

QUALIFICATION FILE – Micro Credentials

Life Sciences GMP: Computer System Validation - Lifecycle & Risk Assessment

☒ Public ☐ Private

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

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

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

1.	Micro Credential-Qualification Name	Life Sciences GMP: Computer System Validation - Lifecycle & Risk Assessment													
2.	Sector/s	Life Sciences													
3.	National Qualification Register (NQR) Code & Version	NM-5.5-LS-04432-2025-V2-LSSSDC	4. NCrF/NSQF Level: 5.5												
5.	Brief Description of the Micro Credential	The Computer System Validation (CSV) Lifecycle and Risk Assessment Program equips life sciences professionals with essential knowledge and practical skills to navigate the validation lifecycle using risk-based methodologies. Covering key stages like URS, FRS, DQ, IQ, OQ, and PQ, the program ensures compliance with FDA 21 CFR Part 11 and EU Annex 11. It emphasizes high-level risk assessments with tools like FMEA and Risk Assessment Matrices to enhance system integrity and validation outcomes. With hands-on training in validation planning, test execution, and risk assessment on systems like LIMS, participants gain practical expertise to master CSV processes effectively.													
6.	Eligibility Criteria for Entry for Students/Trainee/Learner/Employee	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>3 yr UG Degree</td><td>(with Subjects Biotechnology/ Life Sciences/Chemistry/Biology/ Computer Science related subjects)</td></tr><tr><td>2.</td><td>Pursuing 3rd Year of B. Pharma / B. Tech</td><td>Biotech/ Bio medical / Computer Science) and LSSSDC Certificate for Computer System Validation - Fundamentals</td></tr><tr><td>3.</td><td>Completed 2nd year of 2-year diploma after 12th</td><td>(In Pharmacy) with 1 year experience in Pharma Manufacturing Plant</td></tr></table> b. Age: Any		S. No.	Academic/Skill Qualification (with specialization- if applicable)	Relevant Experience (with specialization- if applicable)	1.	3 yr UG Degree	(with Subjects Biotechnology/ Life Sciences/Chemistry/Biology/ Computer Science related subjects)	2.	Pursuing 3rd Year of B. Pharma / B. Tech	Biotech/ Bio medical / Computer Science) and LSSSDC Certificate for Computer System Validation - Fundamentals	3.	Completed 2nd year of 2-year diploma after 12th	(In Pharmacy) with 1 year experience in Pharma Manufacturing Plant
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7.	Credits Assigned to this Qualification, Subject to Assessment (as per National Credit Framework (NCrF))	0.25	8. Common Cost Norm Category (I/II/III) (wherever applicable): I																										
9.	Any Licensing Requirements/ Pre-requisites for Undertaking Training (wherever applicable)	NA																											
10.	Expected Outcomes of the Micro Credential	Terminal learning outcomes are: - explain the significance of GAMP 5 standards and their application to system validation. - Categorize and apply the stages of the validation lifecycle in practical scenarios. - Identify, analyze, and mitigate risks using structured methodologies. - Develop validation and test plans that meet regulatory and industry best practices. - Prepare and evaluate Test Summary Reports to support CSV compliance and system acceptance. - Gain confidence in applying CSV concepts to real-world systems such as LIMS.																											
11.	Training Duration by Modes of Training Delivery (Specify Total Duration as per selected training delivery modes and as per requirement of the qualification)	☒ 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">07:30</td></tr><tr><td>Classroom</td><td>03:00</td><td>04:30</td></tr><tr><td colspan="3">OR</td></tr><tr><td>Blended Mode</td><td>03:00</td><td>04:30</td></tr><tr><td>Offline (As part of blended mode)</td><td>01:30</td><td>04:30</td></tr><tr><td>Online (As part of blended mode)</td><td>01:30</td><td>00:00</td></tr></table>					Training Delivery Mode	Theory (Hours)	Practical (Hours)	Total (Hours)	Offline Mode			07:30	Classroom	03:00	04:30	OR			Blended Mode	03:00	04:30	Offline (As part of blended mode)	01:30	04:30	Online (As part of blended mode)	01:30	00:00
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12.	Assessment Criteria	<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>					Theory (Marks)	Practical (Marks)	Project (Marks)	Viva (Marks)	Total (Marks)	Passing %age	50	50	-	-	100	70											
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13.	Is the Qualification Amenable to Persons with Disability	☐ Yes ☒ No If “Yes”, specify applicable type of Disability:	
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	☐ Yes ☒ No URLs of similar Qualifications:	
17.	Name and Contact Details Submitting / Awarding Body SPOC	Name: Mrs. Shivi Chaudhary Email: shivi.chaudhary@lsssd.in Website: https://www.lsssd.in/ Contact No.: + 91 11 41042407/ 408, +91 9315747189	
18.	NSQC Approval Date: 29 September 2025	19. Validity Duration:3 years	20. Next Review Date: 29 September 2028

