QUALIFICATION FILE – Standalone NOS

Aggregate Report writing for Regulatory Compliance

☐ Horizontal/Generic ☒ Vertical/Specialization

☒ Upskilling ☒ Dual/Flexi Qualification ☒ For ToT ☒ For ToA

☐General ☐ Multi-skill (MS) ☐ Cross Sectoral (CS) ☒ Future Skills

NCrF/NSQF Level: 5.5

Submitted by:

Life Sciences Sector Skill Development Council

14, Palam Marg, Rear 2nd Floor, Vasant Vihar, New Delhi, PIN 110057

Phone: +91 11 41042407/ 408, E-mail: info@lsssdc.in

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Section 1: Basic Details

<table>
<tr><td>1.</td><td>NOS-Qualification Name</td><td colspan="2">Aggregate Report writing for Regulatory Compliance</td></tr>
<tr><td>2.</td><td>Sector/s</td><td colspan="2">Life Sciences</td></tr>
<tr><td>3.</td><td>Type of Qualification ☒ New ☐ Revised</td><td>NQR Code & version of the existing /previous qualification: NA</td><td>Qualification Name of the existing/previous version: NA</td></tr>
<tr><td>4.</td><td>National Qualification Register (NQR) Code & Version</td><td>NG-5.5-LS-01296-2023-V1-LSSSDC</td><td>5. NCrF/NSQF Level:5.5</td></tr>
<tr><td>6.</td><td>Brief Description of the Standalone NOS</td><td colspan="2">This NOS on Aggregate Report writing for Regulatory Compliance will enable individual to have the capability to independently draft comprehensive Aggregate Reports that adhere to strict regulatory compliance standards, ensuring the accurate and timely submission of critical pharmacovigilance data, and demonstrating proficiency in the application of industry-specific best practices for report writing.</td></tr>
<tr><td>7.</td><td>Eligibility Criteria for Entry for a Student/Trainee/Learner/Employee</td><td colspan="2">a. Entry Qualification & Relevant Experience:
<table>
<tr><th>S. No.</th><th>Academic/Skill Qualification (with Specialization - if applicable)</th><th>Relevant Experience (with Specialization - if applicable)</th></tr>
<tr><td>1.</td><td>Pursuing Final Year of B.Sc (Microbiology) / B. Pharma / B. Tech (Biotech) (Indian / foreign universities)</td><td></td></tr>
<tr><td>2.</td><td>Pursuing Final Year of MBBS/BDS/BPT/BOT/BAMS/BHMS (in any medical subject)/ (Indian / recognized foreign universities)</td><td></td></tr>
</table>
b. Age 20 year</td></tr>
<tr><td>8.</td><td>Credits Assigned to this NOS-Qualification, Subject to Assessment (as per National Credit Framework (NCrF))</td><td>2.0</td><td>9. Common Cost Norm Category (I/II/III) (wherever applicable):II</td></tr>
<tr><td>10.</td><td>Any Licensing Requirements for Undertaking Training on This Qualification (wherever applicable)</td><td colspan="2">NA</td></tr>
</table>

<table>
<tr><td>11.</td><td>Training Duration by Modes of Training Delivery (Specify Total Duration as per selected training delivery modes and as per requirement of the qualification)</td><td>☒ Offline Only ☐ Online Only ☒ Blended
<table>
<tr><th>Training Delivery Mode</th><th>Theory (Hours)</th><th>Practical (Hours)</th><th>Total (Hours)</th></tr>
<tr><td>Offline Mode</td><td></td><td></td><td rowspan="6">60:00</td></tr>
<tr><td>Classroom</td><td>30:00</td><td>30:00</td></tr>
<tr><td colspan="3">OR</td></tr>
<tr><td>Blended Mode</td><td>30:00</td><td>30:00</td></tr>
<tr><td>Offline (As part of blended mode)</td><td>15:00</td><td>30:00</td></tr>
<tr><td>Online (As part of blended mode)</td><td>15:00</td><td>00:00</td></tr>
</table></td></tr>
<tr><td>12.</td><td>Assessment Criteria</td><td>
<table>
<tr><th>Theory (Marks)</th><th>Practical (Marks)</th><th>Project (Marks)</th><th>Viva (Marks)</th><th>Total (Marks)</th><th>Passing %age</th></tr>
<tr><td>50</td><td>50</td><td></td><td></td><td>100</td><td>70</td></tr>
</table></td></tr>
<tr><td>13.</td><td>Is the NOS Amenable to Persons with Disability</td><td>☐ Yes ☒ No If “Yes”, specify applicable type of Disability:</td></tr>
<tr><td>14.</td><td>Progression Path After Attaining the Qualification, wherever applicable (Please show Professional and Academic progression)</td><td>Horizontal progression
Analyst- Drug Safety/ Pharmacovigilance</td></tr>
<tr><td>15.</td><td>How participation of women will be encouraged?</td><td>This micro credential is gender agnostic, and all genders will be encouraged to take this training. LSSSDC is working with industry to launch the program in diversity and inclusion initiative</td></tr>
<tr><td>16.</td><td>Other Indian languages in which the Qualification & Model Curriculum are being submitted</td><td>English and Hindi</td></tr>
<tr><td>17.</td><td>Is similar NOS available on NQR-if yes, justification for this qualification</td><td>☐ Yes ☒ No URLs of similar Qualifications:</td></tr>
<tr><td>18.</td><td>Name and Contact Details Submitting / Awarding Body SPOC
(In case of CS or MS, provide details of both Lead AB & Supporting ABs)</td><td>Name: Mrs. Shivi Chaudhary
Email: shivi.chaudhary@lsssdc.in Contact No.: + 91 11 41042407/ 408, +91 9315747189
Website: https://www.lsssdc.in/</td></tr>
</table>

