

**CONTACT DETAILS OF THE BODY SUBMITTING THE QUALIFICATION FILE**

**Name and address of submitting body:**

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**List of documents submitted in support of the Qualifications File**

- 1 [Qualifications Pack](#)
- 2 [LSSSDC Protocol for Accreditation of Assessment Agencies and Assessment Guidelines](#)
- 3 [Minutes of meeting of Governing Body](#)
  - [Composition of National Committee of NOS](#)
- 4 [NSDC Sector Skill Gap Report for Life Sciences Sector is available at <http://nsdcindia.org/sites/default/files/files/Pharmaceuticals.pdf>](#)
- 5 [Occupational Map and Career Progression Map](#)
- 6 [List of companies and Industry associations participated in the development of this qualification](#)
- 7 [List of Qualification/NOS validating companies](#)

**Model Curriculum (attached as annexure) including the following:**

- Indicative list of tools/equipment to conduct the training
- Trainers & Assessor qualification
- Unit Plan with Learning Objective

## NSQF QUALIFICATION FILE

Approved in 14<sup>th</sup> NSQC, dated- 30/12/2021

Rationalized on file 20.03.2023

- Distribution of training duration into theory/skill practical/Project and Viva component

### SUMMARY

1	<b>Qualification Title</b>	Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device)
2	<b>Qualification Code, if any</b>	LFS/Q0302 Ver 3.0
3	<b>NCO code and occupation</b>	NCO 2015/ 2113.0901  Quality
4	<b>Nature and purpose of the qualification (Please specify whether qualification is short term or long term)</b>	Short term training with or without apprenticeship And Elective Subject in B. Pharma. 8 <sup>th</sup> Sem
5	<b>Body/bodies which will award the qualification</b>	Life Sciences Sector Skill Development Council
6	<b>Body which will accredit providers to offer courses leading to the qualification</b>	Life Sciences Sector Skill Development Council
7	<b>Whether accreditation/affiliation norms are already in place or not, if applicable (if yes, attach a copy)</b>	Yes, attached the copy as annexure 1
8	<b>Occupation(s) to which the qualification gives access</b>	Quality
9	<b>Job description of the occupation</b>	Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) performs in-process quality checks for all the manufacturing products while conducting documentation and verification exercise. The individual is responsible to ensure compliance to systems and procedures, undertakes risk control assessment, and conducts/coordinates in internal/external audit. The role holder also carries out sampling of in-process, finished product.
10	<b>Licensing requirements</b>	Not applicable

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1 1	Statutory and Regulatory requirement of the relevant sector (documentary evidence to be provided)	Nil
1 2	Level of the qualification in the NSQF	5
1 3	Anticipated volume of training/learning required to complete the qualification	<p>Compulsory Notional Hours  Theory= 155 Hours  Practical=265 Hours  Employability Skills= 90 Hours  Total Compulsory Notional Hours= 510 Hours</p> <p>with mandatory apprenticeship training for 12 Months  Note:  B. Tech Biotech/ B. Pharma is exempted from Mandatory Apprenticeship</p>
1 4	Indicative list of training tools required to deliver this qualification	Attached as annexure 2
1 5	Entry requirements and/or recommendations and minimum age	<p>B. Pharma (7th Semester) or  B. Tech (Biotechnology/Chemical Engineering/Instrumentation &amp; Electronics) 3rd year or  M.Sc. (Chemistry/ Microbiology/ Biotechnology/ Life Sciences)</p> <p>Age: 21 years</p>
1 6	Progression from the qualification (Please show Professional and academic progression)	<p><b>Vertical progression</b></p> <p>1. Quality Assurance Specialist (Level 6)</p> <p>2. Quality Assurance Manager (Food Processing</p>

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		<p>Sector) Level 6 as cross sector progression</p> <p><b>Lateral/Horizontal progression</b></p> <p>1. Cross Sectoral in Process Industries like Food Processing / Bio Agri Fertilizers/Pesticide/Chemical Manufacturers</p>
<b>17</b>	<b>Arrangements for the Recognition of Prior Learning (RPL)</b>	<p>The process to award the qualification via RPL mode and detailed methodology is given in point No.22</p>
<b>18</b>	<b>International comparability Whether known (research evidence to be provided)</b>	<p>While preparing the NOSs, a detailed secondary desk research was conducted. The European, South African and Australian NOSs were referred to. The relevant International NOSs for the job role are listed below for reference:</p> <p>UK NOS</p> <ul style="list-style-type: none"><li>• COGLS213 Preparing biological specimens or samples for investigations in life sciences and related industries</li><li>• COGLS216 Operating in a clean room or aseptic facility in life sciences and related industries</li><li>• COGLS318 Maintaining cell lines in life sciences and related industries</li><li>• COGLS329 Culturing or fermenting cells for life sciences and related industries</li><li>• SFHPHARM23 check documentation and materials</li><li>• COGLS2 Maintain effective and efficient working relationships</li><li>• COGLS15 Improve product(s) and process quality within life</li></ul>

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		<ul style="list-style-type: none"> <li>• COGLS206 Preparing reagents in life sciences and related industries</li> <li>• COGLS212 Carry out testing using manual or automated equipment</li> <li>• COGLS215 Carry out sampling operations in life sciences</li> <li>• COGPI03.2 control emergencies</li> <li>• COGLS201 Follow health and safety procedures in life sciences</li> <li>• COGLS301 Maintain health and safety in life sciences</li> </ul> <p><b>Switzerland NOS</b></p> <ul style="list-style-type: none"> <li>• Refer page no. 196 Unit Group 3212, page no. 123 Unit Group 2113, page no. 190 Unit Group 3141</li> </ul> <p><b>Australia NOS</b></p> <ul style="list-style-type: none"> <li>• Apply sampling procedures</li> <li>• Communicate workplace information</li> <li>• Operate a separation process using chromatography</li> <li>• Participate in OHS processes</li> <li>• Perform basic tests</li> <li>• Participate in work teams and groups</li> </ul> <p><b>South Africa NOS</b></p> <ul style="list-style-type: none"> <li>• Apply the principles of asepsis and sterility in a healthcare environment</li> <li>• Act in accordance with ethical and legal codes of pharmaceutical representation and the laws of the country</li> </ul>
<b>19</b>	<b>Date of planned review of the qualification</b>	<b>31 December 2024</b>

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Formal structure of the qualification

Mandatory components

NOS/ Module Details	Total Duration Hours	Level	Credit
<b>Compulsory Bridge Module</b> Introduction to Life Sciences industry and the job role & managing environmental sustainability	90:00	Level-5	3.00
<b>Compulsory Module</b> LFS/N0341 V2.0: Perform quality checks in the manufacturing/ production units in compliance with regulatory guidelines	180:00	Level-5	6.00
<b>Compulsory Module</b> LFS/N0110 v2.0: Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab	30:00	Level-5	1.00
<b>Compulsory Module</b> LFS/N0345 V2.0: Perform reporting and documentation to meet regulatory standards	60:00	Level-5	2.00
<b>Compulsory Module</b> LFS/N0346 V2.0: Coordinate with supervisor, functional team, cross-functional teams and auditors	60:00	Level-5	3.00
<b>DGT/VSQ/N0103: Employability Skills (90 Hours)</b>	90:00		3.00
<b>Total Duration (A)</b>	510.00		17.00

Apprenticeship Component

<b>Mandatory Apprenticeship</b>	<b>12 Months</b>
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Body/Bodies which will carry out assessment:

Following assessment agencies will carry out assessments:

1. Induslynk Training Services Pvt. Ltd.- Mercer- Mettl, 7&8th Floor, SN 1&2, Good Earth Business Bay, Sector 58, Gurugram, 122101

2. SHL (India) Pvt. Ltd.- 6-Tower-B, 10, DLF Building, DLF Cyber City, Gurugram, Haryana, 122002

3. Cleveratti Skill Pvt. Ltd.- 3704, DLF Phase IV, Near Galleria Market, Gurugram 122002, Haryana

**2  
2****How will RPL assessment be managed and who will carry it out?****Assessment process for RPL programs (Candidates with experience in the occupation or for informally trained and employed trainees):**

- Every RPL batch is uploaded on Skill Development Management System (SDMS) managed by National Skill Development Corporation (NSDC). SDMS reflects the proposed date of assessment for the batch. The batch is uploaded on SDMS by RPL project implementation agency.
- LSSSDC conducts Assessments via its empaneled Assessment Agencies and assigns the batch to an assessment agency pre-notified with NSQC for the job role.
- Assessment agency ensures the availability of required infrastructure, tools for the assessment.
- Assessments for RPL candidates are conducted in following two modes:  
A) Theory and Skill Practical on a fully digital platform.  
B) Theory part digital and practical part through actual assessor observation.
- The authenticity of Trainee's identity and eligibility is verified by project implementation agency by verifying the ID proof documents (any document issued by GOI, such as Aadhaar Card, Driving License, Passport, election card etc.) and experience proof (industry endorsement, experience letters)
- Assessment agency collects evidences of the assessment in best possible way (videos, pictures, assessment logs etc.)
- The assessment agency after processing the results and putting them in standard format hands over to LSSSDC within 7 days from the date of assessment.
- LSSSDC validates the assessment results and announces the result on SDMS within 15 days of assessment date.
- Passed candidates are provided with qualification certificate.