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. / Btech (Life Sciences, Pharmacy, Biotechnology, Biomedical Engineering, Information Technology, or a related field)/ B. Pharma with 4 years Industry of experience in Computer System Validation and 2 years of training experience. OR Postgraduate in M.Sc. (Life Sciences, Pharmacy, Biotechnology, Biomedical Engineering, Information Technology, or a related field)/ M. Pharmacy with 4 years Industry of experience in Computer System Validation and 1 years of training experience. Certified for Micro credentials: “Life Sciences GMP: Computer System Validation - Lifecycle & Risk Assessment” mapped to MCr: “LFS/MCr-0021, v1.0” with minimum accepted score of 80%.
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		Recommended that the Trainer is certified for the Job Role: “Trainer (VET and SKILLS)”, mapped to the Qualification Pack: “MEP/Q2601 ver 3.0 ” with minimum score of 80%.
2.	Master Trainer’s Qualification and experience in relevant sector (in years) <i>(as per requirement and NCVET guidelines)</i>	Graduate in Sciences - B.Sc./ B.tech (Life Sciences, Pharmacy, Biotechnology, Biomedical Engineering, Information Technology, or a related field) with 6 years Industry of experience in Computer System Validation and 4 years of training experience. OR Postgraduate in Sciences -M.Sc. (Life Sciences, Pharmacy, Biotechnology, Biomedical Engineering, Information Technology, or a related field), M. Tech (Biotechnology), M. Pharmacy) with 5 years Industry of experience in Computer System Validation and 4 years of training experience. Certified for Micro credentials: “Life Sciences GMP: Computer System Validation - Lifecycle & Risk Assessment” mapped to MCr: “LFS/MCr-0021, 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 ver 3.0 ” with minimum score of 80%.
3.	Tools and Equipment Required for Training	☐ Yes ☒ No <i>(If “Yes”, details to be provided in Annexure)</i>

Section 3: Assessment Related

1.	Assessor’s Qualification and experience in relevant sector (in years) <i>(as per requirement and NCVET guidelines)</i>	Graduate in Sciences -B.Sc. (Life Sciences, Pharmacy, Biotechnology, Biomedical Engineering, Information Technology, or a related field), B. Pharmacy, B. Tech (Biotechnology)) with 4 years Industry of experience in Computer System Validation and 2 years of training experience. OR Postgraduate in Sciences (M.Sc. (Life Sciences, Pharmacy, Biotechnology, Biomedical Engineering, Information Technology, or a related field) / M. Pharmacy with 4 years Industry of experience in Computer System Validation and 1 years of training experience.
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		Certified for Micro credentials: “Life Sciences GMP: Computer System Validation - Lifecycle & Risk Assessment” mapped to MCr: “LFS/MCr-0021, 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 Micro credentials: “MEP/Q2701 ver 3.0” with minimum score of 80%.
2.	Proctor’s Qualification and experience in relevant sector (in years) <i>(as per requirement and NCVET guidelines)</i>	Graduate in Sciences -B.Sc. (Life Sciences, Pharmacy, Biotechnology, Biomedical Engineering, Information Technology, or a related field), B. Pharmacy, B. Tech (Biotechnology)) with 4 years Industry of experience in Computer System Validation and 2 years of training experience. OR Postgraduate in Sciences (M.Sc. (Life Sciences, Pharmacy, Biotechnology, Biomedical Engineering, Information Technology, or a related field) / M. Pharmacy with 4 years Industry of experience in Computer System Validation and 1 years of training experience. Certified for Micro credentials: “Life Sciences GMP: Computer System Validation - Lifecycle & Risk Assessment” mapped to MCr: “LFS/MCr-0021, v1.0” with minimum accepted score of 80%.
3.	Lead Assessor’s/Proctor’s Qualification and experience in relevant sector (in years) <i>(as per requirement and NCVET guidelines)</i>	Graduate in Sciences (B.Sc. (Life Sciences, Pharmacy, Biotechnology, Biomedical Engineering, Information Technology, or a related field), B. Pharmacy, B. Tech (Biotechnology) with 6 years Industry of experience in Computer System Validation and 4 years of training experience. OR Postgraduate in Sciences (M.Sc. (Life Sciences, Pharmacy, Biotechnology, Biomedical Engineering, Information Technology, or a related field), M. Tech (Biotechnology), M. Pharmacy) with 5 years Industry of experience in Computer System Validation and 4 years of training experience.