19.	Final Approval Date by NSQC: 1 November 2023	20. Validity Duration:3 years	21. Next Review Date: 1 November 2026

Section 2: Training Related

1.	**Trainer's Qualification and experience in the relevant sector (in years)** *(as per NCVET guidelines)*	MBBS/PhD/ BDS/ BAMS/ BHMS/ BPT/BOT/ PharmaD with atleast 5 years relevant insustry experience In pharmacovigilance and 2 year experience On the job assessment/ Training experience/ Vocational assessment/ Academic assessment B.Pharma (with Pharmacognosy Subject) OR B.Tech in (Relevant Field) with 7 years of industry relevant experience in Pharmacovigilance activities and 2 year experience On the job assessment/ Training experience/ Vocational assessment/ Academic assessment Or M. Sc. (with relevant Subjects)/ M. Pharma/MSC (OT/PT/AST), MSc(Pharmacology, Physiology/ Biochemistry/ Anatomy/ Forensic Medicine)/ MD (Pharmacology) with 5 years of industry relevant experience in Pharmacovigilance activities and 2-year experience on the job assessment/ Training experience/ Vocational assessment/ Academic assessment Certified for job role: "Aggregate Report writing for Regulatory Compliance" mapped to Qualification Pack: "LFS/N0708, V1.0" with minimum accepted score of 80%. Recommended that the Trainer is certified for the Job Role: "Trainer", mapped to the Qualification Pack: "MEP/Q2601, v2.0" with minimum score of 80%.
2.	**Master Trainer's Qualification and experience in the relevant sector (in years)** *(as per NCVET guidelines)*	MBBS/PhD/ BDS/ BAMS/ BHMS/ BPT/BOT/ PharmaD with atleast 5 years relevant insustry experience In pharmacovigilance and 2 year experience On the job assessment/ Training experience/ Vocational assessment/ Academic assessment M.Pharma OR M.Tech in (relevant field to Drugs/ Vaccines) with 8 years of industry relevant experience in Pharmacovigilance activities and 4 year experience On the job assessment/ Training experience/ Vocational assessment/ Academic assessment Or

		M. Sc. (with relevant Subjects) with 8 years of industry relevant experience in Pharmacovigilance activities and 4-year experience on the job assessment/ Training experience/ Vocational assessment/ Academic assessment Certified for job role: "Aggregate Report writing for Regulatory Compliance" mapped to Qualification Pack: "LFS/N0708, V1.0" with minimum accepted score of 80%. Recommended that the Trainer is certified for the Job Role: "Master Trainer (VET and SKILLS)", mapped to the Qualification Pack: "MEP/Q2602, v2.0" with minimum score of 80%.
3.	**Tools and Equipment Required for the Training**	☒Yes ☐No (*If "Yes", details to be provided in Annexure)*
4.	**In Case of Revised NOS, details of Any Upskilling Required for Trainer**	NA

Section 3: Assessment Related

1.	**Assessor's Qualification and experience in relevant sector (in years)** *(as per NCVET guidelines)*	MBBS/BAMS/BHMS/PharmD/ PhD with 7-9 years experience in pharmacovigilance and 2 year experience On the job assessment/ Training experience/ Vocational assessment/ Academic assessment Post Graduate in M. Sc. with 8 years of industry relevant experience in Pharmacovigilance activities and 2 year experience with specialization of the job assessment/ Training experience/ Vocational assessment/ Academic assessment Or M.Tech /M. Pharma (Relevant Field) with 7 years of industry relevant experience in Pharmacovigilance activities and 2 year experience On the job assessment/ Training experience/ Vocational assessment/ Academic assessment Or B.Pharma / B. Tech Biotech (with relevant Subjects) with 9 years of industry relevant experience Pharmacovigilance activities and 2 year experience on the job assessment/ Training experience/ Vocational assessment/ Academic assessment Certified for job role: "Aggregate Report writing for Regulatory Compliance" mapped to Qualification Pack: "LFS/N0708, V1.0" with minimum accepted score of 80%.

