

## QUALIFICATION FILE – Standalone NOS

### Human Error Reduction (Behavioral GMP)

☒ Horizontal/Generic ☐ Vertical/Specialization

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

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

NCrF/NSQF Level: 5.5

Submitted By:

Life Sciences Sector Skill Development Council

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## Section 1: Basic Details

| 1.     | <b>NOS-Qualification Name</b>                                                                                                                                                                                             | <b>Human Error Reduction (Behavioral GMP)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                |        |                                                                    |                                                           |    |                                                                                                                                                                                                                           |  |
|--------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|--------|--------------------------------------------------------------------|-----------------------------------------------------------|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| 2.     | <b>Sector/s</b>                                                                                                                                                                                                           | <b>Life Sciences</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                |        |                                                                    |                                                           |    |                                                                                                                                                                                                                           |  |
| 3.     | <b>Type of Qualification</b> <input checked="" type="checkbox"/> New <input type="checkbox"/> Revised                                                                                                                     | <b>NQR Code &amp; version of the existing /previous qualification: NA</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Qualification Name of the existing/previous version: NA</b> |        |                                                                    |                                                           |    |                                                                                                                                                                                                                           |  |
| 4.     | <b>National Qualification Register (NQR) Code &amp; Version</b>                                                                                                                                                           | <b>NG-5.5-LS-04429-2025-V2-LSSSDC</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>5. NCrF/NSQF Level:5.5</b>                                  |        |                                                                    |                                                           |    |                                                                                                                                                                                                                           |  |
| 6.     | <b>Brief Description of the Standalone NOS</b>                                                                                                                                                                            | This NOS program equips individuals in pharmaceutical manufacturing with the skills to understand, investigate, prevent, and reduce human errors. It covers key aspects of human behaviour, error investigation techniques, and prevention tools such as Root Cause Analysis, Fishbone Diagrams, Poka-Yoke, and SOPs. The program emphasizes leadership, organizational culture, and continuous monitoring for creating a sustainable error-free environment. Through practical exercises and case studies, participants will gain hands-on experience in mitigating errors, improving product quality, safety, and efficiency. |                                                                |        |                                                                    |                                                           |    |                                                                                                                                                                                                                           |  |
| 7.     | <b>Eligibility Criteria for Entry for a Student/Trainee/Learner/Employee</b>                                                                                                                                              | <b>a. Entry Qualification &amp; Relevant Experience:</b> <table border="1"> <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>B. Tech (in relevant field)/B. Pharma with 2 Years experience (Quality Assurance/Quality Control/production)<br/>Or<br/>M. Sc (in relevant subjects) with 2 Years experience (Quality Assurance/Quality Control/production)</td> <td></td> </tr> </tbody> </table>                                                          |                                                                | S. No. | Academic/Skill Qualification (with Specialization - if applicable) | Relevant Experience (with Specialization - if applicable) | 1. | B. Tech (in relevant field)/B. Pharma with 2 Years experience (Quality Assurance/Quality Control/production)<br>Or<br>M. Sc (in relevant subjects) with 2 Years experience (Quality Assurance/Quality Control/production) |  |
| S. No. | Academic/Skill Qualification (with Specialization - if applicable)                                                                                                                                                        | Relevant Experience (with Specialization - if applicable)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                |        |                                                                    |                                                           |    |                                                                                                                                                                                                                           |  |
| 1.     | B. Tech (in relevant field)/B. Pharma with 2 Years experience (Quality Assurance/Quality Control/production)<br>Or<br>M. Sc (in relevant subjects) with 2 Years experience (Quality Assurance/Quality Control/production) |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                |        |                                                                    |                                                           |    |                                                                                                                                                                                                                           |  |