**Assessment tools:** 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.

**Digital Written test for knowledge assessment:**

Scope – Is used to test the knowledge component of the Qualification.

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 in sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.

**Digital Written test for skill assessment**



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	<p><u>Scope</u> – Is used to test primarily the Skill component of the Qualification. Trainee's expertise in handling and managing the situation is tested.</p> <p><u>Tools</u> – computer or tab based online or offline questions.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – Question paper is divided in sections. Each Section intends to assess a particular skill field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.</p> <p><b>Following assessment agencies will carry out assessments:</b></p> <ol style="list-style-type: none"><li>1. Induslynk Training Services Pvt. Ltd.- Mercer- Mettl, 7&amp;8th Floor, SN 1&amp;2, Good Earth Business Bay, Sector 58, Gurugram, 122101</li><li>2. SHL (India) Pvt. Ltd.- 6-Tower-B, 10, DLF Building, DLF Cyber City, Gurugram, Haryana, 122002</li><li>3. Cleveratti Skill Pvt. Ltd.- 3704, DLF Phase IV, Near Galleria Market, Gurugram 122002, Haryana</li></ol>
2 3	<p><b>Describe the overall assessment strategy and specific arrangements which have been put in place to ensure that assessment is always valid, reliable and fair and show that these are in line with the requirements of the NSQF.</b></p> <p><b>Assessment Agencies:</b> An assessment agency is selected based on</p> <ul style="list-style-type: none"><li>• Prior experience and understanding of Life Sciences or similar sector.</li><li>• Experience in conducting assessments for similar job roles.</li><li>• Manpower and Technical capabilities.</li><li>• Geographical reach</li><li>• Existing Network in the Life Sciences Sector</li><li>• Agency's internal policies to maintain Standards, Quality &amp; professional Integrity</li><li>• Agency's policy in assessor management</li></ul> <p><b>Assessment development:</b> The assessment development is done with close monitoring and under supervision of LSSDC at every stage.</p> <p>Steps for assessment development:</p> <ul style="list-style-type: none"><li>• Selection of assessment tool(s) is done as per the assessment criteria prescribed in Qualification.</li><li>• For Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) a blue print of the question paper, is part of assessment tool for training.</li><li>• Development of lay-out of Question paper is such that the entire PCs (Performance Criteria) of that Qualification are covered.</li><li>• Score per question maps with the weightage given to that PC, in the assessment criteria and the level of difficulty of the question.</li><li>• 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 quality occupation.</li></ul>



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

**Assessor:** The Assessors are engaged to conduct the assessments. Assessor guidelines are followed as below:

Assessor Prerequisites						
Minimum Educational Qualification	Specialization	Relevant Industry Experience		Training/Assessment Experience		Remarks
		Years	Specialization	Years	Specialization	
Graduate	Pharmacy / Biotechnology Engg.	6	Quality Assurance	1	On the job assessment/ Training experience/ Vocational assessment/ Academic assessment	
Post Graduate	Pharmacy/ Chemistry/ Biotechnology	4	Quality Assurance	1	On the job assessment/ Training experience/ Vocational assessment/ Academic assessment	
Post Graduate	Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) (LFS/Q030 2, V1.0/ V2.0)	4	Quality Assurance	1	On the job assessment/ Training experience/ Vocational assessment/ Academic assessment	

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	Level-5 qualified					
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Assessor Certification	
Domain Certification	Platform Certification
Chemist- In-process Quality Assurance(Pharma, Biologics and Medical Device) mapped to the Qualification Pack: "LFS/Q0302, v3. " with minimum accepted score of 80%.	Recommended that the Assessor is certified for the Job Role: "Assessor (VET and Skills)", mapped to the Qualification Pack: "MEP/Q2701 v2.0 , with minimum score of 80%.

**Assessment process for fresh skill development programs (Short term without apprenticeship):**

- Every fresh batch is uploaded on Skill Development Management System (SDMS) managed by National Skill Development Corporation (NSDC). SDMS reflects the Start date, end date of the training and date of assessment for the batch. The batch is uploaded on SDMS by Vocational Training Centre.
- LSSSDC conducts Assessments via its empaneled Assessment Agencies and assigns the batch to an assessment agency pre-notified with NSQC for the job role.
- Assessment agency ensures the availability of required infrastructure, tools for the assessment.
- Assessments for Fresh candidates are conducted in mode of Theory and Viva for Skill Practical. Skill Viva is conducted by an Assessor.
- In case an assessor is involved in the assessment methodology, the trainees are scheduled in such a way that an assessor shall not assess more than 30 candidates in a day.
- Assessor and proctor from Assessment agency are present on the day of assessment to manage the process at assessment location.
- The assessor carry Aadhaar card and which has been pre informed to the vocational training center.
- Assessor ensures authenticity of Trainee's identity by verifying the documents (any document issued by GOI, such as Aadhar Card, Driving License, Passport, election card etc.)
- Assessor collects evidences of the assessment in best possible way (videos, pictures etc.)
- Proctor maintains the records of attendance, verified documents, and whatever other evidence of assessment as applicable.
- Assessor maintains complete confidentiality of the score, compiles the data and document and sends it to assessment agency.
- In cases where 100% digital assessment methodology is used, the above verifications and document collection and maintenance is done by the proctor.

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- The assessment agency after processing the results and putting them in standard format hands over to LSSSDC within 7 days from the date of assessment.
- LSSSDC validates the assessment results and announces the result on SDMS within 15 days of assessment date.
- Passed candidates are provided with qualification certificate.

**Assessment tools:** Assessment tools for a Qualification are decided based on composition of knowledge and skill in that Qualification. All assessments shall have at least two tools unless indicated otherwise. All assessments carry time allotment required per trainee, within which the assessment should be completed.

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

Scope – Is used to test the knowledge component of the Qualification.

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 in sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.

### **Digital Written test for skill assessment**

Scope – Is used to test primarily the Skill component of the Qualification.

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 in sections. Each Section intends to assess a particular skill field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.

### **Assessment process for Apprenticeship linked fresh skill development programs (Short term with apprenticeship):**

The assessment for the Basic Training and On the Job Training will be conducted toward the end of the OJT duration.

#### **Assessment Process:**

The assessment will be in two parts as below:

#### **Part 1: OJT Assessment**

For OJT assessment the Industry nominated assessor will be assessing the candidates based on the OJT monitoring report submitted by Industry supervisor and Viva by the Industry nominated assessor

**1.1 Industry nominated assessor:**

The Assessors are engaged to conduct the assessments by Industry. The selection takes place as follows

- Industry defines the criteria for profile of an assessor.
- Assessor is a person who is currently working in the same industry on same or higher job role and has minimum 5-7 years of experience.
- Once selected, the assessor is oriented by Industry using LSSSDC guidelines on various aspects of the assessment and management of assessment, such as
  - Qualification and its background.
  - Training on Assessment methodology and how to use Assessment tools. Scoring system. (as per the attached assessment guide)
  - Maintain integrity at the assessment site.
  - Crisis handling and support system available for the same.
  - Scope of his authorities
  - Administrative responsibilities.
  - Required documentation of Trainee credentials, mark sheet management.
  - Confidentiality management.