		Recommended that the Assessor is certified for the Job Role: "Assessor (VET and SKILLS)", mapped to the Qualification : "MEP/Q2701 Ver 2.0" with minimum score of 80%.
2.	**Proctor's Qualification and experience in relevant sector (in years)** *(as per NCVET guidelines), (wherever applicable)*	MBBS/BAMS/BHMS/PharmD/ PhD with 7-9 years experience in pharmacovigilance and 2 year experience On the job assessment/ Training experience/ Vocational assessment/ Academic assessment Or Post Graduate in M. Sc. with 8 years of industry relevant experience in Pharmacovigilance activities and 2 year experience with specialization of the job assessment/ Training experience/ Vocational assessment/ Academic assessment Or M.Tech in (Relevant Field) with 8 years of industry relevant experience in Pharmacovigilance activities and 2 year experience On the job assessment/ Training experience/ Vocational assessment/ Academic assessment Or M. Pharma (with relevant Subjects) with 6 years of industry relevant experience in Pharmacovigilance activities and 2 year experience on the job assessment/ Training experience/ Vocational assessment/ Academic assessment Certified for job role: "Aggregate Report writing for Regulatory Compliance" mapped to Qualification Pack: "LFS/N0708, V1.0" with minimum accepted score of 80%.
3.	**Lead Assessor's/Proctor's Qualification and experience in relevant sector (in years)** *(as per NCVET guidelines)*	MBBS/BAMS/BHMS/PharmD/ PhD with 7-9 years experience in pharmacovigilance and 2 year experience On the job assessment/ Training experience/ Vocational assessment/ Academic assessment OR Post Graduate in M.Sc. OR M.Pharma with 8 years of industry relevant experience in Pharmacovigilance activities and 4 year experience On the job assessment/ Training experience/ Vocational assessment/ Academic assessment OR B. Pharma/ B.Tech (Biotechnology) with 12 years of industry relevant experience in Pharmacovigilance activities and 4 year experience on the job assessment/ Training experience/ Vocational assessment/ Academic assessment Certified for job role: "Aggregate Report writing for Regulatory Compliance" mapped to Qualification Pack: "LFS/N0708, V1.0" with minimum accepted score of 80%. Recommended that the Assessor is certified for the Job Role: "Lead Assessor (VET and SKILLS)", mapped to the Qualification : "MEP/Q2702 Ver 2.0" with minimum score of 80%.

4.	**Assessment Mode** *(Specify the assessment mode)*	**Mode: ☒ Online Only ☐ Offline Only ☐ Blended**
5.	**Tools and Equipment Required for Assessment**	**☐ Same as for training ☐ Yes ☒ No**

Section 4: Evidence of the Need for the Standalone NOS

Provide Annexure/Supporting documents name.

1.	Government /Industry initiatives/ requirement (Yes/No):yes
2.	Number of Industry validation provided: 12
3.	Estimated number of people to be trained: 1000
4.	Evidence of Concurrence/Consultation with Line/State Departments (In case of regulated sectors): (Yes/No): If "No", why: No mail has been sent

Section 5: Annexure & Supporting Documents Check List

Specify Annexure Name / Supporting document file name

1.	**Annexure:** NCrF/NSQF level justification based on NCrF/NSQF descriptors *(Mandatory)*	Yes
2.	**Annexure:** List of tools and equipment relevant for NOS *(Mandatory, except in case of online course)*	Yes
3.	**Annexure:** Performance and Assessment Criteria *(Mandatory)*	Yes
4.	**Annexure:** Assessment Strategy *(Mandatory)*	Yes

5.	**Annexure:** Blended Learning *(Mandatory, in case selected Mode of delivery is Blended Learning)*	Yes
6.	**Annexure:** Acronym and Glossary *(Optional)*	Yes
7.	**Annexure/Supporting Document:** Standalone NOS-Performance Criteria Details Annexure/Document with PC-wise detailing as per NOS format (Mandatory- Public view)	yes
8.	**Supporting Document:** Model Curriculum *(Mandatory – Public view)*	yes

Annexure: Evidence of Level

NCrF/NSQF Level Descriptors	Key requirements of the job role/ outcome of the qualification	How the job role/ outcomes relate to the NCrF/NSQF level descriptor	NCrF/NSQF Level
Professional Theoretical Knowledge/Process	Few of the job elements, expected to be performed by Aggregate Report writing for Regulatory Compliance • life sciences industry and Aggregate Reports • Report Structure and Writing Skills for pharmacovigilance reporting. • Signal Detection and Evaluation for Pharmacovigilance • Risk Minimization and Compliance for Pharmacovigilance • Application and Emerging Technologies For Pharmacovigilance	Aggregate Report writing for Regulatory Compliance follows standard operating procedures for data collection of ICSR's, processing of ICSR and triage, coding using MedDRA Dictionary, WHO Drug Dictionary and Medical terminologies. Also, he/she study Drug Safety Databases like Argus, ArisGlobal, Safety Easy (AB Cube) and work with Pharmacovigilance Databases.	5.5