|                                   |                                                                                                                                                                            | <b>b. Age :</b> As per Government Norms                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |               |               |                                                                            |  |  |                        |                   |                   |               |                     |              |    |       |           |       |       |    |  |  |  |                     |       |       |                                   |       |       |                                  |       |       |  |
|-----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|---------------|----------------------------------------------------------------------------|--|--|------------------------|-------------------|-------------------|---------------|---------------------|--------------|----|-------|-----------|-------|-------|----|--|--|--|---------------------|-------|-------|-----------------------------------|-------|-------|----------------------------------|-------|-------|--|
| <b>8.</b>                         | <b>Credits Assigned to this NOS-Qualification, Subject to Assessment</b><br>(as per National Credit Framework (NCrF))                                                      | 1.5                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |               |               | <b>9. Common Cost Norm Category (I/II/III)</b><br>(wherever applicable):II |  |  |                        |                   |                   |               |                     |              |    |       |           |       |       |    |  |  |  |                     |       |       |                                   |       |       |                                  |       |       |  |
| <b>10.</b>                        | <b>Any Licensing Requirements for Undertaking Training on This Qualification</b> (wherever applicable)                                                                     | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |               |               |                                                                            |  |  |                        |                   |                   |               |                     |              |    |       |           |       |       |    |  |  |  |                     |       |       |                                   |       |       |                                  |       |       |  |
| <b>11.</b>                        | <b>Training Duration by Modes of Training Delivery</b> (Specify <b>Total Duration</b> as per selected training delivery modes and as per requirement of the qualification) | <input checked="" type="checkbox"/> Offline Only <input type="checkbox"/> Online Only <input checked="" type="checkbox"/> Blended<br><table border="1"> <thead> <tr> <th>Training Delivery Mode</th><th>Theory (Hours)</th><th>Practical (Hours)</th><th>Total (Hours)</th></tr> </thead> <tbody> <tr> <td><b>Offline Mode</b></td><td></td><td></td><td rowspan="5">45:00</td></tr> <tr> <td>Classroom</td><td>20:00</td><td>25:00</td></tr> <tr> <td colspan="4">OR</td></tr> <tr> <td><b>Blended Mode</b></td><td>20:00</td><td>25:00</td></tr> <tr> <td>Offline (As part of blended mode)</td><td>10:00</td><td>30:00</td></tr> <tr> <td>Online (As part of blended mode)</td><td>10:00</td><td>00:00</td><td></td></tr> </tbody> </table> |               |               |                                                                            |  |  | Training Delivery Mode | Theory (Hours)    | Practical (Hours) | Total (Hours) | <b>Offline Mode</b> |              |    | 45:00 | Classroom | 20:00 | 25:00 | OR |  |  |  | <b>Blended Mode</b> | 20:00 | 25:00 | Offline (As part of blended mode) | 10:00 | 30:00 | Online (As part of blended mode) | 10:00 | 00:00 |  |
| Training Delivery Mode            | Theory (Hours)                                                                                                                                                             | Practical (Hours)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Total (Hours) |               |                                                                            |  |  |                        |                   |                   |               |                     |              |    |       |           |       |       |    |  |  |  |                     |       |       |                                   |       |       |                                  |       |       |  |
| <b>Offline Mode</b>               |                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 45:00         |               |                                                                            |  |  |                        |                   |                   |               |                     |              |    |       |           |       |       |    |  |  |  |                     |       |       |                                   |       |       |                                  |       |       |  |
| Classroom                         | 20:00                                                                                                                                                                      | 25:00                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |               |               |                                                                            |  |  |                        |                   |                   |               |                     |              |    |       |           |       |       |    |  |  |  |                     |       |       |                                   |       |       |                                  |       |       |  |
| OR                                |                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |               |               |                                                                            |  |  |                        |                   |                   |               |                     |              |    |       |           |       |       |    |  |  |  |                     |       |       |                                   |       |       |                                  |       |       |  |
| <b>Blended Mode</b>               | 20:00                                                                                                                                                                      | 25:00                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |               |               |                                                                            |  |  |                        |                   |                   |               |                     |              |    |       |           |       |       |    |  |  |  |                     |       |       |                                   |       |       |                                  |       |       |  |
| Offline (As part of blended mode) | 10:00                                                                                                                                                                      | 30:00                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |               |               |                                                                            |  |  |                        |                   |                   |               |                     |              |    |       |           |       |       |    |  |  |  |                     |       |       |                                   |       |       |                                  |       |       |  |
| Online (As part of blended mode)  | 10:00                                                                                                                                                                      | 00:00                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |               |               |                                                                            |  |  |                        |                   |                   |               |                     |              |    |       |           |       |       |    |  |  |  |                     |       |       |                                   |       |       |                                  |       |       |  |
| <b>12.</b>                        | <b>Assessment Criteria</b>                                                                                                                                                 | <table border="1"> <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>50</td><td>50</td><td></td><td></td><td>100</td><td>70</td></tr> </tbody> </table>                                                                                                                                                                                                                                                                                                                                                                                                                                                    |               |               |                                                                            |  |  | Theory (Marks)         | Practical (Marks) | Project (Marks)   | Viva (Marks)  | Total (Marks)       | Passing %age | 50 | 50    |           |       | 100   | 70 |  |  |  |                     |       |       |                                   |       |       |                                  |       |       |  |
| Theory (Marks)                    | Practical (Marks)                                                                                                                                                          | Project (Marks)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Viva (Marks)  | Total (Marks) | Passing %age                                                               |  |  |                        |                   |                   |               |                     |              |    |       |           |       |       |    |  |  |  |                     |       |       |                                   |       |       |                                  |       |       |  |
| 50                                | 50                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |               | 100           | 70                                                                         |  |  |                        |                   |                   |               |                     |              |    |       |           |       |       |    |  |  |  |                     |       |       |                                   |       |       |                                  |       |       |  |
| <b>13.</b>                        | <b>Is the NOS Amenable to Persons with Disability</b>                                                                                                                      | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If “Yes”, specify applicable type of Disability:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |               |               |                                                                            |  |  |                        |                   |                   |               |                     |              |    |       |           |       |       |    |  |  |  |                     |       |       |                                   |       |       |                                  |       |       |  |
| <b>14.</b>                        | <b>Progression Path After Attaining the Qualification, wherever applicable</b> (Please show Professional and Academic progression)                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |               |               |                                                                            |  |  |                        |                   |                   |               |                     |              |    |       |           |       |       |    |  |  |  |                     |       |       |                                   |       |       |                                  |       |       |  |

|     |                                                                                                                                            |                                                                                                                                                                                                 |                                                |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| 15. | <b>How participation of women will be encouraged?</b>                                                                                      | 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 |                                                |
| 16. | <b>Other Indian languages in which the Qualification &amp; Model Curriculum are being submitted</b>                                        | English and Hindi                                                                                                                                                                               |                                                |
| 17. | <b>Is similar NOS available on NQR-if yes, justification for this qualification</b>                                                        | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No URLs of similar Qualifications:                                                                                             |                                                |
| 18. | <b>Name and Contact Details Submitting / Awarding Body SPOC</b><br>(In case of CS or MS, provide details of both Lead AB & Supporting ABs) | <b>Name:</b> Mrs. Shivi Chaudhary<br><b>Email:</b> shivi.chaudhary@lsssd.in <b>Contact No.:</b> + 91 11 41042407/ 408, +91 9315747189<br><b>Website:</b> https://www.lsssd.in/                  |                                                |
| 19. | <b>Final Approval Date by NSQC: 29 September 2025</b>                                                                                      | <b>20. Validity Duration:3 years</b>                                                                                                                                                            | <b>21. Next Review Date: 29 September 2028</b> |

