QUALIFICATION FILE – Micro Credentials

Life Sciences GMP: Investigative Steps and Analytical Tools for Deviation

☒ 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

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Section 1: Basic Details

<table>
<tr><td>1.</td><td>Micro Credential-Qualification Name</td><td colspan="3">Life Sciences GMP: Investigative Steps and Analytical Tools for Deviation</td></tr>
<tr><td>2.</td><td>Sector/s</td><td colspan="3">Life Sciences</td></tr>
<tr><td>3.</td><td>National Qualification Register (NQR) Code & Version</td><td colspan="3">NM-5.5-LS-04437-2025-V2-LSSSDC | 4. NCrF/NSQF Level: 5.5</td></tr>
<tr><td>5.</td><td>Brief Description of the Micro Credential</td><td colspan="3">The Investigative Steps and Analytical Tools for Deviation Program equips life sciences professionals with necessary tools and methodologies to effectively investigate deviations in pharmaceutical manufacturing processes. Through understanding the structured approach to deviation investigation and applying key analytical tools such as 5 Whys, Fishbone Diagram, and Failure Mode and Effects Analysis (FMEA), learners will gain the ability to identify root causes, mitigate risks, and improve processes.</td></tr>
<tr><td>6.</td><td>Eligibility Criteria for Entry for Students/Trainee/Learner/Employee</td><td colspan="3">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 3rd Year of UG (B. Pharma / B. Tech</td><td>(Biotech/ Bio medical / Computer Science) and Certificate for deviation investigation and regulatory requirements)</td></tr>
<tr><td>2.</td><td>3 yr UG Degree</td><td>(with Subjects Biotechnology/ Life Sciences/ Chemistry/ Biology/ Computer Science related subjects)</td></tr>
<tr><td>3.</td><td>Completed 2nd year of 2-year diploma after 12th (In Pharmacy)</td><td>with 1 year experience in Pharma Manufacturing Plant</td></tr>
</table>
b. Age: – As per the Government Norms</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 colspan="2">8. Common Cost Norm Category (I/II/III) (wherever applicable): I</td></tr>
</table>

<table>
<tr><td>9.</td><td>Any Licensing Requirements/ Pre-requisites for Undertaking Training (wherever applicable)</td><td>NA</td></tr>
<tr><td>10.</td><td>Expected Outcomes of the Micro Credential</td><td>Terminal learning outcomes are:
Demonstrate a comprehensive understanding of deviation investigation methodologies including root cause analysis, impact assessment, and risk management techniques.
Apply investigative tools such as 5 Whys, Fishbone Diagram, and FMEA to analyze deviations, identify root causes, and recommend corrective and preventive actions.
Create and execute a structured deviation investigation plan in response to real-world case studies, ensuring regulatory compliance and continuous improvement.
Demonstrate effective communication and interview techniques to gather data and insights during an investigation, ensuring accurate reporting and documentation.
Propose strategies for immediate containment and long-term corrective actions based on investigation findings, ensuring that deviations are properly managed and risk is minimized.</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>06:00</td><td>09:00</td></tr>
<tr><td colspan="3">OR</td></tr>
<tr><td>Blended Mode</td><td>06:00</td><td>09:00</td></tr>
<tr><td>Offline (As part of blended mode)</td><td>03:00</td><td>09:00</td></tr>
<tr><td>Online (As part of blended mode)</td><td>03:00</td><td>09:00</td></tr>
</table></td></tr>
</table>

<table>
<tr><td>12.</td><td>Assessment Criteria</td><td colspan="2"><table><tr><th>Theory (Marks)</th><th>Practical (Marks)</th><th>Project (Marks)</th><th>Viva (Marks)</th><th>Total (Marks)</th><th>Passing %age</th></tr><tr><td>50</td><td>50</td><td>-</td><td>-</td><td>100</td><td>70</td></tr></table></td></tr>
<tr><td>13.</td><td>Is the Qualification Amenable to Persons with Disability</td><td colspan="2">☐ Yes ☒ No If “Yes”, specify applicable type of Disability:</td></tr>
<tr><td>14.</td><td>How participation of women will be encouraged?</td><td colspan="2">This micro credential is gender agnostic, and all genders will be encouraged to take this training. LSSSDC is working with industry to launch the program in diversity and inclusion initiative</td></tr>
<tr><td>15.</td><td>Other Indian Languages in which the Micro Credential will be implemented.</td><td colspan="2">English and Hindi</td></tr>
<tr><td>16.</td><td>Is similar Micro Credential Qualification(s) available on NQR-if yes, justification for this qualification</td><td colspan="2">☐ Yes ☒ No URLs of similar Qualifications:</td></tr>
<tr><td>17.</td><td>Name and Contact Details Submitting / Awarding Body SPOC</td><td colspan="2">Name: Mrs. Shivi Chaudhary
Email: shivi.chaudhary@lsssdc.in Contact No.: + 91 11 41042407/ 408, +91 9315747189
Website: https://www.lsssdc.in/</td></tr>
<tr><td>18.</td><td>NSQC Approval Date: 1 November 2023</td><td>19. Validity Duration:3 years</td><td>20. Next Review Date: 1 November 2026</td></tr>
</table>

