QUALIFICATION FILE – Micro Credentials

Basics of Clinical Data Management

☒ Public ☐ Private

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

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

NCrF/NSQF Level: 5

Submitted By:

Life Sciences Sector Skill Development Council

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Section 1: Basic Details

<table>
<tr><td>1.</td><td>Micro Credential-Qualification Name</td><td colspan="2">Basics of Clinical Data Management</td></tr>
<tr><td>2.</td><td>Sector/s</td><td colspan="2">Life Sciences</td></tr>
<tr><td>3.</td><td>National Qualification Register (NQR) Code & Version</td><td>NM-05-LS-01298-2023-V1-LSSSDC</td><td>4. NCrF/NSQF Level: 5</td></tr>
<tr><td>5.</td><td>Brief Description of the Micro Credential</td><td colspan="2">The professional with Basics of Clinical Data Management have foundational knowledge and skills in the field of clinical data management (CDM). This includes understanding of the importance of CDM in clinical research, learn key terminology and concepts, explore data sources in clinical trials, delve into the design of case report forms (CRFs), and understand the critical processes of data entry, cleaning, and quality assurance in CDM. The professional with Basics of Clinical Data Management has good knowledge of regulatory guidelines and data privacy regulations that impact CDM practices.</td></tr>
<tr><td>6.</td><td>Eligibility Criteria for Entry for Students/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 2nd-year of Graduation Degree in relevant Field and continuous education</td><td></td></tr>
<tr><td>2.</td><td>Pursuing 2nd year of 2-year Diploma (after 12th Class) in relevant field</td><td></td></tr>
</table>
b. Age: – 18 years</td></tr>
<tr><td>7.</td><td>Credits Assigned to this Qualification, Subject to Assessment (as per National Credit Framework (NCrF))</td><td>0.5</td><td>8. Common Cost Norm Category (I/II/III) (wherever applicable): II</td></tr>
<tr><td>9.</td><td>Any Licensing Requirements/ Pre-requisites for Undertaking Training (wherever applicable)</td><td colspan="2">NA</td></tr>
<tr><td>10.</td><td>Expected Outcomes of the Micro Credential</td><td colspan="2">Terminal learning outcomes are:
• Comprehensive knowledge of clinical data management.</td></tr>
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<tr><td></td><td></td><td>

- Demonstrate proficiency in clinical data management, including data collection, verification, validation, and cleaning, ensuring data accuracy and reliability.
- Understand and apply international regulatory guidelines, such as ICH-GCP, and ensure compliance with data privacy and protection regulations, safeguarding patient data and maintaining ethical standards.
- Understanding the role of data monitoring and audits in maintaining data integrity .
- Understand how regulatory requirements shape CDM practices.
- Ensure data integrity, confidentiality, and compliance with industry standards.

</td></tr>
<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">15:00</td></tr>
<tr><td>Classroom</td><td>12:00</td><td>03:00</td></tr>
<tr><td colspan="3">OR</td></tr>
<tr><td>Blended Mode</td><td>12:00</td><td>03:00</td></tr>
<tr><td>Offline (As part of blended mode)</td><td>06:00</td><td>03:00</td></tr>
<tr><td>Online (As part of blended mode)</td><td>06:00</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>76</td><td>24</td><td>-</td><td>-</td><td>100</td><td>70</td></tr>
</table>

</td></tr>
<tr><td>13.</td><td>Is the Qualification Amenable to Persons with Disability</td><td>☐ Yes ☒ No If “Yes”, specify applicable type of Disability: Hearing disabilities, Speech Disabilities</td></tr>
<tr><td>14.</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>
</table>

15.	**Other Indian Languages in which the Micro Credential will be implemented.**	English and Hindi	
16.	**Is similar Micro Credential Qualification(s) available on NQR-if yes, justification for this qualification**	**☐ Yes ☒ No URLs of similar Qualifications:**	
17.	**Name and Contact Details Submitting / Awarding Body SPOC**	**Name: Mrs. Shivi Chaudhary** **Email: shivi.chaudhary@lsssdc.in Contact No.: + 91 11 41042407/ 408, +91 9315747189** **Website: https://www.lsssdc.in/**	
18.	**NSQC Approval Date: 1 November 2023**	**19. Validity Duration:3 years**	**20. Next Review Date: 1 November 2026**