## Section 2: Training Related

|    |                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|----|-----------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. | <b>Trainer's Qualification and experience in the relevant sector (in years) (as per NCVET guidelines)</b> | <p>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 Human Error Reduction (Behavioral GMP) and 2 years of training experience.</p> <p>OR</p> <p>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 Human Error Reduction (Behavioral GMP) and 1 years of training experience.</p> <p>Certified for job role: "Human Error Reduction (Behavioral GMP)" mapped to Qualification Pack: "LFS/N0364, V1.0" 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, v3.0" with minimum score of 80%.</p> |
|----|-----------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|    |                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|----|------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2. | <b>Master Trainer's Qualification and experience in the relevant sector (in years) (as per NCVET guidelines)</b> | <p>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 Human Error Reduction (Behavioral GMP) and 4 years of training experience.</p> <p>OR</p> <p>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 Human Error Reduction (Behavioral GMP) and 4 years of training experience.</p> <p>Certified for job role: "Human Error Reduction (Behavioral GMP)" mapped to Qualification Pack: "LFS/N0364, V1.0" 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, v3.0" with minimum score of 80%.</p> |
| 3. | <b>Tools and Equipment Required for the Training</b>                                                             | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (If "Yes", details to be provided in Annexure)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 4. | <b>In Case of Revised NOS, details of Any Upskilling Required for Trainer</b>                                    | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

### Section 3: Assessment Related

|    |                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|----|--------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. | <b>Assessor's Qualification and experience in relevant sector (in years) (as per NCVET guidelines)</b> | <p>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 Human Error Reduction (Behavioral GMP) and 2 years of training experience.</p> <p>OR</p> <p>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 Human Error Reduction (Behavioral GMP) and 1 years of training experience.</p> |
|----|--------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|    |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|----|-------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    |                                                                                                                                     | <p>Certified for job role: “Human Error Reduction (Behavioral GMP)” mapped to Qualification Pack: “LFS/N0364, V1.0” with minimum accepted score of 80%.</p> <p>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%.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 2. | <b>Proctor’s Qualification and experience in relevant sector (in years)</b> <i>(as per NCVET guidelines), (wherever applicable)</i> | <p>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 Human Error Reduction (Behavioral GMP) and 2 years of training experience.</p> <p>OR</p> <p>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 Human Error Reduction (Behavioral GMP) and 1 years of training experience.</p> <p>Certified for job role: “Human Error Reduction (Behavioral GMP)” mapped to Qualification Pack: “LFS/N0364, V1.0” with minimum accepted score of 80%.</p>                          |
| 3. | <b>Lead Assessor’s/Proctor’s Qualification and experience in relevant sector (in years)</b> <i>(as per NCVET guidelines)</i>        | <p>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 Human Error Reduction (Behavioral GMP) and 4 years of training experience.</p> <p>OR</p> <p>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 Human Error Reduction (Behavioral GMP) and 4 years of training experience.</p> <p>Certified for job role: “Human Error Reduction (Behavioral GMP)” mapped to Qualification Pack: “LFS/N0364, V1.0” with minimum accepted score of 80%.</p> |

|    |                                                               |                                                                                                                                                                                |
|----|---------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    |                                                               | 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. | <b>Assessment Mode</b> ( <i>Specify the assessment mode</i> ) | <b>Mode:</b> <input checked="" type="checkbox"/> Online Only <input type="checkbox"/> Offline Only <input type="checkbox"/> Blended                                            |
| 5. | <b>Tools and Equipment Required for Assessment</b>            | <input checked="" type="checkbox"/> Same as for training <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No                                                   |

## Section 4: Evidence of the Need for the Standalone NOS

Provide Annexure/Supporting documents name.

|    |                                                                                                                                                |
|----|------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. | Government /Industry initiatives/ requirement (Yes/No): No                                                                                     |
| 2. | Number of Industry validation provided: 21                                                                                                     |
| 3. | Estimated number of people to be trained: 1000                                                                                                 |
| 4. | Evidence of Concurrence/Consultation with Line/State Departments (In case of regulated sectors): (Yes/No): If “No”, why: No mail has been sent |

## Section 5: Annexure & Supporting Documents Check List

Specify Annexure Name / Supporting document file name

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



|    |                                                                                                                                                                       |     |
|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|
| 5. | <b>Annexure:</b> Blended Learning ( <i>Mandatory, in case selected Mode of delivery is Blended Learning</i> )                                                         | Yes |
| 6. | <b>Annexure:</b> Acronym and Glossary ( <i>Optional</i> )                                                                                                             | Yes |
| 7. | <b>Annexure/Supporting Document:</b> Standalone NOS- Performance Criteria Details Annexure/Document with PC-wise detailing as per NOS format (Mandatory- Public view) | yes |
| 8. | <b>Supporting Document:</b> Model Curriculum ( <i>Mandatory – Public view</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 |
|---------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| <b>Professional Theoretical Knowledge/Process</b> | <ul style="list-style-type: none"> <li>Knowledge of human behavior, cognition, and error causation.</li> <li>Understanding of organizational impact of human error on quality, safety, and compliance.</li> <li>Familiarity with error investigation methods (RCA, Fishbone, 5 Whys).</li> <li>Awareness of error-proofing tools (Poka-Yoke, SOPs, checklists).</li> <li>Concepts of continuous improvement, Lean Six Sigma, and Kaizen.</li> </ul> | This NOS builds theoretical knowledge of behavioral GMP, enabling individuals to explain human cognition, error types, and organizational consequences of human error. It provides structured understanding of error categorization, error investigation tools like RCA, 5 Whys, and Fishbone, and prevention methods such as Poka-Yoke, SOPs, and competency training. Learners are expected to link theoretical understanding to compliance, quality, and safety standards in pharmaceutical contexts. At NSQF 5.5, learners demonstrate comprehensive theoretical knowledge applied to structured, regulated contexts while addressing unpredictable human error scenarios, aligning | 5.5             |

