



QUALIFICATION FILE – Micro Credentials

Advanced Data Capture Techniques in 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

1.	Micro Credential-Qualification Name	Advanced Data Capture Techniques in Clinical Data Management										
2.	Sector/s	Life Sciences										
3.	National Qualification Register (NQR) Code & Version <i>(Will be issued after NSQC approval.)</i>	NM-05-LS-01299-2023-V1-LSSSDC	4. NCrF /NSQF Level: 5									
5.	Brief Description of the Micro Credential	<p>The professional with Advanced Data Capture Techniques in Clinical Data Management is able to perform cutting-edge data capture techniques within the field of clinical data management. This includes Electronic Data Capture (EDC) systems, mobile health (mHealth) data collection, remote patient monitoring (RPM), electronic patient-reported outcomes (ePRO), and the integration of real-world data (RWD) into clinical databases. The professional with Advanced Data Capture Techniques in Clinical Data Management is prepared for roles demanding in-depth theoretical understanding, specialized technical proficiency, and the ability to make informed decisions in the dynamic field of clinical data management.</p>										
6.	Eligibility Criteria for Entry for Students/Trainee/Learner/Employee	<p>a. Entry Qualification & Relevant Experience</p> <table border="1" data-bbox="1064 874 2067 1145"> <thead> <tr> <th>S. No.</th> <th>Academic/Skill Qualification (with specialization- if applicable)</th> <th>Relevant Experience (with specialization- if applicable)</th> </tr> </thead> <tbody> <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> </tbody> </table> <p>b. Age: – 18 years</p>		S. No.	Academic/Skill Qualification (with specialization- if applicable)	Relevant Experience (with specialization- if applicable)	1.	Pursuing 2nd-year of Graduation Degree in relevant Field and continuous education		2.	Pursuing 2nd year of 2-year Diploma (after 12th Class) in relevant field	
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1.	Pursuing 2nd-year of Graduation Degree in relevant Field and continuous education											
2.	Pursuing 2nd year of 2-year Diploma (after 12th Class) in relevant field											
7.	Credits Assigned to this Qualification, Subject to Assessment <i>(as per National Credit Framework (NCrF))</i>	1.0	8. Common Cost Norm Category (I/II/III) <i>(wherever applicable): II</i>									
9.	Any Licensing Requirements/ Pre-requisites for Undertaking Training <i>(wherever applicable)</i>	NA										

10.	Expected Outcomes of the Micro Credential	<p>Terminal learning outcomes are:</p> <ul style="list-style-type: none"> • Understand Electronic Data Capture (EDC) systems, their benefits, challenges, and validation. • Explore the role of Mobile Health (mHealth) in clinical data collection, including wearable devices and sensor technologies. • Master the implementation of Remote Patient Monitoring (RPM) and ensure data security and privacy. • Utilize Electronic Patient-Reported Outcomes (ePRO) tools to collect patient data effectively. • Learn how to integrate Real-World Data (RWD) sources into clinical databases for enhanced analysis and post-marketing surveillance. 																							
11.	<p>Training Duration by Modes of Training Delivery (<i>Specify Total Duration as per selected training delivery modes and as per requirement of the qualification</i>)</p>	<p><input checked="" type="checkbox"/> Offline Only <input type="checkbox"/> Online Only <input checked="" type="checkbox"/> Blended</p> <table border="1" data-bbox="1021 727 2029 1091"> <thead> <tr> <th>Training Delivery Mode</th> <th>Theory (Hours)</th> <th>Practical (Hours)</th> <th>Total (Hours)</th> </tr> </thead> <tbody> <tr> <td colspan="3">Offline Mode</td> <td rowspan="6" style="text-align: center; vertical-align: middle;">30:00</td> </tr> <tr> <td>Classroom</td> <td style="text-align: center;">20:00</td> <td style="text-align: center;">10:00</td> </tr> <tr> <td colspan="3" style="text-align: center;">OR</td> </tr> <tr> <td colspan="3">Blended Mode</td> </tr> <tr> <td>Offline (As part of blended mode)</td> <td style="text-align: center;">10:00</td> <td style="text-align: center;">10:00</td> </tr> <tr> <td>Online (As part of blended mode)</td> <td style="text-align: center;">10:00</td> <td style="text-align: center;">00:00</td> </tr> </tbody> </table>	Training Delivery Mode	Theory (Hours)	Practical (Hours)	Total (Hours)	Offline Mode			30:00	Classroom	20:00	10:00	OR			Blended Mode			Offline (As part of blended mode)	10:00	10:00	Online (As part of blended mode)	10:00	00:00
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12.	Assessment Criteria	<table border="1" data-bbox="1021 1126 1984 1238"> <thead> <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> </thead> <tbody> <tr> <td style="text-align: center;">67</td> <td style="text-align: center;">33</td> <td style="text-align: center;">-</td> <td style="text-align: center;">-</td> <td style="text-align: center;">100</td> <td style="text-align: center;">70</td> </tr> </tbody> </table>	Theory (Marks)	Practical (Marks)	Project (Marks)	Viva (Marks)	Total (Marks)	Passing %age	67	33	-	-	100	70											
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67	33	-	-	100	70																				
13.	Is the Qualification Amenable to Persons with Disability	<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If “Yes”, specify applicable type of Disability: Hearing disabilities, Speech Disabilities</p>																							