Section 2: Training Related

1.	**Trainer's Qualification and experience in relevant sector (in years)** *(as per requirement and NCVET guidelines)*	Graduate in B.Sc. (Biology/Nursing/Medical Lab technician/Life Sciences/ Biotechnology) / MBBS/B. Pharmacy/B. Tech (Biotechnology) with 4 years Industry of experience in Pharmaceutical/ Biopharmaceutical/AYUSH- Clinical Research and 2 years of training experience. OR Postgraduate in M.Sc. (Biology/Nursing/Medical Lab technician/Life Sciences/ Biotechnology)/ M. Tech (Biotechnology)/ M. Pharmacy with 4 years Industry of experience in Pharmaceutical/ Biopharmaceutical/AYUSH - Clinical Research and 1 years of training experience. Certified for Micro credentials: "Basics of Clinical Data Management" mapped to MCr: "LFS/MCr-0009, v1" with minimum accepted score of 80%. Recommended that the Trainer is certified for the Job Role: "Trainer (VET and SKILLS)", mapped to the Qualification Pack: "MEP/Q2601 ver 2.0 " with minimum score of 80%.
2.	**Master Trainer's Qualification and experience in relevant sector (in years)** *(as per requirement and NCVET guidelines)*	Graduate in Sciences **(**B.Sc. (Biology/Nursing/Medical Lab technician/Life Sciences/ Biotechnology) , MBBS, B. Pharmacy, B. Tech (Biotechnology)) with 6 years Industry of experience in Pharmaceutical/ Biopharmaceutical/AYUSH- Clinical Research and 4 years of training experience.

		OR Postgraduate in Sciences (M.Sc. (Biology/Nursing/Medical Lab technician/Life Sciences/ Biotechnology), M. Tech (Biotechnology), M. Pharmacy) with 5 years Industry of experience in Pharmaceutical/ Biopharmaceutical/AYUSH - Clinical Research and 4 years of training experience. Certified for Micro credentials: "Basics of Clinical Data Management" mapped to MCr: "LFS/MCr-0009, v1" 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 ver 2.0 " with minimum score of 80%.
3.	**Tools and Equipment Required for Training**	☐ **Yes** ☒ **No** *(If "Yes", details to be provided in Annexure)*

Section 3: Assessment Related

1.	**Assessor's Qualification and experience in relevant sector (in years)** *(as per requirement and NCVET guidelines)*	Graduate in Sciences **(**B.Sc. (Biology/Nursing/Medical Lab technician/Life Sciences/ Biotechnology) , MBBS, B. Pharmacy, B. Tech (Biotechnology)) with 4 years Industry of experience in Pharmaceutical/ Biopharmaceutical/AYUSH- Clinical Research and 2 years of training experience. OR Postgraduate in Sciences (M.Sc. (Biology/Nursing/Medical Lab technician/Life Sciences/ Biotechnology), M. Tech (Biotechnology), M. Pharmacy) with 4 years Industry of experience in Pharmaceutical/ Biopharmaceutical/AYUSH - Clinical Research and 1 years of training experience. Certified for Micro credentials: "Basics of Clinical Data Management" mapped to MCr: "LFS/MCr-0009, v1" with minimum accepted score of 80%. Recommended that the Assessor is certified for the Job Role: "Assessor (VET and SKILLS)", mapped to the Micro credentials: "MEP/Q2701 ver 2.0" with minimum score of 80%.

2.	**Proctor's Qualification and experience in relevant sector (in years)** *(as per requirement and NCVET guidelines)*	Graduate in Sciences **(**B.Sc. (Biology/Nursing/Medical Lab technician/Life Sciences/ Biotechnology) , MBBS, B. Pharmacy, B. Tech (Biotechnology)) with 6 years Industry of experience in Pharmaceutical/ Biopharmaceutical/AYUSH- Clinical Research and 4 years of training experience. OR Postgraduate in Sciences (M.Sc. (Biology/Nursing/Medical Lab technician/Life Sciences/ Biotechnology), M. Tech (Biotechnology), M. Pharmacy) with 5 years Industry of experience in Pharmaceutical/ Biopharmaceutical/AYUSH - Clinical Research and 4 years of training experience. Certified for Micro credentials: "Basics of Clinical Data Management" mapped to MCr: "LFS/MCr-0009, v1" with minimum accepted score of 80%.
3.	**Lead Assessor's/Proctor's Qualification and experience in relevant sector (in years)** *(as per requirement and NCVET guidelines)*	Graduate in Sciences **(**B.Sc. (Biology/Nursing/Medical Lab technician/Life Sciences/ Biotechnology) , MBBS, B. Pharmacy, B. Tech (Biotechnology)) with 6 years Industry of experience in Pharmaceutical/ Biopharmaceutical/AYUSH- Clinical Research and 4 years of training experience. OR Postgraduate in Sciences (M.Sc. (Biology/Nursing/Medical Lab technician/Life Sciences/ Biotechnology), M. Tech (Biotechnology), M. Pharmacy) with 5 years Industry of experience in Pharmaceutical/ Biopharmaceutical/AYUSH - Clinical Research and 4 years of training experience. Certified for Micro credentials: "Basics of Clinical Data Management" mapped to MCr: "LFS/MCr-0009, v1" with minimum accepted score of 80%. Recommended that the Assessor is certified for the Job Role: "Lead Assessor (VET and SKILLS)", mapped to the Micro credentials: "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 Need of the Micro Credential