|                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |     |
|---------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|
|                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                          | with the descriptor's focus on analytical depth and contextual application.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |     |
| <b>Professional and Technical Skills/ Expertise/ Professional Knowledge</b>                 | <ul style="list-style-type: none"> <li>• Skill in applying investigation tools to identify root causes.</li> <li>• Competence in preparing SOPs, checklists, and documentation.</li> <li>• Ability to apply NLP techniques for error reduction.</li> <li>• Use of automation and technology for error minimization.</li> <li>• Applying error-proofing methodologies in pharma manufacturing.</li> </ul> | The NOS equips learners with practical technical skills to investigate, document, and prevent human errors in pharmaceutical processes. This includes applying structured methodologies (RCA, Fishbone, 5 Whys), preparing SOPs and checklists, creating Poka-Yoke solutions, and evaluating automation technologies. Learners also use NLP techniques to improve communication and behavior. These skills align with NSQF 5.5 descriptors that emphasize applied technical expertise, problem-solving competence, and the ability to adapt learned methods to workplace challenges. The NOS ensures learners can transform theoretical knowledge into actionable practices, directly supporting GMP compliance and sustainable error reduction strategies in complex pharma settings. | 5.5 |
| <b>Employment Readiness &amp; Entrepreneurship Skills &amp; Mind-set/Professional Skill</b> | <ul style="list-style-type: none"> <li>• Problem-solving mindset for error remediation.</li> <li>• Ability to work in teams for quality improvement projects.</li> <li>• Adaptability to pharma GMP workplace requirements.</li> <li>• Initiative-taking in developing preventive strategies.</li> <li>• Professional attitude towards compliance and risk mitigation.</li> </ul>                        | This NOS develops employability by fostering analytical thinking, teamwork, adaptability, and a compliance-driven mindset. Learners apply problem-solving approaches to reduce errors, contribute to team-based investigations, and take initiative in implementing preventive measures. They also build an entrepreneurial mindset by proactively designing error-proof processes and improvement strategies. The NSQF 5.5 descriptor emphasizes readiness to perform in structured industry contexts while demonstrating independence, responsibility, and contribution to organizational improvement. By combining                                                                                                                                                                  | 5.5 |

|                                           |                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |     |
|-------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|
|                                           |                                                                                                                                                                                                                                                                                                                                                                                                  | professional ethics with continuous improvement skills, this NOS ensures learners are industry-ready and capable of sustaining organizational quality and compliance in regulated environments.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |     |
| <b>Broad Learning Outcomes/Core Skill</b> | <ul style="list-style-type: none"> <li>Analytical skills to assess and categorize human errors.</li> <li>Communication and reporting of investigation findings.</li> <li>Critical thinking to design prevention strategies.</li> <li>Leadership orientation for building error-free culture.</li> <li>Continuous learning approach for improvement initiatives.</li> </ul>                       | The NOS develops broad learning outcomes such as analysis, communication, critical thinking, and leadership. Learners interpret error data, communicate findings, propose preventive actions, and lead error-reduction initiatives. Continuous learning and adaptability are emphasized to cope with evolving GMP requirements. At NSQF 5.5, core skills extend beyond routine operations to include analytical depth and cognitive flexibility for unpredictable contexts. This NOS ensures learners not only execute assigned tasks but also contribute to sustainable error-free culture through leadership and collaborative problem-solving, aligning well with the level descriptor's emphasis on both professional competence and organizational contribution. | 5.5 |
| <b>Responsibility</b>                     | <ul style="list-style-type: none"> <li>Accountable for ensuring error reduction in pharma processes.</li> <li>Responsible for accurate documentation and compliance with SOPs.</li> <li>Leading or supporting error investigation teams.</li> <li>Responsibility to train peers/subordinates on error prevention.</li> <li>Maintaining quality, safety, and efficiency in operations.</li> </ul> | Learners completing this NOS take responsibility for executing and documenting human error reduction activities within pharmaceutical manufacturing. They ensure compliance with SOPs, GMP standards, and safety requirements, while also supporting or leading investigations. The NOS emphasizes accountability for maintaining documentation accuracy, mentoring others, and ensuring quality outcomes in error-prone processes. This aligns with NSQF 5.5 descriptors where learners are accountable for their outputs and responsible for guiding                                                                                                                                                                                                                | 5.5 |

|  |  |                                                                                                                                                                                                                   |  |
|--|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  |  | or supporting peers in structured workplace functions. The responsibility dimension highlights leadership in promoting error-free operations and sustaining organizational performance in regulated environments. |  |
|--|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|

### Annexure: Tools and Equipment (lab set-up)

#### List of Tools and Equipment

##### Batch Size:

| S. No. | Tool / Equipment Name               | Specification    | Quantity for specified Batch size |
|--------|-------------------------------------|------------------|-----------------------------------|
| 1.     | 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 attached to LCD projector.
4. Computer speaker
5. Pencil