**1.2 Assessment Tool for OJT:****1.2.1 OJT Monitoring Report:**

- As in Life Sciences Sector reproducing the evidence for assessment is not feasible due to constraints like cost, confidentiality and controlled environment, every apprentice is required to record the evidences performed during the OJT and the same gets authorized by his/her supervisor.
- The evidence recording is done in a structured monitoring report, termed as OJT monitoring report.
- During the OJT, every trainee is required to fill the OJT monitoring report which is required to be signed by his/her supervisor.
- Towards the end of OJT period these reports are submitted with the HR department of company
- These duly submitted reports are then verified by an Industry nominated assessor for verification of evidence.

**1.2.2 Viva:**

**Scope** – Is used to test the knowledge and understanding and skills acquired during the OJT as well as to conform the OJT monitoring report.

Some personality traits and generic skills (such as – promptness, sharpness, communication skills, depth of knowledge, comprehension, presentation, patience etc) can also be tested required for the Qualification.

**Tools** – Direct dialogue between assessor and Trainee.

**Method** – Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions.

Different questions are included to test relevant PCs from the Qualification

**Analysis** – Assessor draws a spectrum of ready answers to be expected from trainee. This reduces effect of subjectivity of the assessor. Comparative quality of trainees within a batch or different institutes can be gauged.

### **1.3 Execution of OJT Assessment:**

- HR department then hands over the individual OJT monitoring report with Industry nominated assessor and schedules an assessment meeting for each trainee
- Industry nominated assessor assesses each trainee based on OJT monitoring report, viva on each PC and attendance with each trainee towards the end of the OJT period.
- The OJT marks are compiled for each NOS by the Industry nominated assessor and submitted with HR department of company.
- The OJT assessment results are then sent to LSSSDC by HR department of company in a sealed envelope for compiling the assessment results.

## **Part 2: Basic Training Assessment**

For Execution of the assessment for basic training, LSSSDC will be engaging more than one assessment agencies/ body.

### **2.1 Criteria of selection of assessment body/agency:**

The assessment body/agency is selected on the basis of

- 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 in assessor management

### **2.2 Assessment tool for Basic Training:**

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

#### **2.2.1 Digital Written test for knowledge assessment:**

**Scope** – Is used to test the knowledge component of the Qualification.

**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 in sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or

expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.

### **2.2.2 Digital Written test for skill assessment:**

**Scope** – Is used to test primarily the Skill component of the qualification. 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 in sections. Each Section intends to assess a particular skill field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.

### **2.3 Steps for assessment development:**

- Selection of assessment tool(s) is done as per the assessment criteria prescribed in Qualification.
- For Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) assessment a blue print of the question paper, is part of assessment tool for basic training.
- Development of lay-out of Question paper is such that the entire PCs (Performance Criteria) of that qualification 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 same occupation.
- SME is screened and approved by LSSSDC. He is oriented by both LSSSDC and Assessment agency on – creating question Bank, level of questions, end desired outcome of the assessment.

### **2.4 Execution of Basic Training Assessment:**

- Post the assessment schedule confirmation of all trainees due for assessments through Apprenticeship India portal, the assessment date for basic training is decided with common agreement of Industry and LSSSDC and LSSSDC directs it's an assessment body/agency.
- Assessment agency ensures the availability of required infrastructure, tools for the assessment.
- The assessment is executed in two possible ways depending on the choice of industry:

2.4.1 Tab based assessment using physical proctoring

2.4.2 Smart phone-based assessment using e-proctoring

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



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- A representative from Assessment agency are present on the day of assessment to execute the assessment at venue in case of physical proctoring.
- Assessment agency representative carries an identity card and letter from the council authorising to conduct the assessment.
- Assessment agency representative ensures authenticity of Trainee's identity by verifying the documents (any document issued by GOI, such as Ration card, Aadhaar Card, Driving Licence, Passport, election card etc)
- Assessment agency representative maintains the records of attendance, verified documents and tablet instruments used in assessment.
- Assessment agency representative collects evidences of the assessment in best possible way (videos, pictures, voice recordings etc)
- Assessment agency representative transfer 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.

### 2.4.2 Smart phone-based assessment using e-proctoring

- All trainees due for assessments are registered on a 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 smart phone or a web camera enabled computer system
- Using the unique credentials and govt ID number, trainee logs in for start of assessment and completes the assessment.
- 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 candidate during the assessment is captured to collect the evidences of the assessment
- Once the assessment is complete, the assessment application automatically assessment scores 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.

#### Assessment Result compilation:

- In case of offline OJT assessment -The OJT assessment results are sent to LSSSDC by HR department of company in a sealed envelope for compiling the assessment results.



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	<ul style="list-style-type: none"><li>• LSSSDC cross checks and validates the data and declares the result to Industry and trainee.</li><li>• In case of online OJT assessment-Industry nominated assessor certified by LSSSDC will be uploading the results on apprenticeshipindia.org portal.</li><li>• Passed trainees are provided with certificate.</li></ul> <p>Note: At any point of time assessment strategy would be as per the current guidelines from MSDE.</p>
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### SECTION 1

#### ASSESSMENT

- LSSSDC Protocol for Accreditation of Assessment Agencies and Assessment Guideline Ver1.00 is attached as annexure 3

NSQC Approved

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**ASSESSMENT EVIDENCE**

Marks Allocation					
Assessment outcomes	Assessment Criteria for outcomes	Theor y	Skills Practic al	Proj ect	Viv a
1. LFS/N0341 v2.0: Perform quality checks in the manufacturing/pr oduction units in compliance with regulatory guidelines	<i>Pre-production checks</i>	8	15	3	4
	PC1. check if the manufacturing facility (area & process) is meeting the basic GMP requirements (e.g. facility upkeep, labeling policy, environmental conditions, cross-contamination guidelines, segregation of materials)	-	-	-	-
	PC2. determine appropriate quality monitoring arrangements for the processes and procedures of manufacturing, quality control, warehouse and engineering departments	-	-	-	-
	PC3. monitor the validation and qualification activities of machines as per validation master plan for compliances with regulatory guidelines	-	-	-	-
	PC4. implement regulatory policies and procedures in the manufacturing facility	-	-	-	-
	<i>In-Process checks</i>	8	15	3	4
	PC5. ensure in-process checks are conducted at relevant processing stages as per required specifications	-	-	-	-
	PC6. perform material verification activities to check if the right material, in the right quantity for the batch has been issued	-	-	-	-
	PC7. collect control samples from each batch of finished goods, manufactured goods	-	-	-	-

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Marks Allocation					
Assessment outcomes	Assessment Criteria for outcomes	Theor y	Skills Practic al	Proj ect	Viv a
	and raw material ingredients received				
	PC8. verify production area and equipment to ensure that there is no chance of contamination for the next product from the traces of previous product	-	-	-	-
	PC9. ensure the quality management system (QMS) elements such as change control, incident management, CAPA management are adhered to on the shop floor	-	-	-	-
	PC10. carry out investigations related to complaints, batch failures, Out of Specification (OOS) incidents and report monthly and year-to-date comparisons	-	-	-	-
	PC11. check the causes of any non-conformity from the standard protocols and work on its corrective/preventive action	-	-	-	-
	PC12. carry out sampling activities for quality assurance audit across stages	-	-	-	-
	PC13. provide document support to regulatory departments for the compilation of various regulatory documents	-	-	-	-
	PC14. conduct the product quality review and communicate the findings to the quality management review members and regulatory bodies	-	-	-	-
	PC15. assist the quality manager in continuous improvement				