14.	How participation of women will be encouraged?	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	
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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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)	<p>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.</p> <p>OR</p> <p>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.</p> <p>Certified for Micro credentials: “Advanced Data Capture Techniques in Clinical Data Management” mapped to MCr: “LFS/MCr-0010, v1” with minimum accepted score of 80%.</p> <p>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%.</p>
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2.	Master Trainer’s Qualification and experience in relevant sector (in years) (as per requirement and NCVET guidelines)	<p>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.</p> <p>OR</p> <p>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.</p> <p>Certified for Micro credentials: “Advanced Data Capture Techniques in Clinical Data Management” mapped to MCr: “LFS/MCr-0010, v1” with minimum accepted score of 80%.</p> <p>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%.</p>
3.	Tools and Equipment Required for Training	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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)	<p>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.</p> <p>OR</p> <p>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.</p> <p>Certified for Micro credentials: “Advanced Data Capture Techniques in Clinical Data Management” mapped to MCr: “LFS/MCr-0010, v1” with minimum accepted score of 80%.</p>
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		<p>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%.</p>
2.	<p>Proctor’s Qualification and experience in relevant sector (in years) <i>(as per requirement and NCVET guidelines)</i></p>	<p>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.</p> <p>OR</p> <p>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.</p> <p>Certified for Micro credentials: “Advanced Data Capture Techniques in Clinical Data Management” mapped to MCr: “LFS/MCr-0010, v1” with minimum accepted score of 80%.</p>
3.	<p>Lead Assessor’s/Proctor’s Qualification and experience in relevant sector (in years) <i>(as per requirement and NCVET guidelines)</i></p>	<p>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.</p> <p>OR</p> <p>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.</p> <p>Certified for Micro credentials: “Advanced Data Capture Techniques in Clinical Data Management” mapped to MCr: “LFS/MCr-0010, v1” with minimum accepted score of 80%.</p> <p>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%.</p>

4.	Assessment Mode <i>(Specify the assessment mode)</i>	Mode: <input checked="" type="checkbox"/> Online Only <input type="checkbox"/> Offline Only <input type="checkbox"/> Blended
5.	Tools and Equipment Required for Assessment	<input type="checkbox"/> Same as for training <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <i>(details to be provided in Annexure-if it is different for Assessment)</i>

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):
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 <i>(Mandatory)</i>	Yes
2.	Annexure: Learning Outcomes and Assessment Criteria <i>(Mandatory)</i>	Yes
3.	Annexure: Assessment Strategy <i>(Mandatory)</i>	Yes
4.	Annexure: List of tools and equipment relevant for qualification <i>(Mandatory – Except in case of online course)</i>	Yes
5.	Annexure: Blended Learning <i>(Mandatory in case selected mode of delivery is “Blended Learning”)</i>	Yes
6.	Annexure: Acronym and Glossary <i>(Optional)</i>	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	<ul style="list-style-type: none"> • Electronic Data Capture (EDC) Systems • EDC system selection and validation • Wearable devices and sensors for data capture • RPM technologies and applications • Utilizing ePRO tools for patient data collection • Data integration challenges and solutions • Integrating Real-World Data (RWD) into CDM 	<p>The Micro credentials should equip individuals with advanced theoretical knowledge of data capture techniques and processes, including Electronic Data Capture (EDC) systems, mobile health (mHealth) data collection, and real-world data (RWD) integration. This aligns with the need for deep theoretical understanding at NCrF/NSQF Level Descriptor 5.</p>	5
Professional and Technical Skills/ Expertise/ Professional Knowledge	<ul style="list-style-type: none"> • Electronic Data Capture (EDC) Systems • EDC system selection and validation • Wearable devices and sensors for data capture • RPM technologies and applications • Utilizing ePRO tools for patient data collection • Data integration challenges and solutions • Integrating Real-World Data (RWD) into CDM 	<p>The program should equip individuals with developing specialized technical skills in utilizing EDC systems, mHealth technologies, and RWD integration. They also acquire expertise in data analysis, security, and privacy. These skills align with Level 5's requirement for specialized professional and technical skills.</p>	5