		Certified for Micro credentials: “Life Sciences GMP: Computer System Validation - Lifecycle & Risk Assessment” mapped to MCr: “LFS/MCr-0021, 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 Micro credentials: “MEP/Q2702 ver 3.0” with minimum score of 80%.
4.	Assessment Mode (<i>Specify the assessment mode</i>)	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): NO
2.	Number of Industry validation provided: 20
3.	Estimated number of people to be trained: 1500

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	• Introduction to GAMP 5 and Documentation Standards • Master Validation Lifecycle Stages • Risk Assessment and Mitigation • Validation Plan and Test Plan Development • Test Summary Reporting and Documentation	The qualification builds advanced conceptual knowledge of the CSV lifecycle, integrating regulatory requirements from GAMP 5 and 21 CFR Part 11. Learners understand structured processes such as URS to PQ, and risk assessment frameworks like FMEA. This aligns with NSQF Level 5.5, where specialized theoretical knowledge is required for interdisciplinary application, especially in documentation-heavy compliance environments like pharma, biotech, and med-tech.	5.5
Professional and Technical Skills/ Expertise/ Professional Knowledge	• Introduction to GAMP 5 and Documentation Standards • Master Validation Lifecycle Stages • Risk Assessment and Mitigation • Validation Plan and Test Plan Development • Test Summary Reporting and Documentation	Aligned with NSQF 5.5, this Micro credential equips learners with technical proficiency in preparing validation and test documentation, conducting risk assessments, and supporting compliance in simulated environments. The application of FMEA, preparation of validation/test plans, and execution of summary reporting reflect advanced cognitive and applied skills. These activities meet the level descriptor of executing specialized tasks with analytical reasoning and adherence to industry standards.	5.5
Employment Readiness & Entrepreneurship Skills & Mind-set/Professional Skill	• Introduction to GAMP 5 and Documentation Standards • Master Validation Lifecycle Stages • Risk Assessment and Mitigation • Validation Plan and Test Plan Development	The program fosters job readiness by enabling learners to contribute to CSV documentation, risk management, and regulatory compliance. They develop structured thinking, accountability, and attention to detail—key for functioning in QA, validation, or compliance roles. The credential supports independent contribution in a guided	5.5

	• Test Summary Reporting and Documentation	environment and is consistent with NSQF 5.5, which expects learners to operate with initiative and responsibility in specialized tasks or emerging technical domains.	
Broad Learning Outcomes/Core Skill	• Introduction to GAMP 5 and Documentation Standards • Master Validation Lifecycle Stages • Risk Assessment and Mitigation • Validation Plan and Test Plan Development • Test Summary Reporting and Documentation	This micro-credential develops analytical, digital, and communication skills through structured validation tasks. Learners synthesize CSV lifecycle concepts into practical documentation (URS, test plans, risk reports), fostering strong core competencies. They communicate compliance gaps, collaborate effectively in simulated teams, and adapt documentation practices to regulatory demands. These outcomes align with NSQF 5.5 by promoting interdisciplinary learning and advanced core skills in a defined technical setting.	5.5
Responsibility	• Introduction to GAMP 5 and Documentation Standards • Master Validation Lifecycle Stages • Risk Assessment and Mitigation • Validation Plan and Test Plan Development • Test Summary Reporting and Documentation	Learners are prepared to take structured responsibility in documentation, validation, and compliance activities within the CSV lifecycle. Under guided supervision, they assist in preparing test plans, conducting risk assessments, and generating traceable reports. Their role involves evidence-based decision-making and risk mitigation aligned to regulatory norms. This fits NSQF Level 5.5's expectation of partial independence, accountability in specialized tasks, and contribution to project-based workstreams in compliance-driven industries.	5.5