Professional and Technical Skills/ Expertise/ Professional Knowledge	Few of the job elements, expected to be performed by Aggregate Report writing for Regulatory Compliance • life sciences industry and Aggregate Reports • Report Structure and Writing Skills for pharmacovigilance reporting. • Signal Detection and Evaluation for Pharmacovigilance • Risk Minimization and Compliance for Pharmacovigilance Application and Emerging Technologies For Pharmacovigilance	To perform the tasks given in the left-hand side box, an Aggregate Report writing for Regulatory Compliance needs to have the factual knowledge of Adverse Drug Reactions (ADR)/Adverse Events (AEs) / Product Quality Complaints (PQC) / Pharmacovigilance Databases and local regulations and company Global Pharmacovigilance requirements.	5.5
Employment Readiness & Entrepreneurship Skills & Mind-set/Professional Skill	Few of the job elements, expected to be performed by Aggregate Report writing for Regulatory Compliance • life sciences industry and Aggregate Reports • Report Structure and Writing Skills for pharmacovigilance reporting. • Signal Detection and Evaluation for Pharmacovigilance • Risk Minimization and Compliance for Pharmacovigilance • Application and Emerging Technologies For Pharmacovigilance	To perform the tasks of data collection, its processing and Triage of ICSR`s, an Aggregate Report writing for Regulatory Compliance utilizes the professional skills like, Analytical Skills, Critical Skills, Problem Solving, Decision Making	5.5
Broad Learning Outcomes/Core Skill	Few of the job elements, expected to be performed by Aggregate Report writing for Regulatory Compliance	To perform the tasks written on the left-hand side box, Aggregate Report writing for Regulatory Compliance uses	5.5

	• life sciences industry and Aggregate Reports • Report Structure and Writing Skills for pharmacovigilance reporting. • Signal Detection and Evaluation for Pharmacovigilance • Risk Minimization and Compliance for Pharmacovigilance • Application and Emerging Technologies For Pharmacovigilance	organizing information, communication, and problem-solving skills. For reporting and documentation proposed, he/she applies the basics of arithmetic and algebraic principles and organizational skills.	
Responsibility	Few of the job elements, expected to be performed by Aggregate Report writing for Regulatory Compliance • life sciences industry and Aggregate Reports • Report Structure and Writing Skills for pharmacovigilance reporting. • Signal Detection and Evaluation for Pharmacovigilance • Risk Minimization and Compliance for Pharmacovigilance • Application and Emerging Technologies For Pharmacovigilance	Aggregate Report writing for Regulatory Compliance has responsibility for his/her work and learning	5.5

Annexure: Tools and Equipment (lab set-up)

List of Tools and Equipment

Batch Size:

S. No.	Tool / Equipment Name	Specification	Quantity for specified Batch size
1	Indian Pharmacopoeia 2022 - Ninth edition	As per standard requirement	3
2	Pharmacovigilance Program of India Guidelines	As per standard requirement	3
3	Draft sample copy of Pharmacovigilance System Master File (PSMF)	As per standard requirement	3
4	Indian Good Pharmacovigilance Practices and Good Clinical Practices (GCP) e-subscription	As per standard requirement	1
5	Excel based replica of drug safety databases	As per standard requirement	For demonstration
6	Excel-based replica of MedDRA Dictionary	As per standard requirement	For demonstration
7	Excel-based replica of WHO Drug Dictionary	As per standard requirement	For demonstration
8	Sample Periodic Safety Update Reports	As per standard requirement	4
9	sample Adverse Events (AE) reporting forms	As per standard requirement	4
10	Sample Individual Case Safety Report (ICSR)	As per standard requirement	4
11	Sample Risk Management Plan (RMP)	As per standard requirement	4
12	Sample Patient Information Leaflet Reports(PSURs)	As per standard requirement	4
13	PubMed for published articles Indian Drug Formulary	As per standard requirement	2
14	Permission to access the scientific search engines like Google Scholar, Science-direct, Scopus	As per standard requirement	1
15	High speed internet connection	As per standard requirement	1
16	E module of ICH guideline	As per standard requirement	1
17	NDCT guideline	As per standard requirement	1
18	Drug safety databases e.g., Argus Safety, ArusG, Argus dossier, Aris Lifesphere etc.	As per standard requirement	1
19	FDA guidelines on pharmacovigilance	As per standard requirement	1

Classroom Aids

The aids required to conduct sessions in the classroom are:

1. Whiteboard
2. Marker Pen
3. Computer or Laptop attached to LCD projector.
4. Computer speaker
5. Pencil

Annexure: Industry Validations Summary

S. No	Organization Name	Representative Name	Designation	Contact Address	Contact Phone No	E-mail ID	LinkedIn Profile *(if available)*
1	Venus Remedies Ltd	Dr Sumit Saxena	DGM		9875910291	pv_hod@venusremedies.com	
2	Tirupati Wellness	Jagdish Chauhan	Manager - CHRD		9816633372	jagdish.chauhan@tirupatiwellness.in	
3	Bio-Med Private Limited	Divyanshu Sirohi	QA- Manager		7503804891	divyanshu988@gmail.com	
4	Jagan Institute of Pharmaceutical Sciences	S Angala Parameshwari	Principal		7680077736	principal.scp@gmail.com	
5	Sri Sai Ram Engineering College	Dr. T. Sheela	Head of IT		8754502225	hod.it@sairam.edu.in	
6	Tirupati Medicare	Jagdish Chauhan	Manager - CHRD		9816633372	jagdish.chauhan@tirupatiwellness.in	
7	Vignan Pharmacy College	Dr. P. Srinivasa Babu	Principal		9866399382	psbabu0104@gmail.com	
8	Serum Institute of India Pvt. Ltd.	Dr. Prasad S. Kulkarni, MD	Executive Director		9890679415	drpsk@seruminstitute.com	
9	Tirupati Lifesciences	Jagdish Chauhan	Manager - CHRD		9816633372	jagdish.chauhan@tirupatiwellness.in	
10	Think-i	Kamal Shahani	Managing Director		9810068241	kshahani@thinki.in	

11	Hetero Labs Limited	Dr. Subhadeep Sinha	Sr. VP & HOD (Global)-Clinical Developments and Medical affairs Department		9393922434	SD.Sinha@hetero.com	
12	Let's Evolve Life Private limited	Vidhu Shekhar Mishra	Director-Operations		9978928890	Vidhumishra@letsevolvelife.com	

Annexure: Training Details

Training Projections:

Year	Estimated Training # of Total Candidates	Estimated training # of Women	Estimated training # of People with Disability
1	500	50	
2	1000	100	
3	1000	100	

Data to be provided year-wise for next 3 years.

Annexure: Blended Learning

Blended Learning Estimated Ratio & Recommended Tools:

Refer NCVET "Guidelines for Blended Learning for Vocational Education, Training & Skilling" available on:
https://ncvet.gov.in/sites/default/files/Guidelines%20for%20Blended%20Learning%20for%20Vocational%20Education,%20Training%20&%20Skilling.pdf

S. No.	Select the Components of the NOS	List Recommended Tools – for all Selected Components	Offline: Online Ratio
1	☐Theory/ Lectures - Imparting theoretical and conceptual knowledge	LMS Portal- LSSSDC Daksh Portal will be utilized with online content/virtual lectures	50:50
2	☐Imparting Soft Skills, Life Skills and Employability Skills /Mentorship to Learners	LMS Portal- LSSSDC Daksh Portal will be utilized with online content/virtual lectures	50:50
3	☐Showing Practical Demonstrations to the learners	LMS Portal- LSSSDC Daksh Portal will be utilized with online content/virtual lectures / Skill labs	100:00
4	☐Imparting Practical Hands-on Skills/ Lab Work/ workshop/ shop floor training	Skill Labs	100:00
5	☐Tutorials/ Assignments/ Drill/ Practice	LMS Portal- LSSSDC Daksh Portal will be utilized with online content/virtual lectures / Field Visits	50:50
6	☐Proctored Monitoring/ Assessment/ Evaluation/ Examinations	Parakh	0:100
7	☐On the Job Training (OJT)/ Project Work Internship/ Candidate Training	Offline	100:00

Annexure: Standalone NOS- Performance Criteria details

1. **Description:**

This NOS on Aggregate Report writing for Regulatory Compliance will enable individual to have the capability to independently draft comprehensive Aggregate Reports that adhere to strict regulatory compliance standards, ensuring the accurate and timely submission of critical pharmacovigilance data, and demonstrating proficiency in the application of industry-specific best practices for report writing.

2. **Scope:**

The scope covers the following:

- life sciences industry and Aggregate Reports
- Report Structure and Writing Skills for pharmacovigilance reporting.
- Signal Detection and Evaluation for Pharmacovigilance
- Risk Minimization and Compliance for Pharmacovigilance
- Application and Emerging Technologies For Pharmacovigilance

3. Elements and Performance Criteria

Life sciences industry and Aggregate Reports

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

PC 1 analyze a sample Aggregate Report and discuss a case study on regulatory compliance in pharmacovigilance.
PC 2 outline data sources and their management in pharmacovigilance.

Report Structure and Writing Skills for pharmacovigilance reporting

PC 3 submit a written assignment with sections of Aggregate Reports based on provided templates to demonstrate their understanding of report structure and regulatory writing.
PC 4 participate in group exercises to collaboratively create a comprehensive Aggregate Report section, which will be evaluated for completeness and regulatory compliance.
PC 5 explore best practices in writing skills for regulatory compliance.

