15**	**25**	**5**	**5**
PC1. ensure energy conservation by switching off the machine and equipment post operations	-	-	-	-
PC2. identify ways to optimize the usage of electricity/energy in various tasks/activities/processes	-	-	-	-
PC3. ensure energy conservation by optimizing the machine/ equipment performance	-	-	-	-
PC4. identify recyclable and non-recyclable, and hazardous waste generated	-	-	-	-
PC5. segregate waste into different categories to achieve minimum pollution of land and water	-	-	-	-
PC6. check for water leakage in plant/ work area and take corrective actions	-	-	-	-
Sensitivity towards all genders and people with disability	**15**	**25**	**5**	**5**
PC7. respect all genders, religions, and caste	-	-	-	-
PC8. empathize with the people with disability	-	-	-	-
PC9. offer support or help to a person with a disability only when asked	-	-	-	-
PC10. ensure to adhere to the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act	-	-	-	-
PC11. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee	-	-	-	-
NOS Total	**30**	**50**	**10**	**10**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0119
NOS Name	Ensure environment sustainability and sensitivity towards all genders and people with disability
Sector	Life Sciences
Sub-Sector	Bio Pharmaceutical, Pharmaceutical, Contract Research
Occupation	Clinical Trials
NSQF Level	5
Credits	2.00
Version	2.0
Last Reviewed Date	01/11/2023
Next Review Date	01/11/2026
NSQC Clearance Date	01/11/2023

DGT/VSQ/N0102: Employability Skills (60 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. identify employability skills required for jobs in various industries

PC2. identify and explore learning and employability portals

Constitutional values – Citizenship

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

PC3. 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.

PC4. follow environmentally sustainable practices

Becoming a Professional in the 21st Century

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

PC5. recognize the significance of 21st Century Skills for employment

PC6. 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

Basic English Skills

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

PC7. use basic English for everyday conversation in different contexts, in person and over the telephone

PC8. read and understand routine information, notes, instructions, mails, letters etc. written in English

PC9. 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:

PC10. understand the difference between job and career

PC11. prepare a career development plan with short- and long-term goals, based on aptitude

Communication Skills

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

PC12. follow verbal and non-verbal communication etiquette and active listening techniques in various settings

PC13. work collaboratively with others in a team

Diversity & Inclusion

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

PC14. communicate and behave appropriately with all genders and PwD

PC15. 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:

PC16. select financial institutions, products and services as per requirement

PC17. carry out offline and online financial transactions, safely and securely

PC18. identify common components of salary and compute income, expenses, taxes, investments etc

PC19. 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:

PC20. operate digital devices and carry out basic internet operations securely and safely

PC21. use e- mail and social media platforms and virtual collaboration tools to work effectively

PC22. use basic features of word processor, spreadsheets, and presentations

Entrepreneurship

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

PC23. identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research

PC24. develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion

PC25. 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:

PC26. identify different types of customers

PC27. identify and respond to customer requests and needs in a professional manner.

PC28. follow appropriate hygiene and grooming standards

Getting ready for apprenticeship & Jobs

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

PC29. create a professional Curriculum vitae (Résumé)

PC30. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively

PC31. apply to identified job openings using offline /online methods as per requirement

PC32. answer questions politely, with clarity and confidence, during recruitment and selection

PC33. 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. 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 and use applications such as word processors, spreadsheets etc.

KU16. how to identify business opportunities

KU17. types and needs of customers

KU18. how to apply for a job and prepare for an interview

KU19. 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

GS2. communicate effectively using appropriate language in formal and informal settings

GS3. behave politely and appropriately with all
GS4. how to work in a virtual mode
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. identify employability skills required for jobs in various industries	-	-	-	-
PC2. identify and explore learning and employability portals	-	-	-	-
Constitutional values – Citizenship	**1**	**1**	**-**	**-**
PC3. 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.	-	-	-	-
PC4. follow environmentally sustainable practices	-	-	-	-
Becoming a Professional in the 21st Century	**2**	**4**	**-**	**-**
PC5. recognize the significance of 21st Century Skills for employment	-	-	-	-
PC6. 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	-	-	-	-
Basic English Skills	**2**	**3**	**-**	**-**
PC7. use basic English for everyday conversation in different contexts, in person and over the telephone	-	-	-	-
PC8. read and understand routine information, notes, instructions, mails, letters etc. written in English	-	-	-	-
PC9. write short messages, notes, letters, e-mails etc. in English	-	-	-	-
Career Development & Goal Setting	**1**	**2**	**-**	**-**