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. / B. Tech (Life Sciences, Pharmacy, Biotechnology, Biomedical Engineering, Information Technology, or a related field)/ B. Pharma with 4 years Industry of experience in Good Manufacturing Practices (GMP) Compliance 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 Good Manufacturing Practices (GMP) Compliance and 1 years of training experience. Certified for Micro credentials: "Life Sciences GMP: Investigative Steps and Analytical Tools for Deviation" mapped to MCr: "LFS/MCr-0025, 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 3.0 " 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./ B. Tech (Life Sciences, Pharmacy, Biotechnology, Biomedical Engineering, Information Technology, or a related field) with 6 years Industry of experience in Good Manufacturing Practices (GMP) Compliance 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 Good Manufacturing Practices (GMP) Compliance and 4 years of training experience. Certified for Micro credentials: "Life Sciences GMP: Investigative Steps and Analytical Tools for Deviation" mapped to MCr: "LFS/MCr-0025, 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 3.0 " 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. (Life Sciences, Pharmacy, Biotechnology, Biomedical Engineering, Information Technology, or a related field), B. Pharmacy, B. Tech (Biotechnology) with 4 years Industry of experience in Good Manufacturing Practices (GMP) Compliance 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 Good Manufacturing Practices (GMP) Compliance and 1 years of training experience. Certified for Micro credentials: "Life Sciences GMP: Investigative Steps and Analytical Tools for Deviation" mapped to MCr: "LFS/MCr-0025, 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 3.0" 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. (Life Sciences, Pharmacy, Biotechnology, Biomedical Engineering, Information Technology, or a related field), B. Pharmacy, B. Tech (Biotechnology) with 4 years Industry of experience in Good Manufacturing Practices (GMP) Compliance 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 Good Manufacturing Practices (GMP) Compliance and 1 years of training experience. Certified for Micro credentials: "Life Sciences GMP: Investigative Steps and Analytical Tools for Deviation" mapped to MCr: "LFS/MCr-0025, 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. (Life Sciences, Pharmacy, Biotechnology, Biomedical Engineering, Information Technology, or a related field), B. Pharmacy, B. Tech (Biotechnology)) with 6 years Industry of experience in Good Manufacturing Practices (GMP) Compliance 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 Good Manufacturing Practices (GMP) Compliance and 4 years of training experience. Certified for Micro credentials: "Life Sciences GMP: Investigative Steps and Analytical Tools for Deviation" mapped to MCr: "LFS/MCr-0025, 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 3.0" 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): 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 *(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	• Understand deviation investigation processes and root cause analysis principles. • Apply RCA tools such as 5 Whys and Fishbone diagrams to identify causes of deviations. • Assess risks and impacts using FMEA and containment strategies. • Plan and conduct deviation investigations using structured methods and case studies. • Document findings and implement CAPA to prevent recurrence of deviations.	At NSQF Level 5.5, individuals demonstrate advanced theoretical knowledge of deviation investigation processes and analytical tools. They interpret regulatory requirements, apply structured frameworks like RCA, and design containment strategies. This level emphasizes understanding complex quality systems and integrating compliance principles into decision-making. Learners move beyond basic comprehension to synthesize and apply theoretical concepts in real-world deviation management, ensuring alignment with organizational goals, product quality standards, and safety requirements through systematic and documented investigative processes.	5.5
Professional and Technical Skills/ Expertise/ Professional Knowledge	• Understand deviation investigation processes and root cause analysis principles. • Apply RCA tools such as 5 Whys and Fishbone diagrams to identify causes of deviations. • Assess risks and impacts using FMEA and containment strategies.	The role at NSQF Level 5.5 demands proficiency in specialized tools like 5 Whys, Fishbone Diagrams, and FMEA for in-depth deviation investigations. Individuals apply technical expertise to identify root causes, evaluate risks, and develop robust CAPA strategies. This level reflects the ability to execute, lead, and monitor investigations, ensuring adherence to compliance frameworks. Skills include conducting simulations, leveraging digital reporting systems, and driving continuous improvement initiatives,	5.5