Signal Detection and Evaluation for Pharmacovigilance

PC 6 participate in discussions and answer questions related to signal detection methods in pharmacovigilance.
PC 7 evaluate their knowledge of benefit-risk assessment in pharmacovigilance.

Risk Minimization and Compliance for Pharmacovigilance

PC 8 Identify and evaluate various risk minimization strategies applicable to different contexts within the pharmaceutical industry.
PC 9 Prepare a sample comprehensive risk minimization plans for hypothetical scenarios, considering diverse risk factors and potential mitigations

PC 10 Apply theoretical knowledge to real-world scenarios by creating a detailed risk minimization plan for a hypothetical drug.
PC 11 Engage in a simulated audit scenario to identify and address compliance challenges.

Application and Emerging Technologies For Pharmacovigilance

PC 12 Evaluate the impact of ethical decisions on public health and regulatory compliance.
PC 13 Apply CAPA principles through a demonstration study, identifying and addressing compliance issues effectively.
PC 14 Evaluate the potential benefits and challenges associated with integrating AI and blockchain technologies into aggregate reporting processes.
PC 15 Evaluate case studies and examples illustrating the successful integration of AI and blockchain in pharmacovigilance

4. Knowledge and Understanding (KU):

The individual on the job needs to know and understand:

1. Understanding the roles and responsibilities of regulatory authorities in overseeing drug safety.
2. IT rules and policies of company
3. data integrity related SOPs
4. SOP for accessing the computer systems and emails
5. procedures for reporting of faulty system or software problems
6. escalation procedures
7. quality management SOPs including those for change control, deviations and CAPAs and BCP
8. operating procedure of software like MedDRA, WHO Drug dictionary, SAS, Drug Study
9. Database like Argus and ArisGlobal, ADR reporting software like VigiFlow, VigiBase
10. GCP guidelines and ICH E2B standard
11. computer handling (MS Word, Excel, Power Point Presentation, Outlook and Skype)
12. software validation procedures
13. changes/new regulations affecting pharmacovigilance activities
14. Familiarity with the legal requirements for reporting adverse events to regulatory agencies.
15. Knowledge of the differences in reporting requirements among various regions, including the FDA, EMA, and WHO.
16. Recognizing the consequences of non-compliance with regulatory reporting obligations.
17. Understanding the challenges and potential solutions for the integration of AI into regulatory compliance processes.
18. Classifying adverse events into different categories, including serious, non-serious, expected, and unexpected.

19. Understanding the various sources of adverse event data, such as spontaneous reports, data from clinical trials, and information from social media.
20. Recognizing the importance of data quality and reliability in the context of pharmacovigilance.
21. Analyzing the challenges and opportunities associated with mining data for adverse event identification.
22. Grasping the ethical considerations involved in utilizing diverse data sources for safety monitoring.

5. Generic Skills (GS):

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

1. use reading and comprehension skills to read instructions, guidelines, procedures, rules, and signages
2. use written communication skills to accurately record every information required to be reported as per SOP and regulatory guidelines in the language prescribed by the company's SOP
3. apply planning and organizing skills to plan and organize tools and material required for work to fulfil environment, health, safety and security requirements
4. use critical thinking skills to ascertain the breach/ compliance of EHS protocols
5. apply customer centricity to remain compliant with data integrity rules and regulatory guideline to evaluate impact of wrongdoings
6. apply decision-making skills to make balanced judgments within the authority in different situations while dealing with hazards and breaches
7. apply problem-solving skills to find solutions for workflow-related difficulties
8. use verbal communication skills to communicate with supervisor/ manager/ EHS Incharge or any other concerned authority clearly for escalating any emergency situation or hazard
9. Identify and resolve the issues and challenges

Annexure: Assessment Criteria

Detailed PC-wise assessment criteria and assessment marks for the NOS are as follows:

S. No.	Assessment Criteria for Performance Criteria	Theory Marks	Practical Marks	Project Marks	Viva Marks
1.LFS/N0708: Aggregate Report writing for Regulatory Compliance	**Life sciences industry and Aggregate Reports**	5	5		
	PC 1 analyze a sample Aggregate Report and discuss a case study on regulatory compliance in pharmacovigilance.				
	PC 2 outline data sources and their management in pharmacovigilance.				
	Report Structure and Writing Skills for pharmacovigilance reporting	10	10		
	PC 3 submit a written assignment with sections of Aggregate Reports based on provided templates to demonstrate their understanding of report structure and regulatory writing.				
	PC 4 participate in group exercises to collaboratively create a comprehensive Aggregate Report section, which will be evaluated for completeness and regulatory compliance.				
	PC 5 explore best practices in writing skills for regulatory compliance.				
	Signal Detection and Evaluation for Pharmacovigilance	12	13		
	PC 6 Collaboratively analyze real-world data sets containing adverse event reports and identify potential safety signals, providing recommendations for further investigation.				
	PC 7 participate in discussions and answer questions related to signal detection methods in pharmacovigilance.				
	PC 8 evaluate their knowledge of benefit-risk assessment in pharmacovigilance				
	Risk Minimization and Compliance for Pharmacovigilance	13	12		
	PC 9 Identify and evaluate various risk minimization strategies applicable to different contexts within the pharmaceutical industry.				
	PC 10 Prepare a sample comprehensive risk minimization plans for hypothetical scenarios, considering diverse risk factors and potential mitigations				
	PC 11 Apply theoretical knowledge to real-world scenarios by creating a detailed risk minimization plan for a hypothetical drug.				
	PC 12 Engage in a simulated audit scenario to identify and address compliance challenges.				
	Application and Emerging Technologies for Pharmacovigilance	10	10		
	PC 13 Evaluate the impact of ethical decisions on public health and regulatory compliance.				