### Annexure: Industry Validations Summary

| S. No | Organization Name | Representative Name | Designation | Contact Address | Contact Phone No | E-mail ID | LinkedIn Profile (if |
|-------|-------------------|---------------------|-------------|-----------------|------------------|-----------|----------------------|
|-------|-------------------|---------------------|-------------|-----------------|------------------|-----------|----------------------|

|    |                                       |                      |                                             |                                                                                  |             |                                                                                              | available<br>) |
|----|---------------------------------------|----------------------|---------------------------------------------|----------------------------------------------------------------------------------|-------------|----------------------------------------------------------------------------------------------|----------------|
| 1. | Auriga Research Private Limited       | Dr. Neha S. Arora    | Director                                    | 3/17, Kirti Nagar Industrial Area, New Delhi-15, India                           | 8800330033  | Neha@arbropharma.com,<br>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  | <a href="mailto:praveen.vajjah@msnlabs.com">praveen.vajjah@msnlabs.com</a>                   |                |
| 3. | Beta Drug Limited                     | Sarita               | Deputy Manager. HR                          | Kharuni Lodhimajra Road, Village: Nandpur, Tehsil: Baddi. Distt. Solan (H.P)     | 9625840405  | <a href="mailto:sarita@betadrugslimited.com">sarita@betadrugslimited.com</a>                 |                |
| 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,<br>Neha@aurigaresearch.com                                             |                |
| 5. | Bio-Med private Ltd.                  | Divyanshu Sirohi     | QA Manager                                  | C-96&98, Bulandsheher Road Industrial Area Ghaziabad- 201009                     | 7503804891  | <a href="mailto:divyanshu988@gmail.com">divyanshu988@gmail.com</a>                           |                |
| 6. | Tirupati Lifescience Limited          | Jagdish Chauhan      | Manager HRD                                 | Nahan Road, Ponta Sahib, Distt Sirmour (H.P)                                     | 9816633372  | <a href="mailto:jagdish.chauhan@tirupatiwellness.in">jagdish.chauhan@tirupatiwellness.in</a> |                |
| 7. | Tirupati Medicare Limited             | Jagdish Chauhan      | Manager HRD                                 | Nahan Road, Ponta Sahib, Distt Sirmour (H.P)                                     | 9816633372  | <a href="mailto:jagdish.chauhan@tirupatiwellness.in">jagdish.chauhan@tirupatiwellness.in</a> |                |
| 8. | Tirupati Wellness Limited             | Jagdish Chauhan      | Manager HRD                                 | Nahan Road, Ponta Sahib, Distt Sirmour (H.P)                                     | 9816633372  | <a href="mailto:jagdish.chauhan@tirupatiwellness.in">jagdish.chauhan@tirupatiwellness.in</a> |                |
| 9. | Venus Remedies Ltd.                   | Arunava Pal          | Assistant General Manager (Skill Developmen | Head Office: Plot No. 51-52, Industrial Area, Phase-1, PANCHKULA                 | 90735-02801 | <a href="mailto:skilldev_hod@venusremedies.com">skilldev_hod@venusremedies.com</a>           |                |

|     |                                                 |                                |                                                       |                                                                                                                                                                                  |                 |                                                                                        |  |
|-----|-------------------------------------------------|--------------------------------|-------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|----------------------------------------------------------------------------------------|--|
|     |                                                 |                                | t<br>Department)                                      |                                                                                                                                                                                  |                 |                                                                                        |  |
| 10. | Dr. Reddys<br>Laboratories<br>Ltd.              | Y Nagender                     | Technical<br>Capabilities<br>Expert                   | 8-2-337, Road No. 3, Banjara Hills,<br>Hydrabad, Telangana, India 500034                                                                                                         | 9844928279<br>1 | <a href="mailto:nagendery@srreddys.com">nagendery@srreddys.com</a>                     |  |
| 11. | INTAS<br>Pharmaceutical<br>s Ltd.               | Amit Kanabar                   | Sr. Manager,<br>Head- Intas<br>Center f<br>Excellence | Plot No. 457, 458 Sarkhej Bavla<br>Highway, Matoda Village, Sanand,<br>Taluka, Ahmedabad, Gujarat 382210                                                                         | 8141841287      | <a href="mailto:Amit_Kanabar@intaspharma.com">Amit_Kanabar@intaspharma.com</a>         |  |
| 12. | Emcure<br>Pharmaceutical<br>s Limited           | Rajesh Nair                    | President HR                                          | Plot No. P-1 & P-2, IT-BT Park, Phase-<br>II, MIDC, Hinjawadi, Pune- 411057<br>Maharashtra                                                                                       | 9373314937      | <a href="mailto:Prakash.Khandare@emcure.com">Prakash.Khandare@emcure.com</a>           |  |
| 13. | BLUE CROSS<br>LABORATORIES<br>PVT LTD.          | ASHOK KUMAR<br>GUPTA           | TECHNICAL<br>DIRECTOR                                 | A-12, AMBAD INDUSTRIAL AREA,<br>NASHIK<br>Regd Office:<br>Peninsula Chambers, Peninsula<br>Corporate Park, G.K Marg, Lower<br>Parel (West)Mumbai - 400013,<br>Maharashtra, INDIA | 9167244064      | <a href="mailto:ashok.g@bluecrosslabs.com">ashok.g@bluecrosslabs.com</a>               |  |
| 14. | MAJUSHREE<br>TECHNOPACK<br>LIMITED              | KISHORE                        | HR<br>MANAGER                                         | Near fire station, Vadlapudi village,<br>Kurmannapalem, Visakhapatnam,<br>Andhra Pradesh 530046.                                                                                 | 9581199200      | <a href="mailto:Kishore.karrimanjushreeindia.com">Kishore.karrimanjushreeindia.com</a> |  |
| 15. | CMS<br>Laboratories<br>India Private<br>Limited | Guntuku<br>Jagadeeswara<br>Rao | Managing<br>Director                                  | 47-10-50, Dwaraka Nagar, 4th Lane,<br>3rd Floor, Above Union Bank,<br>Visakhapatnam-530016                                                                                       | 8919168131      | <a href="mailto:jdguntuku@gmail.com">jdguntuku@gmail.com</a>                           |  |
| 16. | Synaptics Labs<br>Pvt Ltd                       | M BHARATH                      | SENIOR<br>MANAGER                                     | Plot No:28-B,APIIC, Lalamkoduru Vill,<br>Rambill( MD),Visakhapatnam,Andhr<br>a Pradesh-531011                                                                                    | 7569279497      | <a href="mailto:hr@synapticlabs.com">hr@synapticlabs.com</a>                           |  |