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
LFS/MCr-0021: Life Sciences GMP: Computer System Validation - Lifecycle & Risk Assessment	CSV Lifecycle and Risk Assessment	50	50		
	PC 1 Illustrate the required documentation under GAMP 5 is complete and compliant with regulatory standards.				
	PC 2 Categorize and describe the stages of the validation lifecycle, emphasizing their purpose and regulatory importance.				
	PC 3 Recall the roles of User Requirements Specification (URS), Functional Requirements Specification (FRS), and Design Qualification (DQ) in validation planning.				
	PC 4 Interpret the significance of Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) in ensuring system compliance.				
	PC 5 Demonstrate the stepwise method to conduct a high-level risk assessment effectively.				
	PC 6 Calculate risk severity, occurrence, and detectability using the Failure Modes and Effects Analysis (FMEA) methodology.				
	PC 7 Record risk assessment outcomes and propose actionable corrective measures to address identified risks.				
	PC 8 Identify the components of validation and test plans, ensuring they meet industry best practices and regulatory requirements.				
	PC 9 Develop a validation plan that includes scope, objectives, responsibilities, and acceptance criteria for compliance.				
	PC 10 Prepare detailed test plans featuring test cases, acceptance criteria, and execution procedures, aligned with CSV (Computer System Validation) objectives.				
	PC 11 Prepare and ensure completeness of Test Summary Reports, highlighting their role in system validation and acceptance.				
	PC 12 Analyze simulated systems (e.g., LIMS) to identify compliance risks and propose optimized risk mitigation strategies.				
	PC 13 Prepare detailed and accurate Test Summary Reports to support validation processes, ensuring documentation clarity for continuous improvement.				
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/ 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 Life Sciences GMP: Computer System Validation - Lifecycle & Risk 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 Computer System Validation 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.	CO2 Fire Extinguisher	As per standards	2
2.	Computer workstation along with LAN	As per standards	30

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.	Auriga Research Private Limited	Dr. Neha S. Arora	Director	3/17, Kirti Nagar Industrial Area, New Delhi-15, India	8800330033	Neha@arbropharma.com, Neha@aurigaresearch.com	
2.	MSN Laboratories Pvt. Ltd	Vajjah Praveen Kumar	Lead Technical Treaning	MSN Corporate, H.No. 2-91/10 & 11/MSN, White fields, Kondapur, Telangana, 500084	9154395569	praveen.vajjah@msnlab.com	
3.	Beta Drug Limited	Sarita	Deputy Manager. HR	Kharuni Lodhimajra Road, Village: Nandpur, Tehsil: Baddi. Distt. Solan (H.P)	9625840405	sarita@betadrugslimited.com	
4.	Arbro Pharmaceuticals Private Limited	Dr. Neha S. Arora	Director	6/14 Block 6, kirti Nagar Industrial Area, Kirti Nagar, New Delhi, Delhi, 11015	8800330033	Neha@arbropharma.com, Neha@aurigaresearch.com	
5.	Bio-Med private Ltd.	Divyanshu Sirohi	QA Manager	C-96&98, Bulandsheher Road Industrial Area Ghaziabad- 201009	7503804891	divyanshu988@gmail.com	
6.	Tirupati Lifescience Limited	Jagdish Chauhan	Manager HRD	Nahan Road, Ponta Sahib, Distt Sirmour (H.P)	9816633372	jagdish.chauhan@tirupatiwellness.in	
7.	Tirupati Medicare Limited	Jagdish Chauhan	Manager HRD	Nahan Road, Ponta Sahib, Distt Sirmour (H.P)	9816633372	jagdish.chauhan@tirupatiwellness.in	
8.	Tirupati Wellness Limited	Jagdish Chauhan	Manager HRD	Nahan Road, Ponta Sahib, Distt Sirmour (H.P)	9816633372	jagdish.chauhan@tirupatiwellness.in	
9.	Venus Remedies Ltd.	Arunava Pal	Assistant General Manager (Skill Development Department)	Head Office: Plot No. 51-52, Industrial Area, Phase-1, PANCHKULA	90735-02801	skilldev_hod@venusremedies.com	