	PC 14 Apply CAPA principles through a demonstration study, identifying and addressing compliance issues effectively.				
	PC 15 Evaluate the potential benefits and challenges associated with integrating AI and blockchain technologies into aggregate reporting processes.				
	PC 16 Evaluate case studies and examples illustrating the successful integration of AI and blockchain in pharmacovigilance				
Total Marks		**50**	**50**		

Annexure: Assessment Strategy

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

Mention the detailed assessment strategy in the provided template.

1. Assessment System Overview:

The assessment for the Training will be conducted toward the end of the training duration. The assessment of the qualification shall be carried out by NCVET approved assessment agencies empaneled by LSSSDC after a defined evaluation process. For Execution of the assessment for training for the qualification, LSSSDC will be engaging more than one NCVET approved assessment agency/ body.

1.1 Criteria of selection of assessment body/agency:

The assessment body/agency is selected based on:

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

1.2 Assessment tool development for assessment of Training:

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

1.2.1 Digital Written test for knowledge assessment:

Scope – Is used to test the knowledge component of the Qualification/ NOS/ Micro Credentials.

Tools –computer or tab based online or offline.

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

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

1.2.2 Digital Written test for skill assessment:

Scope – Is used to test primarily the Skill component of the Qualification/ NOS/ Micro Credentials. Trainee's expertise in handling and managing the situation is tested.

Tools – computer or tab based online or offline questions

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

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

1.3 Steps for assessment tool development:

- The selection of assessment tool(s) is done as per the assessment criteria prescribed in Qualification Pack.
- For Aggregate Report writing for Regulatory Compliance assessment a blueprint of the question paper is part of the assessment tool for training.
- Development of layout of Question paper is such that the entire PCs (Performance Criteria) of that Qualification/ NOS/ Micro Credentials are covered.
- Score per question maps with the weightage given to that PC, in the assessment criteria, and the level of difficulty of the question.
- An expert from industry is selected who is called "Subject Matter Expert" (SME). This SME must have over 13-15 years of experience in the industry in Pharmacovigilance occupation.
- SME is screened and approved by LSSSDC. He/she is oriented by both LSSSDC and Assessment agency on – creating question Bank, level of questions, end the desired outcome of the assessment.

1.4 Execution of Training Assessment/ RPL Assessment:

- Once the assessment date for training is decided with common agreement of Industry/ Vocational Training Centre and LSSSDC, LSSSDC allocates the batch to an NCVET approved and LSSSDC empaneled assessment body/agency.
- Assessment agency ensures
    - the availability of required infrastructure
    - the availability of validated assessment tools for the assessment of training for the assigned qualification
    - the availability of assessor as per assessor eligibility criteria of the qualification
- Assessment agencies send the assessment confirmation to VTP/TC looping SSC
- Assessment agency deploys LSSSDC certified assessor for executing the assessment
- LSSSDC monitors the assessment process & records
- The assessment is executed in two possible ways depending on the choice of the industry:

1.4.1 Tab based assessment using physical proctoring

1.4.2 Smartphone-based assessment using e-proctoring

1.4.1 Tab-based assessment using physical proctoring

- A representative from the Assessment agency is present on the day of assessment to executing the assessment at the venue in case of physical proctoring.
- The assessment agency representative carries an identity card and letter from the council authorizing to conduct the assessment.

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

1.4.2 Smartphone-based assessment using e-proctoring

- All trainees enrolled in the batch due for assessment, are registered on an assessment tool application using their unique mobile number and e-mail ID along with a Govt. ID issued proof.
- An assessment link is sent to the mail ID of each trainee with a defined expiry date of the link.
- Trainee at any location can click on the link using his/her smartphone or a web camera-enabled computer system
- Using the unique credentials and Govt ID number, the trainee logs in for the start of assessment and completes the assessment.
- The authenticity of Trainee's identity is done by assessment application by verifying the documents (any document issued by GOI, such as Ration card, Aadhaar Card, Driving Licence, Passport, election card, etc.) and a live photo capture
- A live video of the candidate during the assessment is captured to collect the evidence of the assessment

- Once the assessment is complete, the assessment application automatically assessment scores to the assessment agency server, using a secure, encrypted web-based program.
- The assessment agency after processing the results and putting them in standard format hands over to LSSSDC within 7 days of assessment.