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC10. understand the difference between job and career	-	-	-	-
PC11. prepare a career development plan with short- and long-term goals, based on aptitude	-	-	-	-
Communication Skills	**2**	**2**	**-**	**-**
PC12. follow verbal and non-verbal communication etiquette and active listening techniques in various settings	-	-	-	-
PC13. work collaboratively with others in a team	-	-	-	-
Diversity & Inclusion	**1**	**2**	**-**	**-**
PC14. communicate and behave appropriately with all genders and PwD	-	-	-	-
PC15. escalate any issues related to sexual harassment at workplace according to POSH Act	-	-	-	-
Financial and Legal Literacy	**2**	**3**	**-**	**-**
PC16. select financial institutions, products and services as per requirement	-	-	-	-
PC17. carry out offline and online financial transactions, safely and securely	-	-	-	-
PC18. identify common components of salary and compute income, expenses, taxes, investments etc	-	-	-	-
PC19. identify relevant rights and laws and use legal aids to fight against legal exploitation	-	-	-	-
Essential Digital Skills	**3**	**4**	**-**	**-**
PC20. operate digital devices and carry out basic internet operations securely and safely	-	-	-	-
PC21. use e- mail and social media platforms and virtual collaboration tools to work effectively	-	-	-	-
PC22. use basic features of word processor, spreadsheets, and presentations	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Entrepreneurship	**2**	**3**	**-**	**-**
PC23. identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research	-	-	-	-
PC24. develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion	-	-	-	-
PC25. identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity	-	-	-	-
Customer Service	**1**	**2**	**-**	**-**
PC26. identify different types of customers	-	-	-	-
PC27. identify and respond to customer requests and needs in a professional manner.	-	-	-	-
PC28. follow appropriate hygiene and grooming standards	-	-	-	-
Getting ready for apprenticeship & Jobs	**2**	**3**	**-**	**-**
PC29. create a professional Curriculum vitae (Résumé)	-	-	-	-
PC30. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively	-	-	-	-
PC31. apply to identified job openings using offline /online methods as per requirement	-	-	-	-
PC32. answer questions politely, with clarity and confidence, during recruitment and selection	-	-	-	-
PC33. 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/N0102
NOS Name	Employability Skills (60 Hours)
Sector	Cross Sectoral
Sub-Sector	Professional Skills
Occupation	Employability
NSQF Level	4
Credits	2
Version	1.0
Last Reviewed Date	08/05/2025
Next Review Date	08/05/2028
NSQC Clearance Date	08/05/2025

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/N0702.Perform collection, processing, medical coding and assessment of Individual Case Study Reports (ICSRs)	33	33	21	13	100	15
LFS/N0705.Use relevant software systems for various Pharmacovigilance activities (Case Processing, Aggregate Safety reports, signal management , etc.)	34	34	20	12	100	15
LFS/N0706.Prepare and compile Aggregate Safety Reports (PSURs, PBRERs, PADERs, HHE reports), Risk Management Plans & Signal Management Reports	34	34	20	12	100	20
LFS/N0703.Ensure regulatory compliance	33	33	22	12	100	20

Qualification Pack

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0704.Coordinate with relevant internal and external stakeholders	40	29	15	16	100	10
LFS/N0119.Ensure environment sustainability and sensitivity towards all genders and people with disability	30	50	10	10	100	10
DGT/VSQ/N0102.Employability Skills (60 Hours)	20	30	-	-	50	10
Total	**224**	**243**	**108**	**75**	**650**	**100**

Acronyms

NOS	National Occupational Standard(s)
NSQF	National Skills Qualifications Framework
QP	Qualifications Pack
TVET	Technical and Vocational Education and Training
SOP	standard operating procedure
ALCOA	Attributable, Legible, Contemporaneous, Original and Accurate
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GCP	Good Clinical Practices
NABL	National Accreditation Board for Laboratories
WHO	World Health Organization
SOP	Standard Operating Procedures
ICH	International Council for Harmonisation
ISO	International Organization for Standardization
OHSAS	Occupational Health and Safety Assessment Series
ICH	International Council for Harmonisation
CFR	Code of Federal Regulations
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GCP	Good Clinical Practices
NABL	National Accreditation Board for Laboratories
WHO	World Health Organization
MSDS	Material Safety Data Sheet
ALCOA	Attributable, Legible, Contemporaneous, Original and Accurate
PPE	Personal Protective Equipment