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Marks Allocation					
Assessment outcomes	Assessment Criteria for outcomes	Theor y	Skills Practic al	Proj ect	Viv a
	initiatives to enhance product quality, compliance, and efficiency	-	-	-	-
	<i>Post-production checks</i>	<b>5</b>	<b>10</b>	<b>3</b>	<b>2</b>
	PC16. monitor adherence to various good manufacturing practices activities and procedures in the receipt, storage, testing, processing and dispatch of products	-	-	-	-
	PC17. review batch manufacturing/batch processing, packaging and analytical records, equipment logs etc. before batch release	-	-	-	-
	PC18. manage activities such as audits, regulatory agency inspections, or product recalls	-	-	-	-
	PC19. communicate regulatory information to multiple departments for smooth flow of work	-	-	-	-
	<i>Environment Sustainability</i>	<b>5</b>	<b>10</b>	<b>3</b>	<b>2</b>
	PC1. ensure energy conservation by switching off the machine and equipment post operations	-	-	-	-
	PC2. identify ways to optimize the usage of electricity/energy in various tasks/activities/processes	-	-	-	-
	PC3. ensure energy conservation by optimizing the machine/equipment performance	-	-	-	-
	PC4. identify recyclable and non-recyclable, and hazardous waste generated	-	-	-	-
	PC5. segregate waste into different categories to				

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Assessment outcomes	Assessment Criteria for outcomes	Theor y	Skills Practic al	Proj ect	Viv a
	achieve minimum pollution of land and water	-	-	-	-
	<b>Total</b>	<b>26</b>	<b>50</b>	<b>12</b>	<b>12</b>
<b>2</b> LFS/N0345 v2.0: Perform reporting and documentation to meet regulatory standards	<i>Reporting</i>	<b>10</b>	<b>15</b>	<b>5</b>	<b>5</b>
	PC1.follow the reporting procedures and formats as prescribed by the company	-	-	-	-
	PC2. prepare external and internal reports and other documentation required by regulatory agencies, or customers, to support the quality assurance function	-	-	-	-
	PC3. prepare process validation protocols and summary reports based on the analytical results and batch documents data	-	-	-	-
	<i>Recording and documentation</i>	<b>10</b>	<b>15</b>	<b>5</b>	<b>5</b>
	PC4. perform the documentation for all the observations in a prescribed format	-	-	-	-
	PC5. complete all documentation within the stipulated time as per company procedure	-	-	-	-
	PC6. prepare documents required for forthcoming quality audits	-	-	-	-
	PC7. compile statistical data and writes narrative reports summarizing quality assurance findings, along with a review of documents	-	-	-	-
	PC8. maintain complete and accurate documentary evidence concerning Qualification, and Validation exercises	-	-	-	-
	PC9. ensure that the final document meets regulatory				

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Assessment outcomes	Assessment Criteria for outcomes	Theor y	Skills Practic al	Proj ect	Viv a
	and compliance requirements as per GDP and GMP	-	-	-	-
	<i>Data Integrity</i>	10	15	3	2
	PC10. maintain all original and controlled document files and quality records in a timely and accurate manner as per ALCOA PLUS principles	-	-	-	-
	PC11. respond to requests for information in an appropriate manner whilst following organizational procedures	-	-	-	-
	PC12. make sure documents are available to all appropriate authorities to inspect/ audit	-	-	-	-
	<b>Total</b>	<b>30</b>	<b>45</b>	<b>13</b>	<b>12</b>
3. LFS/N0110 v2.0: Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab	<i>Adhere to health and hygiene protocol</i>	10	20	-	-
	PC1. comply with health and personal hygiene-related protocols as per WHO standards and ICH GMP guidelines	-	-	-	-
	PC2. sanitize your hands before entering in laboratory and production area and ensure the adherence of same by subordinates	-	-	-	-
	PC3. report any allergy, sickness or any other environment-related breach before or after entering the work premises to the designated person	-	-	-	-
	PC4. take preventive actions on the report of any allergy, sickness or any other	-	-	-	-

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Marks Allocation					
Assessment outcomes	Assessment Criteria for outcomes	Theor y	Skills Practic al	Proj ect	Viv a
	environment-related breach by subordinates				
	PC5. wear lab coat all the time while working in a laboratory and ensure adherence of the same by every person visiting/ working in the lab area	-	-	-	-
	PC6. follow gowning procedures while entering an environment controlled work area	-	-	-	-
	<i>Adhere to safety and security procedures</i>	10	20	-	5
	PC7. comply with safety and security policies and procedures	-	-	-	-
	PC8. ensure the use of appropriate safety gears like headgear, masks, gloves and other accessories as mentioned in the guidelines, by self and subordinates while carrying out work	-	-	-	-
	PC9. take preventive and corrective actions on the report of any identified breaches in safety and security policies and procedures by subordinates	-	-	-	-
	PC10. ensure proper material segregation and labelling	-	-	-	-
	PC11. comply with material handling, segregation, storage, and MSDS guidelines as per 5S system	-	-	-	-
	PC12. supervise the disposal of waste/unused and expired reagents/ chemicals / biological waste using environmentally sustainable	-	-	-	-



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Assessment outcomes	Assessment Criteria for outcomes	Theor y	Skills Practic al	Proj ect	Viv a
	methods in the presence of EHS personnel				
	PC13. take corrective actions for reported hazards in consultation with EHS personnel	-	-	-	-
	PC14. complete records of safety drills and training undertaken by self and subordinates	-	-	-	-
	<i>Adhere to emergency procedures</i>	10	20	-	5
	PC15. raise the alarm and inform the concerned designated person immediately for action in the cases of spill, fall, injury, toxic inhale, fire or explosion	-	-	-	-
	PC16. follow emergency protocol for any alarms and ensure the safety of subordinates in the area under supervision	-	-	-	-
	PC17. follow emergency procedures efficiently	-	-	-	-
	PC18. ensure injured employees are provided appropriate first aid and medical aid	-	-	-	-
	<b>Total</b>	<b>30</b>	<b>60</b>	<b>-</b>	<b>10</b>
	<i>Coordination with Supervisor</i>	<b>10</b>	<b>15</b>	<b>3</b>	<b>2</b>
3. LFS/N0346 v2.0: Coordinate with Supervisor, team members, cross-functional	PC1. provide support to supervisor for carrying out investigations related to complaints, batch failures, OOS/ OOT, incidents etc.	-	-	-	-
	PC2. communicate any potential hazards or expected process disruptions to the supervisor	-	-	-	-

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Assessment outcomes	Assessment Criteria for outcomes	Theor y	Skills Practic al	Proj ect	Viv a
teams and auditors	PC3. provide the requisite information, documents, clarifications to the supervisor during actual audits	-	-	-	-
	PC4. submit completed work reports to supervisor on time	-	-	-	-
	<i>Coordination with team members</i>	<b>10</b>	<b>15</b>	<b>3</b>	<b>2</b>
	PC5. work as a team with colleagues and share work as per their workload	-	-	-	-
	PC6. collect data to be recorded in logbooks and batch documents from team members and colleagues	-	-	-	-
	PC7. support team members during internal and external audit activities	-	-	-	-
	PC8. communicate workflow related difficulties to find solutions with mutual agreement	-	-	-	-
	PC9. maintain their own as well as team members sense of calm/equilibrium	-	-	-	-
	<i>Coordination with cross-functional teams and auditors</i>	<b>5</b>	<b>10</b>	<b>3</b>	<b>2</b>
	PC10. train staff of other departments in regulatory policies or procedures	-	-	-	-
	PC11. support colleagues of other departments in work	-	-	-	-
	PC12. coordinate with cross-functional teams while performing inspections for various departments as per predefined schedules	-	-	-	-

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Assessment outcomes	Assessment Criteria for outcomes	Theor y	Skills Practic al	Proj ect	Viv a
	PC13. coordinate with production, quality team for line clearance, change control approvals as well as calibration and validation activities	-	-	-	-
	PC14. respond appropriately to the queries of auditors , maintaining integrity and confidence	-	-	-	-
	PC15. provide appropriate documented records of performed activities and operations to auditors	-	-	-	-
	<i>Sensitivity towards all genders and people with disability</i>	5	10	3	2
	PC16. respect all genders, religions, and caste	-	-	-	-
	PC17. empathize with people with disability	-	-	-	-
	PC18. offer support or help to a person with disability only when asked	-	-	-	-
	PC19. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act	-	-	-	-
	PC20. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee	-	-	-	-
	<b>Total</b>	<b>30</b>	<b>50</b>	<b>12</b>	<b>8</b>
	<i>Adhere to health and hygiene protocol</i>	10	20	-	-
	PC1. comply with health and personal hygiene-related	-	-	-	-