	• Plan and conduct deviation investigations using structured methods and case studies. • Document findings and implement CAPA to prevent recurrence of deviations.	positioning the learner as a competent technical resource for quality management teams.	
Employment Readiness & Entrepreneurship Skills & Mind-set/Professional Skill	• Understand deviation investigation processes and root cause analysis principles. • Apply RCA tools such as 5 Whys and Fishbone diagrams to identify causes of deviations. • Assess risks and impacts using FMEA and containment strategies. • Plan and conduct deviation investigations using structured methods and case studies. • Document findings and implement CAPA to prevent recurrence of deviations.	At NSQF Level 5.5, learners develop strong communication, leadership, and ethical decision-making skills essential for professional growth. They cultivate a compliance-oriented mindset while fostering accountability and innovation in quality improvement processes. These skills ensure employment readiness in regulated industries and encourage entrepreneurial thinking for developing innovative solutions to recurring deviations. By managing investigations effectively and leading CAPA initiatives, individuals contribute to operational excellence, team performance, and organizational growth while preparing for higher leadership or independent roles.	5.5
Broad Learning Outcomes/Core Skill	• Understand deviation investigation processes and root cause analysis principles. • Apply RCA tools such as 5 Whys and Fishbone diagrams to identify causes of deviations. • Assess risks and impacts using FMEA and containment strategies.	Broad learning outcomes at NSQF Level 5.5 include the ability to systematically investigate and resolve deviations using analytical reasoning and problem-solving tools. Individuals collaborate across teams to analyze data, identify patterns, and implement preventive actions. Skills like digital documentation, compliance tracking, and effective reporting are integrated into daily practices. This level emphasizes not only solving existing deviations but also preventing recurrence, driving quality improvements, and	5.5

	• Plan and conduct deviation investigations using structured methods and case studies. • Document findings and implement CAPA to prevent recurrence of deviations.	promoting a culture of transparency, accountability, and continuous enhancement in organizational processes.	
Responsibility	• Understand deviation investigation processes and root cause analysis principles. • Apply RCA tools such as 5 Whys and Fishbone diagrams to identify causes of deviations. • Assess risks and impacts using FMEA and containment strategies. • Plan and conduct deviation investigations using structured methods and case studies. • Document findings and implement CAPA to prevent recurrence of deviations.	At NSQF Level 5.5, individuals hold independent responsibility for managing deviation investigations from initiation to resolution. They are accountable for regulatory compliance, documentation accuracy, and the effective implementation of CAPA measures. This includes leading investigation teams, mentoring junior staff, and making informed decisions that impact product quality and patient safety. Their role requires strategic thinking and proactive risk management, reflecting a higher level of trust and autonomy in ensuring organizational quality standards and driving sustainable operational improvements.	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
	Investigative Steps and Analytical Tools	50	50		

LFS/MCr-0025: Life Sciences GMP: Investigative Steps and Analytical Tools for Deviation	PC 1 Demonstrate understanding of the structured approach to deviation investigation by outlining the key steps involved.				
	PC 2 Identify and describe the principles and methodologies of root cause analysis in a deviation scenario.				
	PC 3 Apply the 5 Whys technique effectively to identify the root cause of a deviation in a simulated case study.				
	PC 4 Create a Fishbone Diagram (Ishikawa) for a deviation scenario to illustrate possible causes and effects.				
	PC 5 Perform Failure Mode and Effects Analysis (FMEA) to assess risk and identify areas for improvement in a given deviation case study.				
	PC 6 Demonstrate effective use of immediate containment strategies and impact assessment to manage a deviation's consequences.				
	PC 7 Develop a detailed investigation plan, including timelines, resources, and methods for resolving deviations in a case study.				
	PC 8 Conduct a simulated deviation investigation roleplay, applying investigative tools such as 5 Whys, Fishbone, and FMEA to assess the deviation.				
	PC 9 Use roleplay scenarios to demonstrate interview techniques for gathering information during a deviation investigation.				
	PC 10 Identify and document the corrective and preventive actions (CAPA) necessary to prevent recurrence of a deviation in a simulated investigation.				
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: Investigative Steps and Analytical Tools for Deviation 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 Pharma Manufacturing Plant industry.
- 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@msnlabs.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	Plot No. 457, 458 Sarkhej Bavla Highway, Matoda Village,	8141841287	Amit_Kanabar@intaspharma.com	

			Center f Excellence	Sanand, Taluka, Ahmedabad, Gujarat 382210			
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.karrimanjushreeindia.com	
15.	CMS Laboratories India Private Limted	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, Gandi Maisamma, Hyderabad, Telangana 500043.	8247212205	jayashreem@gmail.com	
18.	Smruthi Organics	Kamlakar Gajjam	Assistant General	Plot No. A-27, MIDC, Chincholi District Solapur413255 Maharashtra, India	7083225457	kdg@smruthiorganics.com	

			Manager (HR)				
19.	Hetero Labs Limited	Dr. Shubhadeep Debabrata Sinha	Senior Vice-President	7-A-2, Insustrial area, Sanathnagar, Hyderabad 500018	9393922434	SD.Sinha@hetero.com	
20.	Zydus Lifesciences Limited	Harsh Raj purohit	Deputy Manager	Zydus corporate park , Ahmedabad	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	100	-
2 Year	500	200	-
3 Year	500	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	☐ 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.