MSDS	Material Safety Data Sheet
GLP	Good Laboratory Practice
EHS	Environment Health and Safety
WHO	World Health Organization
GMP	Good Manufacturing Practice
GLP	Good Laboratory Practice
WHO	World Health Organization
ICH	Council for Harmonisation
GMP	Good Manufacturing Practice
GLP	Good Laboratory Practice
MSDS	Material Safety Data Sheet
EHS	Environment Health and Safety
ALCOA	Attributable, Legible, Contemporaneous, Original and Accurate
SOP	Standard Operating Procedure
QC	Quality Control
QA	Quality Assurance
GMP	Good Manufacturing Practice
NABL	National Accreditation Board for Laboratories
POSH	Prevention of Sexual Harassment
ALCOA	Attributable, Legible, Contemporaneous, Original and Accurate
PwD	Persons with Disabilities
SOP	Standard Operating Procedure
QC	Quality Control
PH	Potential of Hydrogen
SOP	Standard Operating Procedure
OHSAS	Occupational Health and Safety Assessment Series

ISO	International Organization for Standardization
GMP	Good Manufacturing Practice
ALCOA	Attributable, Legible, Contemporaneous, Original and Accurate
GLP	Good Laboratory Practice
PPE	Personal Protective Equipment
STP	Standard Test Protocol
EHS	Environment Health and Safety
PPE	Personal Protective Equipment
MSDS	Material Safety Data Sheet
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
SOP	Standard Operating Procedure
ALCOA	Attributable, Legible, Contemporaneous, Original and Accurate
MedDRA	Medical Dictionary for Regulatory Activities
AE	Adverse Event
PSUR	Periodic Safety Update Reports
ICSR	Individual Case Study Report
SOP	Standard Operating Procedure
ADR	Adverse Drug Reaction
WHO	World Health Organization
ICH	International Council for Harmonisation
CRO	Contract Research Organization
CAPA	Corrective and Preventive Action
PVPI	Pharmacovigilance Programme of India
SAS	Statistical Analysis System
ICSR	Individual Case Study Report

PSUR	Periodic Safety Update Reports
RMP	Registered Medical Practitioners
SOP	Standard Operating Procedure
MedDRA	Medical Dictionary for Regulatory Activities
WHO	World Health Organization
CAPA	Corrective and Preventive Action
ADR	Adverse Drug Reaction
GCP	Good Clinical Practice
ICH	International Council for Harmonisation
PVPI	Pharmacovigilance Programme of India
QA	Quality Assurance
SAS	Statistical Analysis System
ICSR	Individual Case Study Report
ADR	Adverse Drug Reaction
SOP	Standard Operating Procedure
IT	Information Technology
PVPI	Pharmacovigilance Programme of India
ICH	International Council for Harmonisation
WHO	World Health Organization
GCP	Good Clinical Practice
MedDRA	Medical Dictionary for Regulatory Activities
ICSR	Individual Case Study Report
USFDA	United States Food and Drug Administration
EMA	European Medicines Agency
EMA	European Medicines Agency
CDSCO	Central Drugs Standard Control Organisation

UKMHRA	United Kingdom Medicines and Healthcare products Regulatory Agency
CIOMS	Council for International Organizations of Medical Sciences
ICH	International Council for Harmonisation
GVP	Good Vigilance Practice
GPvP	Good pharmacovigilance practices
MedDRA	Medical Dictionary for Regulatory Activities
AE	Adverse Event
PSUR	Periodic Safety Update Reports
ICSR	Individual Case Study Report
SOP	Standard Operating Procedure
ADR	Adverse Drug Reaction
WHO	World Health Organization
ICH	International Council for Harmonisation
CRO	Contract Research Organization
CAPA	Corrective and Preventive Action
PVPI	Pharmacovigilance Programme of India
SAS	Statistical Analysis System
ICSR	Individual Case Study Report
PSUR	Periodic Safety Update Reports
RMP	Registered Medical Practitioners
SOP	Standard Operating Procedure
MedDRA	Medical Dictionary for Regulatory Activities
WHO	World Health Organization
CAPA	Corrective and Preventive Action
ADR	Adverse Drug Reaction
GCP	Good Clinical Practice