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Marks Allocation					
Assessment outcomes	Assessment Criteria for outcomes	Theor y	Skills Practic al	Proj ect	Viv a
4. LFS/N0110 v2.0: Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab	protocols as per WHO standards and ICH GMP guidelines				
	PC2. sanitize your hands before entering in laboratory and production area and ensure the adherence of same by subordinates	-	-	-	-
	PC3. report any allergy, sickness or any other environment-related breach before or after entering the work premises to the designated person	-	-	-	-
	PC4. take preventive actions on the report of any allergy, sickness or any other environment-related breach by subordinates				
	PC5. wear lab coat all the time while working in a laboratory and ensure adherence of the same by every person visiting/ working in the lab area				
	PC6. follow gowning procedures while entering an environment controlled work area and ensure the adherence of the same by subordinates	-	-	-	-
	<i>Adhere to safety and security procedures</i>	<b>10</b>	<b>20</b>	-	<b>5</b>
	PC7. observe compliance by self and subordinates with safety and security policies and procedures	-	-	-	-
	PC8. ensure the use of appropriate safety gears like headgear, masks, gloves and other accessories as	-	-	-	-

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Assessment outcomes	Assessment Criteria for outcomes	Theor y	Skills Practic al	Proj ect	Viv a
	mentioned in the guidelines, by self and subordinates while carrying out work				
	PC9. take preventive and corrective actions on the report of any identified breaches in safety and security policies and procedures by subordinates	-	-	-	-
	PC10. ensure proper material segregation and labelling	-	-	-	-
	PC11. comply with material handling, segregation, storage, and MSDS guidelines as per 5S system	-	-	-	-
	PC12. supervise the disposal of waste/unused and expired reagents/ chemicals / biological waste using environmentally sustainable methods in the presence of EHS personnel	-	-	-	-
	PC13. take corrective actions for reported hazards in consultation with EHS personnel	-	-	-	-
	PC14. complete records of safety drills and training undertaken by self and subordinates	-	-	-	-
	<i>Adhere to emergency procedures</i>	<b>10</b>	<b>20</b>	-	<b>5</b>
	PC15. raise the alarm and inform the concerned designated person immediately for action in the cases of spill, fall, injury, toxic inhale, fire or explosion	-	-	-	-
	PC16. follow emergency protocol for any alarms and ensure	-	-	-	-

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Assessment outcomes	Assessment Criteria for outcomes	Theor y	Skills Practic al	Proj ect	Viv a
	the safety of subordinates in the area under supervision				
	PC17. follow emergency procedures efficiently	-	-	-	-
	PC18. ensure injured employees are provided appropriate first aid and medical aid				
	<b>Total</b>	<b>30</b>	<b>60</b>	<b>-</b>	<b>10</b>
2.DGT/VSQ/N01 03 V1.0: Employability Skills (90 Hours)	<i>Introduction to Employability Skills</i>	1	1	-	-
	PC 1. understand the significance of employability skills in meeting the current job market requirement and future of work.	-	-	-	-
	PC 2. identify and explore learning and employability relevant portals	-	-	-	-
	PC 3. research about the different industries, job market trends, latest skills required and the available opportunities				
	<i>Constitutional values – Citizenship</i>	1	1	-	-
	PC 4. recognize the significance of constitutional values, including civic rights and duties, citizenship, responsibility towards society etc. and personal values and ethics such as honesty, integrity, caring and respecting others, etc.	-	-	-	-

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Assessment outcomes	Assessment Criteria for outcomes	Theor y	Skills Practic al	Proj ect	Viv a
	PC 5. follow environmentally sustainable practices	-	-	-	-
	<i>Becoming a Professional in the 21st Century</i>	1	3	-	-
	PC 6. recognize the significance of 21st Century Skills for employment	-	-	-	-
	PC 7. practice the 21st Century Skills such as Self-Awareness, Behavior Skills, time management, critical and adaptive thinking, problem-solving, creative thinking, social and cultural awareness, emotional awareness, learning to learn for continuous learning etc. in personal and professional life	-	-	-	-
	PC 8. adopt a continuous learning mindset for personal and professional development				
	<i>Basic English Skills</i>	3	4	-	-
	PC 9. use basic English for everyday conversation in different contexts, in person and over the telephone	-	-	-	-
	PC 10. read and understand routine information, notes, instructions, mails, letters etc. written in English	-	-	-	-



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Assessment outcomes	Assessment Criteria for outcomes	Theor y	Skills Practic al	Proj ect	Viv a
	PC 11. write short messages, notes, letters, e-mails etc. in English	-	-	-	-
	<i>Career Development &amp; Goal Setting</i>	1	2	-	-
	PC 12. identify career goals based on the skills, interests, knowledge, and personal attributes	-	-	-	-
	PC 13. prepare a career development plan with short- and long-term goals.	-	-	-	-
	<i>Communication Skills</i>	2	2	-	-
	PC 14. follow verbal and non-verbal communication etiquette while communicating in professional and public settings	-	-	-	-
	PC 15. use active listening techniques for effective communication	-	-	-	-
	PC 16. communicate in writing using appropriate style and format based on formal or informal requirements				
	PC 17. work collaboratively with others in a team				
	<i>Diversity &amp; Inclusion</i>	1	1	-	-
	PC 18. communicate and behave appropriately with all genders and PwD	-	-	-	-

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Assessment outcomes	Assessment Criteria for outcomes	Theor y	Skills Practic al	Proj ect	Viv a
	PC 19. escalate any issues related to sexual harassment at workplace according to POSH Act	-	-	-	-
	<i>Financial and Legal Literacy</i>	2	3	-	-
	PC 20. identify and select reliable institutions for various financial products and services such as bank account, debit and credit cards, loans, insurance etc.	-	-	-	-
	PC 21. carry out offline and online financial transactions, safely and securely, using various methods and check the entries in the passbook	-	-	-	-
	PC 22. identify common components of salary and compute income, expenses, taxes, investments etc	-	-	-	-
	PC 23. identify relevant rights and laws and use legal aids to fight against legal exploitation	-	-	-	-
	<i>Essential Digital Skills</i>	3	5	-	-
	PC 24. operate digital devices and carry out basic internet operations securely and safely	-	-	-	-
	PC 25. carry out basic internet operations by connecting to the internet safely and	-	-	-	-

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Assessment outcomes	Assessment Criteria for outcomes	Theor y	Skills Practic al	Proj ect	Viv a
	securely, using the mobile data or other available networks through Bluetooth, Wi-Fi, etc.				
	PC 26. display responsible online behavior while using various social media platforms	-	-	-	-
	PC 27. create a personal email account, send and process received messages as per requirement				
	PC 28. carry out basic procedures in documents, spreadsheets and presentations using respective and appropriate applications				
	PC 29. utilize virtual collaboration tools to work effectively				
	<i>Entrepreneurship</i>	2	3	-	-
	PC 30. identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research	-	-	-	-
	PC 31. develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion	-	-	-	-
	PC 32. identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the	-	-	-	-

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Assessment outcomes	Assessment Criteria for outcomes	Theor y	Skills Practic al	Proj ect	Viv a
	potential business opportunity				
	<i>Customer Service</i>	1	2	-	-
	PC 33. identify different types of customers and ways to communicate with them	-	-	-	-
	PC 34. identify and respond to customer requests and needs in a professional manner	-	-	-	-
	PC 35. use appropriate tools to collect customer feedback	-	-	-	-
	PC 36. follow appropriate hygiene and grooming standards				
	<i>Getting ready for apprenticeship &amp; Jobs</i>	2	3	-	-
	PC 37. create a professional Curriculum vitae (Résumé)	-	-	-	-
	PC 38. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively	-	-	-	-
	PC 39. apply to identified job openings using offline /online methods as per requirement	-	-	-	-
	PC 40. answer questions politely, with clarity and confidence, during recruitment and selection	-	-	-	-
	PC 41. identify apprenticeship opportunities and register	-	-	-	-

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<b>Marks Allocation</b>					
<b>Assessment outcomes</b>	<b>Assessment Criteria for outcomes</b>	<b>Theor y</b>	<b>Skills Practic al</b>	<b>Proj ect</b>	<b>Viv a</b>
	for it as per guidelines and requirements				
	<b>NOS Total</b>	<b>20</b>	<b>30</b>	<b>-</b>	<b>-</b>