10.	Dr. Reddys Laboratories Ltd.	Y Nagender	Technical Capabilities Expert	8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana, India 500034	98449282791	nagendery@srreddys.com	
11.	INTAS Pharmaceuticals Ltd.	Amit Kanabar	Sr. Manager, Head- Intas Center f Excellence	Plot No. 457, 458 Sarkhej Bavla Highway, Matoda Village, Sanand, Taluka, Ahmedabad, Gujarat 382210	8141841287	Amit_Kanabar@intaspharma.com	
12.	Emcure Pharmaceuticals Limited	Rajesh Nair	President HR	Plot No. P-1 & P-2, IT-BT Park, Phase-II, MIDC, Hinjawadi, Pune- 411057 Maharashtra	9373314937	Prakash.Khandare@emcure.com	
13.	BLUE CROSS LABORATORIES PVT LTD.	ASHOK KUMAR GUPTA	TECHNICAL DIRECTOR	A-12, AMBAD INDUSTRIAL AREA, NASHIK Regd Office: Peninsula Chambers, Peninsula Corporate Park, G.K Marg, Lower Parel (West)Mumbai - 400013, Maharashtra, INDIA	9167244064	ashok.g@bluecrosslabs.com	
14.	MAJUSHREE TECHNOPACK LIMITED	KISHORE	HR MANAGER	Near fire station, Vadlapudi village, Kurmannapalem, Visakhapatnam, Andhra Pradesh 530046.	9581199200	Kishore.karrimanjushreindia.com	
15.	CMS Laboratories India Private Limited	Guntuku Jagadeeswara Rao	Managing Director	47-10-50, Dwaraka Nagar, 4th Lane, 3rd Floor, Above Union Bank, Visakhapatnam-530016	8919168131	jdguntuku@gmail.com	
16.	Synaptics Labs Pvt Ltd	M BHARATH	SENIOR MANAGER	Plot No:28-B,APIIC, Lalamkoduru Vill, Rambill(MD),Visakhapatnam,Andhra Pradesh-531011	7569279497	hr@synapticslabs.com	
17.	VLR FACILITATORS PRIVATE LIMITED	JAYASHREE	HR	Hoty Child School, near dundigal police station, Gandhi Maisamma, Hyderabad, Telangana 500043.	8247212205	jayashreem@gmail.com	

18.	Smruthi Organics	Kamlakar Gajjam	Assistant General Manager (HR)	Plot No. A-27, MIDC, Chincholi District Solapur 413255 Maharashtra, India	7083225457	kdg@smruthiorganics.com	
19.	Hetero Labs Limited	Dr. Shubhadeep Debabrata Sinha	Senior Vice-President	7-A-2, Industrial area, Sanathnagar, Hyderabad 500018	9393922434	SD.Sinha@hetero.com	
20.	Zydus Lifesciences Limited	Harsh Raj purohit	Deputy Manager	Zydus corporate park , Ahemdabad	7041309081	harsh.rajpurohit@zyduslife.com	

Annexure: Training Details

Training Projections:

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

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	☐ Showing Practical Demonstrations to the learners	Skill labs	100:00
3	☐ Imparting Practical Hands-on Skills/ Lab Work/ workshop/ shop floor training	Skill Labs	100:00

4	☐ Proctored Monitoring/ Assessment/ Evaluation/ Examinations	Online Assessments / Parakh	0:100
5	☐ 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.