ICH	International Council for Harmonisation
PVPI	Pharmacovigilance Programme of India
QA	Quality Assurance
SAS	Statistical Analysis System
ICSR	Individual Case Study Report
ADR	Adverse Drug Reaction
SOP	Standard Operating Procedure
IT	Information Technology
PVPI	Pharmacovigilance Programme of India
ICH	International Council for Harmonisation
WHO	World Health Organization
GCP	Good Clinical Practice
MedDRA	Medical Dictionary for Regulatory Activities
ICSR	Individual Case Study Report
USFDA	United States Food and Drug Administration
EMA	European Medicines Agency
EMA	European Medicines Agency
CDSCO	Central Drugs Standard Control Organisation
UKMHRA	United Kingdom Medicines and Healthcare products Regulatory Agency
CIOMS	Council for International Organizations of Medical Sciences
ICH	International Council for Harmonisation
GVP	Good Vigilance Practice
GPvP	Good pharmacovigilance practices
ICSR	Individual Case Study Report
ADR	Adverse Drug Reaction
SOP	Standard Operating Procedure

IT	Information Technology
PVPI	Pharmacovigilance Programme of India
ICH	International Council for Harmonisation
WHO	World Health Organization
GCP	Good Clinical Practice
MedDRA	Medical Dictionary for Regulatory Activities
ICSR	Individual Case Study Report
USFDA	United States Food and Drug Administration
EMA	European Medicines Agency
EMA	European Medicines Agency
CDSCO	Central Drugs Standard Control Organisation
UKMHRA	United Kingdom Medicines and Healthcare products Regulatory Agency
CIOMS	Council for International Organizations of Medical Sciences
ICH	International Council for Harmonisation
GVP	Good Vigilance Practice
GPvP	Good pharmacovigilance practices
MedDRA	Medical Dictionary for Regulatory Activities
AE	Adverse Event
PSUR	Periodic Safety Update Reports
ICSR	Individual Case Study Report
SOP	Standard Operating Procedure
ADR	Adverse Drug Reaction
WHO	World Health Organization
ICH	International Council for Harmonisation
CRO	Contract Research Organization
CAPA	Corrective and Preventive Action

PVPI	Pharmacovigilance Programme of India
SAS	Statistical Analysis System
ICSR	Individual Case Study Report
PSUR	Periodic Safety Update Reports
RMP	Registered Medical Practitioners
SOP	Standard Operating Procedure
MedDRA	Medical Dictionary for Regulatory Activities
WHO	World Health Organization
CAPA	Corrective and Preventive Action
ADR	Adverse Drug Reaction
GCP	Good Clinical Practice
ICH	International Council for Harmonisation
PVPI	Pharmacovigilance Programme of India
QA	Quality Assurance
SAS	Statistical Analysis System
SOP	Standard Operating Procedure
CAPA	Corrective and Preventive Action
ADR	Adverse Drug Reaction
GMP	Good Manufacturing Practice
GCP	Good Clinical Practice
PVPI	Pharmacovigilance Programme of India
WHO	World Health Organization
PSMF	Pharmacovigilance System Master File
QPPV	Qualified Person Responsible For Pharmacovigilance
GCP	Good Clinical Practice
ICH	International Council for Harmonisation

ICSR	Individual Case Study Report
ADR	Adverse Drug Reaction
SOP	Standard Operating Procedure
IT	Information Technology
PVPI	Pharmacovigilance Programme of India
ICH	International Council for Harmonisation
WHO	World Health Organization
GCP	Good Clinical Practice
MedDRA	Medical Dictionary for Regulatory Activities
ICSR	Individual Case Study Report
USFDA	United States Food and Drug Administration
EMA	European Medicines Agency
EMA	European Medicines Agency
CDSCO	Central Drugs Standard Control Organisation
UKMHRA	United Kingdom Medicines and Healthcare products Regulatory Agency
CIOMS	Council for International Organizations of Medical Sciences
ICH	International Council for Harmonisation
GVP	Good Vigilance Practice
GPvP	Good pharmacovigilance practices
MedDRA	Medical Dictionary for Regulatory Activities
AE	Adverse Event
PSUR	Periodic Safety Update Reports
ICSR	Individual Case Study Report
SOP	Standard Operating Procedure
ADR	Adverse Drug Reaction
WHO	World Health Organization