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### 24. Assessment evidences

**Title of Component:** 1. LFS/N0341 v2.0: Perform quality checks in the manufacturing/ production units in compliance with regulatory guidelines

Outcomes to be assessed/NOSs to be assessed	Assessment criteria for the outcome
<i>Pre-production checks</i>	PC1. check if the manufacturing facility (area & process) is meeting the basic GMP requirements (e.g. facility upkeep, labeling policy, environmental conditions, cross-contamination guidelines, segregation of materials)
	PC2. determine appropriate quality monitoring arrangements for the processes and procedures of manufacturing, quality control, warehouse and engineering departments
	PC3. monitor the validation and qualification activities of machines as per validation master plan for compliances with regulatory guidelines
	PC4. implement regulatory policies and procedures in the manufacturing facility
<i>In-Process checks</i>	PC5. ensure in-process checks are conducted at relevant processing stages and met the requisite acceptance criteria/specifications
	PC6. perform material verification activities to check if the right material, in the right quantity for the batch has been issued
	PC7. collected control samples from each batch of finished goods manufactured and from each batch of raw material ingredients received
	PC8. verify adherence to cleaning SOPs and cleanliness of equipment and area used for production to ensure there is no contamination of the next product from the previous product traces
	PC9. ensure the quality management system (QMS) elements such as change control, incident management, CAPA management are adhered to on the shop floor
	PC10. carry out investigations related to complaints, batch failures, Out of Specification (OOS) incidents and report monthly and year-to-date comparisons
	PC11. check the causes of any non-conformity from the standard protocols and work on its corrective/preventive action
	PC12. carry out sampling activities for quality assurance audit across stages

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	<p>PC13. provide document support to regulatory departments for the compilation of various regulatory documents</p> <p>PC14. conduct the product quality review and communicate the findings to the quality management review members and regulatory bodies</p> <p>PC15. assist the quality manager in continuous improvement initiatives to enhance product quality, compliance, and efficiency</p>
<p><i>Post-production checks</i></p>	<p>PC16. monitor adherence to various good manufacturing practices activities and procedures in the receipt, storage, testing, processing and dispatch of products</p> <p>PC17. review batch manufacturing/batch processing, packaging and analytical records, equipment logs etc. before batch release</p> <p>PC18. manage activities such as audits, regulatory agency inspections, or product recalls</p> <p>PC19. communicate regulatory information to multiple departments and ensure that information is interpreted correctly</p>
<p><i>Environment Sustainability</i></p>	<p>PC20. ensure energy conservation by switching off the machine and equipment post operations</p> <p>PC21. identify ways to optimize the usage of electricity/energy in various tasks/activities/processes</p> <p>PC22. ensure energy conservation by optimizing the machine/ equipment performance</p> <p>PC23. identify recyclable and non-recyclable, and hazardous waste generated</p> <p>PC24. segregate waste into different categories to achieve minimum pollution of land and water</p>
<p><b>Means of assessment 1</b></p>	<p><b>Digital Written test for knowledge assessment:</b></p> <p><u>Scope</u> – Is used to test the knowledge component of the Qualification.</p> <p><u>Tools</u> – Computer or tab based online or offline.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – Question paper is divided in sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.</p>



<b>Means of assessment 2</b>	<p><b>Digital Written test for skill assessment</b></p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in handling and managing the situation is tested.</p> <p><u>Tools</u> – computer or tab based online or offline questions.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – Question paper is divided in sections. Each Section intends to assess a particular skill field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.</p>
<b>Means of assessment 3</b>	<p><b>Project Assessment</b></p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in utilization of knowledge and skills in real life job scenarios</p> <p><u>Tools</u> – Project report.</p> <p><u>Method</u> – The trainee is deployed in Industry for on the job trainee or is being asked to work on a specific project (utilizing skills as per qualification). A project report duly endorsed by his/her project supervisor is prepared by the trainee and submitted for evaluation. The Assessor asks Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions based on the project report</p> <p><u>Analysis</u> –Project Assessments are analysed on knowledge and skill component.</p>
<b>Means of assessment 4</b>	<p><b>Viva</b></p> <p><u>Scope</u> – Is used to test the knowledge and understanding and breadth of awareness about the subject.</p> <p>Some personality traits and generic skills (such as – promptness, sharpness, communication skills, depth of knowledge, comprehension, presentation, patience etc) can also be tested required for the qualification.</p> <p><u>Tools</u> – Direct dialogue between assessor and Trainee.</p> <p><u>Method</u> – Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions. Different questions are included to test relevant PCs from the qualification</p> <p><u>Analysis</u> – Assessor is provided with spectrum of ready answers to be expected from trainee. This</p>

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reduces effect of subjectivity of the assessor. Comparative quality of trainees with in a batch or different institutes can be gauged
<b>Pass/Fail</b> The aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment, Project and Viva is 70%. In case of RPL where Project will not be there ,the aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment and Viva shall also be 70%.

**Title of Component:** 2. LFS/N0345 v2.0: Perform reporting and documentation to meet quality and regulatory standards

Outcomes to be assessed/NOSs to be assessed	Assessment criteria for the outcome
Reporting	PC1. follow the reporting procedures and formats as prescribed by the company
	PC2. prepare external and internal reports and other documentation required by regulatory agencies, or customers, to support the quality assurance function
	PC3. prepare process validation protocols and summary reports based on the analytical results and batch documents data
Recording and documentation	PC4. perform the documentation for all the observations in a prescribed format
	PC5. complete all documentation within the stipulated time as per company procedure
	PC6. prepare documents required for forthcoming quality audits
	PC7. compile statistical data and writes narrative reports summarizing quality assurance findings, along with a review of documents
	PC8. maintain complete and accurate documentary evidence concerning Qualification, and Validation exercises
	PC9. ensure that the final document meets regulatory and compliance requirements as per GDP and GMP
Data Integrity	PC10. maintain all original and controlled document files and quality records in a timely and accurate manner as per ALCOA PLUS principles
	PC11. respond to requests for information in an appropriate manner whilst following organizational procedures
	PC12. make sure documents are available to all appropriate authorities to inspect/ audit

<b>Means of assessment 1</b>	<p><b>Digital Written test for knowledge assessment:</b></p> <p><u>Scope</u> – Is used to test the knowledge component of the Qualification.</p> <p><u>Tools</u> – Computer or tab based online or offline.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – Question paper is divided in sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.</p>
<b>Means of assessment 2</b>	<p><b>Digital Written test for skill assessment</b></p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in handling and managing the situation is tested.</p> <p><u>Tools</u> – computer or tab based online or offline questions.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – Question paper is divided in sections. Each Section intends to assess a particular skill field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.</p>
<b>Means of assessment 3</b>	<p><b>Project Assessment</b></p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in utilization of knowledge and skills in real life job scenarios</p> <p><u>Tools</u> – Project report.</p> <p><u>Method</u> – The trainee is deployed in Industry for on the job trainee or is being asked to work on a specific project (utilizing skills as per qualification). A project report duly endorsed by his/her project supervisor is prepared by the trainee and submitted for evaluation. The Assessor asks Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions based on the project report</p> <p><u>Analysis</u> –Project Assessments are analysed on knowledge and skill component.</p>

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### Means of assessment 4

#### Viva

Scope – Is used to test the knowledge and understanding and breadth of awareness about the subject.

Some personality traits and generic skills (such as – promptness, sharpness, communication skills, depth of knowledge, comprehension, presentation, patience etc) can also be tested required for the qualification.

Tools – Direct dialogue between assessor and Trainee.

Method – Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions. Different questions are included to test relevant PCs from the qualification

Analysis – Assessor is provided with spectrum of ready answers to be expected from trainee. This reduces effect of subjectivity of the assessor.

Comparative quality of trainees with in a batch or different institutes can be gauged

### Pass/Fail

The aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment, Project and Viva is 70%. In case of RPL where Project will not be there, the aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment and Viva shall also be 70%.