<p>Employment Readiness & Entrepreneurship Skills & Mind-set/Professional Skill</p>	<ul style="list-style-type: none"> • Electronic Data Capture (EDC) Systems • EDC system selection and validation • Wearable devices and sensors for data capture • RPM technologies and applications • Utilizing ePRO tools for patient data collection • Data integration challenges and solutions • Integrating Real-World Data (RWD) into CDM 	<p>While entrepreneurship may not be the primary focus, participants gain skills crucial for employment readiness, such as advanced communication, problem-solving, and the ability to adapt to evolving technologies. These skills are essential for Level 5.</p>	<p>5</p>
<p>Broad Learning Outcomes/Core Skill</p>	<ul style="list-style-type: none"> • Electronic Data Capture (EDC) Systems • EDC system selection and validation • Wearable devices and sensors for data capture • RPM technologies and applications • Utilizing ePRO tools for patient data collection • Data integration challenges and solutions • Integrating Real-World Data (RWD) into CDM 	<p>This micro credential equips individuals with a broad range of core skills, including data analysis, data security, and effective communication. These skills enable graduates to handle complex tasks, aligning with the broad learning outcomes expected at Level 5.</p>	<p>5</p>
<p>Responsibility</p>	<ul style="list-style-type: none"> • Electronic Data Capture (EDC) Systems • EDC system selection and validation • Wearable devices and sensors for data capture • RPM technologies and applications • Utilizing ePRO tools for patient data collection 	<p>The modules should prepare individuals to Participants learn to take responsibility for managing and integrating data from various sources, ensuring data quality, and making informed decisions. This aligns with</p>	<p>5</p>

	<ul style="list-style-type: none"> • Data integration challenges and solutions • Integrating Real-World Data (RWD) into CDM 	the responsibility associated with Level 5 roles.	
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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-0010: Advanced Data Capture Techniques in Clinical Data Management	Electronic Data Capture (EDC) Systems	13	7		
	PC 1 Ensure the ability to align EDC system selection and validation with evolving regulatory requirements, demonstrating compliance awareness and adaptability.				
	PC 2 Evaluate the efficiency in resolving data queries within the EDC system, emphasizing quick and accurate problem-solving skills.				
	PC 3 Identifying and implementing process improvements in EDC adoption and data management practices				
	PC 4 Demonstrating a proactive approach to enhancing efficiency and quality.				
	Mobile Health (mHealth) Data Collection	14	7		
	PC 5 Evaluate the advantages and limitations of using mHealth for clinical data collection.				
	PC 6 Assess the reliability and accuracy of data obtained through wearable devices and sensors.				
	PC 7 Analyze strategies for seamless integration of mHealth-generated data into existing Clinical Data Management (CDM) systems.				
	PC 8 Evaluate compliance with regulations and guidelines governing the ethical use of mHealth data in clinical research.				
PC 9 Create visualizations that effectively communicate trends and patterns derived from mHealth data.					
Remote Patient Monitoring (RPM)		13	6		
PC 10 Apply RPM technologies to monitor real patients in various healthcare scenarios.					

PC 11	Implement data security and privacy measures for RPM data, including encryption, access controls, and secure transmission protocols.				
PC 12	Analyze strategies for maintaining data consistency and accuracy when incorporating RPM data into clinical databases.				
PC 13	Implement strategies to ensure regulatory compliance with RPM data collection and storage practices.				
ePRO (Electronic Patient-Reported Outcomes)		14	7		
PC 14	Analyze the ability to utilize ePRO tools for collecting patient-reported data				
PC 15	Design patient-friendly ePRO questionnaires that adhere to best practices in usability and patient experience.				
PC 16	Evaluate procedures for handling ePRO data within the CDM process, including data entry, cleaning, and validation.				
PC 17	Implement quality assurance measures to ensure the integrity and reliability of ePRO data.				
Integrating Real-World Data (RWD) into CDM		13	6		
PC 18	Apply practical techniques to integrate and harmonize RWD with traditional clinical trial data within a CDM environment.				
PC 19	Implement strategies to ensure ethical compliance when working with RWD, including obtaining necessary permissions and ensuring data de-identification.				
PC 20	analyze the challenges associated with integrating diverse RWD sources into a unified database.				
Total Marks		67	33	-	-

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 Advanced Data Capture Techniques in 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 Pharmacopeia National Formulary (USP-41- NF-36)	As per Standards	1
5.	Internet Connection	As per Standards	1
6.	Indian Pharmacopeia 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

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	<input type="checkbox"/> Theory/ Lectures - Imparting theoretical and conceptual knowledge	LMS Portal- LSSSDC Daksh Portal will be utilized with online content/virtual lectures	60:40
2	<input type="checkbox"/> 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	<input type="checkbox"/> Showing Practical Demonstrations to the learners	LMS Portal- LSSSDC Daksh Portal will be utilized with online content/virtual lectures / Skill labs	100:00
4	<input type="checkbox"/> Imparting Practical Hands-on Skills/ Lab Work/ workshop/ shop floor training	Skill Labs	100:00
5	<input type="checkbox"/> Tutorials/ Assignments/ Drill/ Practice	LMS Portal- LSSSDC Daksh Portal will be utilized with online content/virtual lectures / Field Visits	50:50
6	<input type="checkbox"/> Proctored Monitoring/ Assessment/ Evaluation/ Examinations	Parakh	0:100
7	<input type="checkbox"/> 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.