ICH	International Council for Harmonisation
CRO	Contract Research Organization
CAPA	Corrective and Preventive Action
PVPI	Pharmacovigilance Programme of India
SAS	Statistical Analysis System
MedDRA	Medical Dictionary for Regulatory Activities
AE	Adverse Event
PSUR	Periodic Safety Update Reports
ICSR	Individual Case Study Report
SOP	Standard Operating Procedure
ADR	Adverse Drug Reaction
WHO	World Health Organization
ICH	International Council for Harmonisation
CRO	Contract Research Organization
CAPA	Corrective and Preventive Action
PVPI	Pharmacovigilance Programme of India
SAS	Statistical Analysis System
PBRERs	Periodic Benefit Risk Evaluation Reports
PADER	Periodic Adverse Drug Experience Report
ICSR	Individual Case Study Report
PSUR	Periodic Safety Update Reports
RMP	Registered Medical Practitioners
SOP	Standard Operating Procedure
MedDRA	Medical Dictionary for Regulatory Activities
WHO	World Health Organization
CAPA	Corrective and Preventive Action

ADR	Adverse Drug Reaction
GCP	Good Clinical Practice
ICH	International Council for Harmonisation
PVPI	Pharmacovigilance Programme of India
QA	Quality Assurance
SAS	Statistical Analysis System
SOP	Standard Operating Procedure
CAPA	Corrective and Preventive Action
ADR	Adverse Drug Reaction
GMP	Good Manufacturing Practice
GCP	Good Clinical Practice
PVPI	Pharmacovigilance Programme of India
WHO	World Health Organization
PSMF	Pharmacovigilance System Master File
QPPV	Qualified Person Responsible For Pharmacovigilance
GCP	Good Clinical Practice
ICH	International Council for Harmonisation
POSH	Prevention Of Sexual Harassment
PWD	People With Disability
SOP	Standard Operating Procedure

Glossary

Sector	Sector is a conglomeration of different business operations having similar business and interests. It may also be defined as a distinct subset of the economy whose components share similar characteristics and interests.
Sub-sector	Sub-sector is derived from a further breakdown based on the characteristics and interests of its components.
Occupation	Occupation is a set of job roles, which perform similar/ related set of functions in an industry.
Job role	Job role defines a unique set of functions that together form a unique employment opportunity in an organisation.
Occupational Standards (OS)	OS specify the standards of performance an individual must achieve when carrying out a function in the workplace, together with the Knowledge and Understanding (KU) they need to meet that standard consistently. Occupational Standards are applicable both in the Indian and global contexts.
Performance Criteria (PC)	Performance Criteria (PC) are statements that together specify the standard of performance required when carrying out a task.
National Occupational Standards (NOS)	NOS are occupational standards which apply uniquely in the Indian context.
Qualifications Pack (QP)	QP comprises the set of OS, together with the educational, training and other criteria required to perform a job role. A QP is assigned a unique qualifications pack code.
Unit Code	Unit code is a unique identifier for an Occupational Standard, which is denoted by an 'N'
Unit Title	Unit title gives a clear overall statement about what the incumbent should be able to do.
Description	Description gives a short summary of the unit content. This would be helpful to anyone searching on a database to verify that this is the appropriate OS they are looking for.
Scope	Scope is a set of statements specifying the range of variables that an individual may have to deal with in carrying out the function which have a critical impact on quality of performance required.

Knowledge and Understanding (KU)	Knowledge and Understanding (KU) are statements which together specify the technical, generic, professional and organisational specific knowledge that an individual needs in order to perform to the required standard.
Organisational Context	Organisational context includes the way the organisation is structured and how it operates, including the extent of operative knowledge managers have of their relevant areas of responsibility.
Technical Knowledge	Technical knowledge is the specific knowledge needed to accomplish specific designated responsibilities.
Core Skills/ Generic Skills (GS)	Core skills or Generic Skills (GS) are a group of skills that are the key to learning and working in today's world. These skills are typically needed in any work environment in today's world. These skills are typically needed in any work environment. In the context of the OS, these include communication related skills that are applicable to most job roles.
Electives	Electives are NOS/set of NOS that are identified by the sector as contributive to specialization in a job role. There may be multiple electives within a QP for each specialized job role. Trainees must select at least one elective for the successful completion of a QP with Electives.
Options	Options are NOS/set of NOS that are identified by the sector as additional skills. There may be multiple options within a QP. It is not mandatory to select any of the options to complete a QP with Options.