|     |                                  |                                |                                |                                                                                                |            |                                                                                    |  |
|-----|----------------------------------|--------------------------------|--------------------------------|------------------------------------------------------------------------------------------------|------------|------------------------------------------------------------------------------------|--|
| 17. | VLR FACILITATORS PRIVATE LIMITED | JAYASHREE                      | HR                             | Hoty Child School, near dundigal police station, Gandhi Maisamma, Hyderabad, Telangana 500043. | 8247212205 | <a href="mailto:jayashreem@gmail.com">jayashreem@gmail.com</a>                     |  |
| 18. | Smruthi Organics                 | Kamlakar Gajjam                | Assistant General Manager (HR) | Plot No. A-27, MIDC, Chincholi District Solapur 413255 Maharashtra, India                      | 7083225457 | <a href="mailto:kdg@smruthiorganics.com">kdg@smruthiorganics.com</a>               |  |
| 19. | Hetero Labs Limited              | Dr. Shubhadeep Debabrata Sinha | Senior Vice-President          | 7-A-2, Industrial area, Sanathnagar, Hyderabad 500018                                          | 9393922434 | <a href="mailto:SD.Sinha@hetero.com">SD.Sinha@hetero.com</a>                       |  |
| 20. | Zydus Lifesciences Limited       | Harsh Raj purohit              | Deputy Manager                 | Zydus corporate park , Ahemdabad                                                               | 7041309081 | <a href="mailto:harsh.rajpurohit@zyduslife.com">harsh.rajpurohit@zyduslife.com</a> |  |

### Annexure: Training Details

#### Training Projections:

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

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

### Annexure: Blended Learning

#### Blended Learning Estimated Ratio & Recommended Tools:

Refer NCVET “Guidelines for Blended Learning for Vocational Education, Training & Skilling” available on:

<https://ncvet.gov.in/sites/default/files/Guidelines%20for%20Blended%20Learning%20for%20Vocational%20Education,%20Training%20&%20Skilling.pdf>

| S. No. | Select the Components of the NOS                                                                             | List Recommended Tools – for all Selected Components                                                 | Offline: Online Ratio |
|--------|--------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|-----------------------|
| 1      | <input type="checkbox"/> Theory/ Lectures - Imparting theoretical and conceptual knowledge                   | LMS Portal- LSSSDC Daksh Portal will be utilized with online content/virtual lectures                | 50:50                 |
| 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/ Candidate Training              | Offline                                                                                              | 100:00                |

## Annexure: Standalone NOS- Performance Criteria details

### 1. Description:

This NOS program equips individuals in pharmaceutical manufacturing with the skills to understand, investigate, prevent, and reduce human errors. It covers key aspects of human behavior, error investigation techniques, and prevention tools such as Root Cause Analysis, Fishbone Diagrams, Poka-Yoke, and SOPs. The program emphasizes leadership, organizational culture, and continuous monitoring for creating a sustainable error-free environment. Through practical exercises and case studies, participants will gain hands-on experience in mitigating errors, improving product quality, safety, and efficiency.



## **2. Scope:**

The scope covers the following:

- Human Behaviour and Organizational Impact of Human Error
- Human Error Investigation Techniques
- Human Error Prevention Tools and Techniques
- Human Error Reduction Strategies

## **3. Elements and Performance Criteria**

### **Human Behaviour and Organizational Impact of Human Error**

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

- PC 1 discuss the cognitive ability, decision-making, and behavioural patterns that contribute to human error
- PC 2 Explain the human brain structure and its role in processing signals that lead to human error.
- PC 3 Identify and categorize types of human errors (slips, lapses, mistakes) and their impact on product quality, safety, and compliance.
- PC 4 Analyze the organizational impact of human errors on product quality, safety, and compliance.
- PC 5 Demonstrate basic NLP techniques to improve behaviour and reduce errors.

### **Human Error Investigation Techniques**

- PC 6 Categorize human errors (learning, memory, inconsistency, application) and explain their impact.
- PC 7 Explain investigation techniques (RCA, Fishbone Diagrams, 5 Whys) for human errors.
- PC 8 Discuss the human error investigation flow, including risk review and evidence gathering.
- PC 9 Perform the documentation of evidence in a human error investigation and identify the root cause.

### **Human Error Prevention Tools and Techniques**

- PC 10 explain the use of effective signals for human error prevention .
- PC 11 demonstrate various error-proofing methodologies (e.g., Poka-Yoke) and their applications process.
- PC 12 Prepare a sample checklist for a critical process in pharmaceutical manufacturing for reducing human errors
- PC 13 explain the importance of on-the-job training and competency assessment in error prevention.

PC 14 discuss how automation and technology can minimize human errors by evaluating a specific automated system.