**Title of Component:**3. LFS/N0346 v2.0: Coordinate with Supervisor, team members, cross-functional teams and auditors

Outcomes to be assessed/NOSs to be assessed	Assessment criteria for the outcome
Coordination with Supervisor	PC1. provide support to supervisor for carrying out investigations related to complaints, batch failures, OOS/ OOT, incidents etc.
	PC2. communicate any potential hazards or expected process disruptions to the supervisor
	PC3. provide the requisite information, documents, clarifications to the supervisor during actual audits
	PC4. submit completed work reports to supervisor on time
Coordination with team members	PC5. work as a team with colleagues and share work as per their workload
	PC6. collect data to be recorded in logbooks and batch documents from team members and colleagues
	PC7. support team members during internal and external audit activities

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Coordination with cross-functional teams and auditors	PC8. communicate workflow related difficulties to find solutions with mutual agreement
	PC9. maintain their own as well as team members sense of calm/equilibrium
	PC10. train staff of other departments in regulatory policies or procedures
	PC11. support colleagues of other departments in work
	PC12. coordinate with cross-functional teams while performing inspections for various departments as per predefined schedules
	PC13. coordinate with production, quality team for line clearance, change control approvals as well as calibration and validation activities
	PC14. respond appropriately to the queries of auditors , maintaining integrity and confidence
Sensitivity towards all genders and people with disability	PC15. provide appropriate documented records of performed activities and operations to auditors
	PC16. respect all genders, religions, and caste
	PC17. empathize with people with disability
	PC18. offer support or help to a person with disability only when asked
	PC19. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act
Means of assessment 1	PC20. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee
	<p><b>Digital Written test for knowledge assessment:</b></p> <p><u>Scope</u> – Is used to test the knowledge component of the Qualification.</p> <p><u>Tools</u> – Computer or tab based online or offline.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – Question paper is divided in sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.</p>
Means of assessment 2	<b>Digital Written test for skill assessment</b>

	<p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in handling and managing the situation is tested.</p> <p><u>Tools</u> – computer or tab based online or offline questions.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – Question paper is divided in sections. Each Section intends to assess a particular skill field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.</p>
<b>Means of assessment 3</b>	<p><b>Project Assessment</b></p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in utilization of knowledge and skills in real life job scenarios</p> <p><u>Tools</u> – Project report.</p> <p><u>Method</u> – The trainee is deployed in Industry for on the job trainee or is being asked to work on a specific project (utilizing skills as per qualification). A project report duly endorsed by his/her project supervisor is prepared by the trainee and submitted for evaluation. The Assessor asks Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions based on the project report</p> <p><u>Analysis</u> –Project Assessments are analysed on knowledge and skill component.</p>
<b>Means of assessment 4</b>	<p><b>Viva</b></p> <p><u>Scope</u> – Is used to test the knowledge and understanding and breadth of awareness about the subject.</p> <p>Some personality traits and generic skills (such as – promptness, sharpness, communication skills, depth of knowledge, comprehension, presentation, patience etc) can also be tested required for the qualification.</p> <p><u>Tools</u> – Direct dialogue between assessor and Trainee.</p> <p><u>Method</u> – Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions. Different questions are included to test relevant PCs from the qualification</p> <p><u>Analysis</u> – Assessor is provided with spectrum of ready answers to be expected from trainee. This reduces effect of subjectivity of the assessor.</p>



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Comparative quality of trainees with in a batch or different institutes can be gauged
<b>Pass/Fail</b> The aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment, Project and Viva is 70%. In case of RPL where Project will not be there ,the aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment and Viva shall also be 70%.

**Title of Component:** 4. LFS/N0110 v2.0: Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab

Outcomes to be assessed/NOSs to be assessed	Assessment criteria for the outcome
Adhere to health and hygiene protocols	PC1. comply with health and personal hygiene-related protocols as per WHO standards and ICH GMP guidelines
	PC2. sanitize your hands before entering in laboratory and production area and ensure the adherence of same by subordinates
	PC3. report any allergy, sickness or any other environment-related breach before or after entering the work premises to the designated person
	PC4. take preventive actions on the report of any allergy, sickness or any other environmentrelated breach by subordinates
	PC5.wear lab coat all the time while working in a laboratory and ensure adherence of the same by every person visiting/ working in the lab area
	PC6.follow gowning procedures while entering an environment controlled work area and ensure the adherence of the same by subordinates
Adhere to safety and security procedures	PC7.observe compliance by self and subordinates with safety and security policies and procedures
	PC8.ensure the use of appropriate safety gears like headgear, masks, gloves and other accessories as mentioned in the guidelines, by self and subordinates while carrying out work
	PC9.take preventive and corrective actions on the report of any identified breaches in safety and security policies and procedures by subordinates
	PC10.ensure proper material segregation and labelling
	PC11.comply with material handling, segregation, storage, and MSDS guidelines as per 5S system

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	PC12.supervise the disposal of waste/unused and expired reagents/ chemicals / biological waste using environmentally sustainable methods in the presence of EHS personnel
	PC13.take corrective actions for reported hazards in consultation with EHS personnel
	PC14.complete records of safety drills and training undertaken by self and subordinates
	PC15.raise the alarm and inform the concerned designated person immediately for action in the cases of spill, fall, injury, toxic inhale, fire or explosion
Adhere to emergency procedures	PC16.follow emergency protocol for any alarms and ensure the safety of subordinates in the area under supervision
	PC17.follow emergency procedures efficiently
	PC18.ensure injured employees are provided appropriate first aid and medical aid
<b>Means of assessment 1</b>	<p><b>Digital Written test for knowledge assessment:</b></p> <p><u>Scope</u> – Is used to test the knowledge component of the Qualification.</p> <p><u>Tools</u> – Computer or tab based online or offline.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – Question paper is divided in sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.</p>
<b>Means of assessment 2</b>	<p><b>Digital Written test for skill assessment</b></p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in handling and managing the situation is tested.</p> <p><u>Tools</u> – computer or tab based online or offline questions.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – Question paper is divided in sections. Each Section intends to assess a particular skill field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or</p>



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	expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.
<b>Means of assessment 3</b>	<b>Project Assessment</b> <u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in utilization of knowledge and skills in real life job scenarios <u>Tools</u> – Project report. <u>Method</u> – The trainee is deployed in Industry for on the job trainee or is being asked to work on a specific project (utilizing skills as per qualification). A project report duly endorsed by his/her project supervisor is prepared by the trainee and submitted for evaluation. The Assessor asks Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions based on the project report <u>Analysis</u> –Project Assessments are analysed on knowledge and skill component.
<b>Means of assessment 4</b>	<b>Viva</b> <u>Scope</u> – Is used to test the knowledge and understanding and breadth of awareness about the subject. Some personality traits and generic skills (such as – promptness, sharpness, communication skills, depth of knowledge, comprehension, presentation, patience etc) can also be tested required for the qualification. <u>Tools</u> – Direct dialogue between assessor and Trainee. <u>Method</u> – Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions. Different questions are included to test relevant PCs from the qualification <u>Analysis</u> – Assessor is provided with spectrum of ready answers to be expected from trainee. This reduces effect of subjectivity of the assessor. Comparative quality of trainees with in a batch or different institutes can be gauged
<b>Pass/Fail</b>	The aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment, Project and Viva is 70%. In case of RPL where Project will not be there ,the aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment and Viva shall also be 70%.

**Title of Component:**5. DGT/VSQ/N0103 : Employability Skills (90 Hours)

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<b>Outcomes to be assessed/NOSs to be assessed</b>	<b>Assessment criteria for the outcome</b>
Introduction to Employability Skills	PC1. understand the significance of employability skills in meeting the current job market requirement and future of work.
	PC2. identify and explore learning and employability relevant portals
	PC3. research about the different industries, job market trends, latest skills required and the available opportunities
Constitutional values – Citizenship	PC4. recognize the significance of constitutional values, including civic rights and duties, citizenship, responsibility towards society etc. and personal values and ethics such as honesty, integrity, caring and respecting others, etc.
	PC5. follow environmentally sustainable practices
Becoming a Professional in the 21st Century	PC6. recognize the significance of 21st Century Skills for employment
	PC7. practice the 21st Century Skills such as Self-Awareness, Behavior Skills, time management, critical and adaptive thinking, problem-solving, creative thinking, social and cultural awareness, emotional awareness, learning to learn for continuous learning etc. in personal and professional life
	PC8. adopt a continuous learning mindset for personal and professional development
Basic English Skills	PC9. use basic English for everyday conversation in different contexts, in person and over the telephone
	PC10. read and understand routine information, notes, instructions, mails, letters etc. written in English
	PC11. write short messages, notes, letters, e-mails etc. in English
Career Development & Goal Setting	PC12. identify career goals based on the skills, interests, knowledge, and personal attributes
	PC13. prepare a career development plan with short- and long-term goals.