As per the NCVET Guidelines for evidence of need, provide the required Annexure/Supporting documents.

1.	Government /Industry initiatives/ requirement (Yes/No):YES
2.	Number of Industry validation provided: 12
3.	Estimated number of people to be trained: 5000

Section 5: Annexure Check List

Specify Annexure Number and Name.

1.	**Annexure:** NCrF/NSQF level justification based on NCrF Level/NSQF descriptors *(Mandatory)*	Yes
2.	**Annexure:** Learning Outcomes and Assessment Criteria *(Mandatory)*	Yes
3.	**Annexure:** Assessment Strategy *(Mandatory)*	Yes
4.	**Annexure:** List of tools and equipment relevant for qualification *(Mandatory – Except in case of online course)*	Yes
5.	**Annexure:** Blended Learning *(Mandatory in case selected mode of delivery is "Blended Learning")*	Yes
6.	**Annexure:** Acronym and Glossary *(Optional)*	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	• Introduction to clinical data management (CDM) • Importance of CDM in clinical research • Key terminology and concepts in CDM • Data sources in clinical trials • Case report form (CRF) design and development • Source data verification and validation • Quality control processes in CDM • Data quality assessment and metrics • International guidelines (ICH-GCP) for data management	This micro credential equips participants with foundational theoretical knowledge in clinical data management (CDM). They gain an understanding of key CDM concepts, terminology, and the importance of CDM in clinical research. This aligns with Level 5, where professionals possess advanced theoretical knowledge in their field.	5
Professional and Technical Skills/ Expertise/ Professional Knowledge	• Importance of CDM in clinical research • Key terminology and concepts in CDM • Data sources in clinical trials • Case report form (CRF) design and development • Source data verification and validation • Quality control processes in CDM • Data quality assessment and metrics • International guidelines (ICH-GCP) for data management	The micro credential acquires essential professional and technical skills required for entry-level positions in CDM. They learn about data sources in clinical trials, CRF design, data entry, cleaning, and quality assurance. These practical skills are vital for performing tasks related to CDM, making them suitable for Level 5 roles	5

Employment Readiness & Entrepreneurship **Skills & Mind-set/Professional Skill**	• Importance of CDM in clinical research • Key terminology and concepts in CDM • Data sources in clinical trials • Case report form (CRF) design and development • Source data verification and validation • Quality control processes in CDM • Data quality assessment and metrics • International guidelines (ICH-GCP) for data management	While entrepreneurship skills may not be the primary focus, this micro credential instills important professional skills. Participants develop skills in data verification, compliance with regulations, and understanding the impact of regulatory requirements on CDM practices. These skills contribute to their readiness for employment in Level 5 positions.	5
Broad Learning Outcomes/Core Skill	• Importance of CDM in clinical research • Key terminology and concepts in CDM • Data sources in clinical trials • Case report form (CRF) design and development • Source data verification and validation • Quality control processes in CDM • Data quality assessment and metrics • International guidelines (ICH-GCP) for data management	The program prepares individuals to perform data management tasks with a focus on data quality and compliance with regulations. This core skill is essential for Level 5 roles, where professionals are expected to manage complex processes and activities.	5
Responsibility	• Importance of CDM in clinical research • Key terminology and concepts in CDM • Data sources in clinical trials • Case report form (CRF) design and development • Source data verification and validation • Quality control processes in CDM	This micro credential prepares individual to take responsibility for data management processes within defined parameters. They learn about data quality assessment, data monitoring, and audits, which align with the responsibilities of Level 5 professionals.	5

	• Data quality assessment and metrics • International guidelines (ICH-GCP) for data management		

Annexure: Learning Outcomes and Assessment Criteria

Detailed learning outcomes and assessment criteria for the qualification are as follows:

S. No.	Learning Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
1. LFS/MCr-0009: Basics of Clinical Data Management	Introduction to Life sciences sector and Clinical Data Management	20	-	-	-
	PC 1 Apply CDM principles in a hypothetical clinical research scenario, demonstrating an understanding of how CDM contributes to data quality.	-	-	-	-
	PC 2 Analyze the significance of CDM in maintaining data integrity and minimizing errors in clinical trials.	-	-	-	-
	PC 3 Engage in discussions and activities that illustrate the practical implications of CDM in real-world clinical research settings	-	-	-	-
	Clinical Data Collection and Source Documentation	20	8	-	-
	PC 4 Identify appropriate data sources for a hypothetical clinical trial scenario, considering factors like data accuracy, accessibility, and regulatory compliance.				
	PC 5 Design a sample CRF for a specific clinical trial, considering data collection requirements, user-friendliness, and data accuracy.				
	PC 6 Apply source data verification and validation techniques to real-world clinical trial data				
	PC 7 demonstrate the ability to verify data accuracy against source documents.				
	PC 8 Analyze and resolve potential data collection challenges in a practical context, highlighting the importance of data quality and integrity.				
	Clinical Data Entry and Cleaning	13	8	-	-
	PC 9 Demonstrate proficiency in data entry techniques, including manual and electronic data entry, by accurately entering data from source documents into a database.				

	PC 10 Apply data cleaning strategies and techniques to identify and rectify data inconsistencies, errors, and outliers in a clinical trial dataset.				
	PC 11 Effectively manage and resolve data queries, demonstrating the ability to communicate with stakeholders and document query resolutions.				
	PC 12 Identify and categorize data discrepancies and propose appropriate resolutions to ensure data consistency and accuracy.				
	Clinical Data Quality Assurance	10	8	-	-
	PC 13 Implement quality control processes in a practical context, including data validation and data cleaning, to ensure data accuracy and consistency.				
	PC 14 Calculate and apply data quality metrics to assess the quality of clinical trial data, identifying areas requiring improvement.				
	PC 15 Participate in simulated data monitoring activities, including interim analysis and risk assessment, to understand their practical implications.				
	PC 16 Develop strategies for continuous data quality improvement throughout the clinical trial, addressing issues proactively.				
	Regulatory Guidelines in CDM	13	-	-	
	PC 17 Ensure that provided data management plan for compliance with ICH-GCP guidelines				
	PC 18 identify areas that may require adjustments to ensure compliance.				
	PC 19 Implement data security protocols and practices in a simulated clinical data management environment to safeguard patient data.				
	PC 20 Analyze and discuss how specific regulatory requirements can impact various aspects of clinical data management, such as data collection, storage, and sharing.				
Total Marks		**76**	**24**	**-**	**-**

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/ Micro Credential/ NOS.
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/ Micro Credential/ NOS. 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/ Micro Credential/ NOS.
- For Basics of Clinical Data Management 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/ Micro Credential/ NOS 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 Clinical Trial 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 License, 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 is 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 is 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 student 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: Tools and Equipment

List of Tools and Equipment

Batch Size: 30

S. No.	Tool / Equipment Name	Specification	Quantity for specified Batch size
1.	Black & White Printer	As per standards	1
2.	Indian Drug Formulary	As per standards	1
3.	Computer	As per standards	1
4.	US Pharmacopia National Formulary (USP-41- NF-36)	As per standards	1
5.	Internet Connection	As per standards	1
6.	Indian Pharmacopia 2018, 8th Edition/ IP 2018	As per standards	1
7.	White OR Black Board with Duster	As per standards	1
8.	Stedman's Medical Dictionary e-subscription	As per standards	2
9.	ICH GCP and GLP Guidelines e-subscription	As per standards	3
10	Opensource Clinical Data Management Software / EDC tool for Clinical Trials, Opensource Clinical Database	As per standards	1

Classroom Aids:

The aids required to conduct sessions in the classroom are:

1. Whiteboard
2. Marker Pen
3. Computer or Laptop
4. LCD projector
5. Flip Chart
6. Scanner
7. Computer speaker

8. 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 Year	1000	100	-
2 Year	2000	200	-
3 Year	2000	200	-

Data to be provided year-wise for the 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 Qualification	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	Offline	100:00

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
NQR	National Qualification Register
NSQF	National Skills Qualifications Framework
OJT	On the Job Training

Glossary

Term	Description
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 based on their main economic function, product, service or technology.