PC 15 create an SOP for a critical process to enhance error prevention by writing a detailed SOP

#### **Human Error Reduction Strategies**

PC 16 discuss the process of error remediation and its steps

PC 17 explain the importance of pictorial descriptions in work instructions by designing a visual work instruction

PC 18 discuss the role of leadership and organizational culture in reducing errors

PC 19 explain proactive approaches for error prediction and prevention

PC 20 discuss the application of Lean Six Sigma and Kaizen in human error management

PC 21 develop a human error reduction strategy for a specific department

#### **4. Knowledge and Understanding (KU):**

The individual on the job needs to know and understand:

- Understanding the cognitive abilities, behavioural patterns, and decision-making processes that lead to human error.
- Familiarity with brain signal processing and its influence on human errors.
- Knowledge of types, causes, and classifications of human errors like slips, lapses, and mistakes.
- Recognizing the impact of human errors on product quality, safety, compliance, and organizational performance.
- Classifying human errors based on categories such as learning, memory, inconsistency, and application issues.
- Analyzing techniques for human error investigation, including Root Cause Analysis, Fishbone Diagrams, and the 5 Whys method.
- Understanding the human error investigation process flow, including risk review, evidence gathering, and documentation.
- Grasping the use of error prevention tools like Poka-Yoke, SOPs, checklists, and automation technologies.
- Understanding the significance of on-the-job training and competency assessments in minimizing human errors.
- Recognizing the value of pictorial work instructions and clear communication tools in error prevention.
- Knowledge of continuous improvement methods, including remediation, proactive error prediction, Lean Six Sigma, and Kaizen.
- Analyzing leadership roles, organizational culture, and feedback systems in sustaining human error reduction strategies.

#### **5. Generic Skills (GS):**

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

1. use reading and comprehension skills to carefully interpret work instructions, guidelines, procedures, and signage, ensuring correct understanding to minimize the likelihood of human errors
2. Use written communication skills to accurately document observations, deviations, and required information as per SOPs and regulatory standards, ensuring traceability and aiding in human error investigations
3. Apply planning and organizing skills to arrange tools, materials, and workspace efficiently, thereby reducing confusion, task slips, and memory lapses during critical operations
4. Utilize critical thinking skills to detect potential breaches or non-compliances in EHS and operational protocols, and evaluate their contribution to human error events
5. Demonstrate customer-centric behavior by ensuring data integrity and regulatory compliance, and critically evaluating how errors or wrongdoings impact product quality, patient safety, and organizational reputation
6. Use decision-making skills to make balanced, informed judgments within authority limits when encountering operational hazards or deviations, supporting quick corrective action to prevent escalation of human errors
7. Apply problem-solving skills to identify workflow disruptions, analyze error patterns, and suggest preventive measures based on investigation findings
8. use verbal communication skills to communicate with supervisor/ manager/ EHS Incharge or any other concerned authority clearly for escalating any emergency situation or hazard
9. identify and resolve operational issues and challenges by applying error-proofing tools like Poka-Yoke, checklists, visual aids, and automation, to proactively reduce the chances of human error

### Annexure: Assessment Criteria

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

| S. No.                                                    | Assessment Criteria for Performance Criteria                                                                 | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|-----------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|--------------|-----------------|---------------|------------|
| 1.LFS/N0364:<br>Human Error Reduction<br>(Behavioral GMP) | <b>Human Behaviour and Organizational Impact of Human Error</b>                                              |              |                 |               |            |
|                                                           | PC 1 discuss the cognitive ability, decision-making, and behavioural patterns that contribute to human error |              |                 |               |            |
|                                                           | PC 2 Explain the human brain structure and its role in processing signals that lead to human error.          |              |                 |               |            |

|                                                    |                                                                                                                                      |  |  |  |  |
|----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|--|--|--|--|
| PC 3                                               | Identify and categorize types of human errors (slips, lapses, mistakes) and their impact on product quality, safety, and compliance. |  |  |  |  |
| PC 4                                               | Analyze the organizational impact of human errors on product quality, safety, and compliance.                                        |  |  |  |  |
| PC 5                                               | Demonstrate basic NLP techniques to improve behaviour and reduce errors                                                              |  |  |  |  |
| <b>Human Error Investigation Techniques</b>        |                                                                                                                                      |  |  |  |  |
| PC 6                                               | Categorize human errors (learning, memory, inconsistency, application) and explain their impact.                                     |  |  |  |  |
| PC 7                                               | Explain investigation techniques (RCA, Fishbone Diagrams, 5 Whys) for human errors.                                                  |  |  |  |  |
| PC 8                                               | Discuss the human error investigation flow, including risk review and evidence gathering.                                            |  |  |  |  |
| PC 9                                               | Perform the documentation of evidence in a human error investigation and identify the root cause.                                    |  |  |  |  |
| <b>Human Error Prevention Tools and Techniques</b> |                                                                                                                                      |  |  |  |  |
| PC 10                                              | explain the use of effective signals for human error prevention .                                                                    |  |  |  |  |
| PC 11                                              | demonstrate various error-proofing methodologies (e.g., Poka-Yoke) and their applications process.                                   |  |  |  |  |
| PC 12                                              | Prepare a sample checklist for a critical process in pharmaceutical manufacturing for reducing human errors                          |  |  |  |  |
| PC 13                                              | explain the importance of on-the-job training and competency assessment in error prevention.                                         |  |  |  |  |
| PC 14                                              | discuss how automation and technology can minimize human errors by evaluating a specific automated system.                           |  |  |  |  |
| PC 15                                              | create an SOP for a critical process to enhance error prevention by writing a detailed SOP                                           |  |  |  |  |
| <b>Human Error Reduction Strategies</b>            |                                                                                                                                      |  |  |  |  |
| PC 16                                              | discuss the process of error remediation and its steps                                                                               |  |  |  |  |
| PC 17                                              | explain the importance of pictorial descriptions in work instructions by designing a visual work instruction                         |  |  |  |  |
| PC 18                                              | discuss the role of leadership and organizational culture in reducing errors                                                         |  |  |  |  |
| PC 19                                              | explain proactive approaches for error prediction and prevention                                                                     |  |  |  |  |
| PC 20                                              | discuss the application of Lean Six Sigma and Kaizen in human error management                                                       |  |  |  |  |

|                    |                                                                    |           |           |  |  |
|--------------------|--------------------------------------------------------------------|-----------|-----------|--|--|
| PC 21              | develop a human error reduction strategy for a specific department |           |           |  |  |
| <b>Total Marks</b> |                                                                    | <b>50</b> | <b>50</b> |  |  |