2. Testing Environment:

- The Centre/ location of the assessment is pre decided and geo tagged in case of physical assessment
- The assessment of LSSSDC qualifications are 99% done in digital environment while 1% pen and paper is used ONLY in business exigencies
- Based on the size of batch the assessment duration/ no. of required assessors are decided to ensure detailed assessment without any negative impact on quality of assessment
- The system driven automated assessment management system ensures uniform time allocation to each student, unique logins for each students and automated randomization of questions for developing multiple sets of question paper for single batch.
- Identity check of the student is mandated

3. Assessment Quality Assurance levels/Framework:

- Question bank is created by the Subject Matter Experts (SME) of Assessment Agency are verified by the other SME of LSSSDC
- All Questions are mapped to the specified assessment criteria
- Assessor eligibility criteria are structured to ensure quality and knowledge credentials of an assessor like-wise the trainer's quality and knowledge credentials.
- Eligible Assessor must be certified by LSSSDC for the respective and relevant qualification
- The tools used for assessment are validated for relevance and feasibility for skill assessment of the qualification in consideration

4. Types of evidence or evidence-gathering protocol:

- Time-stamped & geotagged reporting of the assessor from assessment location
- ID Proof of the students
- Educational qualification of students
- Certificate of Trainer
- In case of Physical assessment, geotagged photographs of the students undergoing assessment
- While students are undergoing assessment on the digital assessment platform the system captures random photos of the student which is audited by LSSSDC

5. Method of verification or validation:

- Surprise visit to the assessment location
- ID Proof of the students for identity verification
- Educational qualification verification of students for validation of entry level criteria
- Certificate of Trainer to verify the credential of vocational educator
- Random photos taken by the digital system are verified during audit by the assessment team

6. Method for assessment documentation, archiving, and access

- Hard copies and digital copies (whichever is applicable) of the assessment evidences are stored with assessment agency team for 5 years
- Assessment transcripts are stored in the server space of assessment agency for 5 years
- Assessment question banks and validation records are stored with assessment agency and LSSSDC digitally

- Assessment records are archived with assessment agency archive server after 5 years for another 5 years
- Access of assessment records are controlled with restricted access to concerned department and stakeholders and is shared on demand after due approval of Head of Assessment and Certification-LSSSDC

7. On the Job Training Assessment (applicable for OJT/ Apprenticeship):

7.1 Each module/ NOS will be assessed separately.

7.2 The candidate must score minimum percentage as per assessment criteria laid out in qualification in each module to successfully complete the OJT exam.

7.3 Tools of OJT Assessment that will be used for assessing whether the candidate is having desired skills and competence, including Soft Skills effectively:

- Videos of Trainees during OJT (wherever possible)
- Observation based mark sheet from Supervisor or OJT examiner
- Simulated question paper
- XR practice module analytics wherever possible

7.4 Assessment of each Module will ensure that the candidate is able to:

- Meet minimum performance criteria of the expected outcome/ skill set for each module/ NOS
- Understand and know the required concepts and its application at workplace
- Has gained the required employability skills

Annexure: Acronym and Glossary

Acronym

Acronym	Description
AA	Assessment Agency
AB	Awarding Body
ISCO	International Standard Classification of Occupations
NCO	National Classification of Occupations
NCrF	National Credit Framework
NOS	National Occupational Standard(s)
NQR	National Qualification Register
NSQF	National Skills Qualifications Framework
OJT	On the Job Training
SOP	Standard Operating Procedure
GMP	Good manufacturing Practices
GLP	Good Laboratory Practices
ALCOA	Attributable, Legible, Contemporaneous, Original, and Accurate.
BPR	Batch Packaging Record
BMR	Batch manufacturing Record
CAPA	Corrective and Preventive Actions
GDP	Good Documentation Practices

SME	Subject Matter Experts

Glossary

Term	Description
National Occupational Standards (NOS)	NOS define the measurable performance outcomes required from an individual engaged in a particular task. They list down what an individual performing that task should know and also do.
Qualification	A formal outcome of an assessment and validation process which is obtained when a competent body determines that an individual has achieved learning outcomes to given standards
Qualification File	A Qualification File is a template designed to capture necessary information of a Qualification from the perspective of NSQF compliance. The Qualification File will be normally submitted by the awarding body for the qualification.
Sector	A grouping of professional activities on the basis of their main economic function, product, service or technology.
Long Term Training	Long-term skilling means any vocational training program undertaken for a year and above. https://ncvet.gov.in/sites/default/files/NCVET.pdf