## Annexure: Assessment Strategy

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

*Mention the detailed assessment strategy in the provided template.*

### 1. Assessment System Overview:

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

#### 1.1 Criteria of selection of assessment body/agency:

The assessment body/agency is selected based on:

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

#### 1.2 Assessment tool development for assessment of Training:

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

**1.2.1 Digital Written test for knowledge assessment:**

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

**Tools** –computer or tab based online or offline.

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

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

**1.2.2 Digital Written test for skill assessment:**

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

**Tools** – computer or tab based online or offline questions

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

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

**1.3 Steps for assessment tool development:**

- The selection of assessment tool(s) is done as per the assessment criteria prescribed in Qualification Pack.
- For Human error Reduction including AI tools assessment a blueprint of the question paper is part of the assessment tool for training.
- Development of layout of Question paper is such that the entire PCs (Performance Criteria) of that Qualification/ NOS/ Micro Credentials are covered.
- Score per question maps with the weightage given to that PC, in the assessment criteria, and the level of difficulty of the question.
- An expert from industry is selected who is called "Subject Matter Expert" (SME). This SME must have over 13-15 years of experience in the industry in Behavioral GMP occupation.

- SME is screened and approved by LSSSDC. He/she is oriented by both LSSSDC and Assessment agency on – creating question Bank, level of questions, end the desired outcome of the assessment.

#### **1.4 Execution of Training Assessment/ RPL Assessment:**

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

##### **1.4.1 Tab based assessment using physical proctoring**

##### **1.4.2 Smartphone-based assessment using e-proctoring**

#### **1.4.1 Tab-based assessment using physical proctoring**

- A representative from the Assessment agency is present on the day of assessment to executing the assessment at the venue in case of physical proctoring.
- The assessment agency representative carries an identity card and letter from the council authorizing to conduct the assessment.
- Assessment agency representative ensures the authenticity of Trainee's identity by verifying the documents (any document issued by GOI, such as Ration card, Aadhaar Card, Driving License, Passport, Election card, etc)
- The assessment agency representative maintains the records of attendance, verified documents, and tablet instruments used in the assessment.
- Assessment agency representative collects evidence of the assessment in the best possible way (videos, pictures, voice recordings, etc)
- Assessment agency representative transfers the assessment scores from tab to assessment agency server, using a secure, encrypted web-based program.

- The assessment agency after processing the results and putting them in standard format hands over to LSSSDC within 7 days of assessment.

#### **1.4.2 Smartphone-based assessment using e-proctoring**

- All trainees enrolled in the batch due for assessment, are registered on an assessment tool application using their unique mobile number and e-mail ID along with a Govt. ID issued proof.
- An assessment link is sent to the mail ID of each trainee with a defined expiry date of the link.
- Trainee at any location can click on the link using his/her smartphone or a web camera-enabled computer system
- Using the unique credentials and Govt ID number, the trainee logs in for the start of assessment and completes the assessment.
- The authenticity of Trainee's identity is done by assessment application by verifying the documents (any document issued by GOI, such as Ration card, Aadhaar Card, Driving Licence, Passport, election card, etc.) and a live photo capture
- A live video of the candidate during the assessment is captured to collect the evidence of the assessment
- Once the assessment is complete, the assessment application automatically assessment scores to the assessment agency server, using a secure, encrypted web-based program.
- The assessment agency after processing the results and putting them in standard format hands over to LSSSDC within 7 days of assessment.

#### **2. Testing Environment:**

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

#### **3. Assessment Quality Assurance levels/Framework:**

- Question bank is created by the Subject Matter Experts (SME) of Assessment Agency are verified by the other SME of LSSSDC
- All Questions are mapped to the specified assessment criteria
- Assessor eligibility criteria are structured to ensure quality and knowledge credentials of an assessor like-wise the trainer's quality and knowledge credentials.



- Eligible Assessor must be certified by LSSSDC for the respective and relevant qualification
- The tools used for assessment are validated for relevance and feasibility for skill assessment of the qualification in consideration

**4. Types of evidence or evidence-gathering protocol:**

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

**5. Method of verification or validation:**

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

**6. Method for assessment documentation, archiving, and access**

- Hard copies and digital copies (whichever is applicable) of the assessment evidences are stored with assessment agency team for 5 years
- Assessment transcripts are stored in the server space of assessment agency for 5 years
- Assessment question banks and validation records are stored with assessment agency and LSSSDC digitally
- Assessment records are archived with assessment agency archive server after 5 years for another 5 years
- Access of assessment records are controlled with restricted access to concerned department and stakeholders and is shared on demand after due approval of Head of Assessment and Certification-LSSSDC

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

7.1 Each module/ NOS will be assessed separately.

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

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

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

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

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

Annexure: Acronym and Glossary

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

|            |                              |
|------------|------------------------------|
| <b>GDP</b> | Good Documentation Practices |
| <b>SME</b> | Subject Matter Experts       |

## Glossary

| <b>Term</b>                                  | <b>Description</b>                                                                                                                                                                                                                     |
|----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>National Occupational Standards (NOS)</b> | NOS define the measurable performance outcomes required from an individual engaged in a particular task. They list down what an individual performing that task should know and also do.                                               |
| <b>Qualification</b>                         | 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                                                       |
| <b>Qualification File</b>                    | 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. |
| <b>Sector</b>                                | A grouping of professional activities on the basis of their main economic function, product, service or technology.                                                                                                                    |
| <b>Long Term Training</b>                    | Long-term skilling means any vocational training program undertaken for a year and above.<br><a href="https://ncvet.gov.in/sites/default/files/NCVET.pdf">https://ncvet.gov.in/sites/default/files/NCVET.pdf</a>                       |