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Communication Skills	PC14. follow verbal and non-verbal communication etiquette while communicating in professional and public settings
	PC15. use active listening techniques for effective communication
	PC16. communicate in writing using appropriate style and format based on formal or informal requirements
	PC17. work collaboratively with others in a team
Diversity & Inclusion	PC18. communicate and behave appropriately with all genders and PwD
	PC19. escalate any issues related to sexual harassment at workplace according to POSH Act
Financial and Legal Literacy	PC20. identify and select reliable institutions for various financial products and services such as bank account, debit and credit cards, loans, insurance etc.
	PC21. carry out offline and online financial transactions, safely and securely, using various methods and check the entries in the passbook
	PC22. identify common components of salary and compute income, expenses, taxes, investments etc
	PC23. identify relevant rights and laws and use legal aids to fight against legal exploitation
Essential Digital Skills	PC24. operate digital devices and carry out basic internet operations securely and safely
	PC25. carry out basic internet operations by connecting to the internet safely and securely, using the mobile data or other available networks through Bluetooth, Wi-Fi, etc.
	PC26. display responsible online behavior while using various social media platforms
	PC27. create a personal email account, send and process received messages as per requirement
	PC28. carry out basic procedures in documents, spreadsheets and presentations using respective and appropriate applications
	PC29. utilize virtual collaboration tools to work effectively

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Entrepreneurship          Customer Service          Getting ready for apprenticeship & Jobs	PC30. identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research
	PC31. develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion
	PC32. identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity
	PC33. identify different types of customers and ways to communicate with them
	PC34. identify and respond to customer requests and needs in a professional manner
	PC35. use appropriate tools to collect customer feedback
	PC36. follow appropriate hygiene and grooming standards
	PC37. create a professional Curriculum vitae (Résumé)
	PC38. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively
	PC39. apply to identified job openings using offline /online methods as per requirement
Means of assessment 1	PC40. answer questions politely, with clarity and confidence, during recruitment and selection
	PC41. identify apprenticeship opportunities and register for it as per guidelines and requirements
<b>Digital Written test for knowledge assessment:</b>  <u>Scope</u> – Is used to test the knowledge component of the Qualification Pack.  <u>Tools</u> – Computer or tab based online or offline.  <u>Method</u> – 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.	

	<p><u>Analysis</u> – Question paper is divided in sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.</p>
<b>Means of assessment 2</b>	<p><b>Digital Written test for skill assessment</b></p> <p><u>Scope</u> – Is used to test primarily the Skill component of the QP. Trainee's expertise in handling and managing the situation is tested.</p> <p><u>Tools</u> – computer or tab based online or offline questions.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – Question paper is divided in sections. Each Section intends to assess a particular skill field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.</p>
<b>Means of assessment 3</b>	<p><b>Project Assessment</b></p> <p><u>Scope</u> – Is used to test primarily the Skill component of the QP. Trainee's expertise in utilization of knowledge and skills in real life job scenarios</p> <p><u>Tools</u> – Project report.</p> <p><u>Method</u> – The trainee is deployed in Industry for on the job trainee or is being asked to work on a specific project (utilizing skills as per qualification pack). A project report duly endorsed by his/her project supervisor is prepared by the trainee and submitted for evaluation. The Assessor asks Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions based on the project report</p>

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	<u>Analysis</u> –Project Assessments are analysed on knowledge and skill component.
<b>Means of assessment 4</b>	<b>Viva</b>  <u>Scope</u> – Is used to test the knowledge and understanding and breadth of awareness about the subject.  Some personality traits and generic skills (such as – promptness, sharpness, communication skills, depth of knowledge, comprehension, presentation, patience etc) can also be tested required for the QP.  <u>Tools</u> – Direct dialogue between assessor and Trainee.  <u>Method</u> – Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions. Different questions are included to test relevant PCs from the QP  Analysis – Assessor is provided with spectrum of ready answers to be expected from trainee. This reduces effect of subjectivity of the assessor. Comparative quality of trainees with in a batch or different institutes can be gauged
<b>Pass/Fail</b>	The aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment, Project and Viva is 70%. In case of RPL where Project will not be there ,the aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment and Viva shall also be 70%.

## SECTION 2

### 25. EVIDENCE OF LEVEL

Title/Name of the qualification/Component Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) Level: 5			
NSQF Domain	Key requirements of the job role	How the job role relates to the NSQF level descriptors	NSQF level
Process	<p>Few of the job elements, expected to be performed by Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) are:</p> <ul style="list-style-type: none"> <li>• Pre-production checks</li> <li>• In process checks</li> <li>• Post production checks</li> <li>• Environment Sustainability</li> <li>• Ensure adherence to health and hygiene protocols</li> <li>• Coordination with the Supervisor</li> <li>• Team coordination</li> <li>• Respond to audit queries</li> <li>• Sensitivity towards all genders and people with disability</li> </ul>	<p>Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) performs pre-production, in-process and post production checks to ensure compliance with regulatory standards and procedures. The job holder is responsible for routine Inspection, identification of non-conformities. He/she is also responsible to perform continuous reporting and documentation at every step. All the above performance outcomes are routine and common in all the work assigned to Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device), hence they are categorized as familiar and predictable processes where the Quality Assurance chemist-IP/QA has a situation of clear choice.</p>	5



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<b>Professional Knowledge</b>	<p>Few of the job elements, expected to be performed by Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) are:</p> <ul style="list-style-type: none"> <li>• Perform production checks</li> <li>• Reporting and documentation</li> <li>• Identification of Non-conformities</li> <li>• Coordinate with Manager, colleagues and auditors</li> </ul>	<p>To perform the tasks given in the left-hand side box, Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) needs to have the factual knowledge of facts, principles, processes and general concepts related to Good Manufacturing Practices(GMP), how to routinely perform production checks investigations and analysis, routine Inspection, identification of non-conformities and labelling by recalling the work safety guidelines. The job holder should also be efficient to coordinate with with Manager, colleagues and auditors to meet the communication needs to fulfill work requirements of Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device)</p>	<b>5</b>
<b>Professional Skills</b>	<p>Few of the job elements, expected to be performed by Chemist- In-process Quality Assurance ((Pharma, Biologics and Medical Device) are:</p> <ul style="list-style-type: none"> <li>• Quality checks</li> <li>• Reporting and documentation</li> <li>• Coordination with the Supervisor</li> <li>• Team coordination</li> <li>• Respond to audit queries</li> </ul>	<p>To perform the tasks of Chemist- In-process Quality Assurance(Pharma, Biologics and Medical Device)the job holder utilizes professional skills like good communication and interpersonal skills, good analytical, reasoning skills, attention to details, critical thinking, and excellent organizational skills.</p>	<b>5</b>



	<ul style="list-style-type: none"> <li>Sensitivity towards all genders and people with disability</li> </ul>	<p>For routine job activities and tasks the Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) uses the planning and organizing skills.</p> <p>The job holder demonstrates analytical and critical thinking skills while performing microbial analysis test.</p> <p>The scope of utilization of all above professional skills remains limited to routine and repetitive and for a narrow range of applications</p>	
<b>Core Skills</b>	<p>Few of the job elements, expected to be performed by Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) are:</p> <ul style="list-style-type: none"> <li>Coordination with Manager</li> <li>Coordination with colleagues and auditors</li> <li>Sensitivity towards all genders and people with disability</li> <li>Recording and Reporting</li> <li>Documentation compliance with GDP, GLP and GMP</li> <li>Data Integrity</li> </ul>	<p>To perform the tasks written on the left-hand side box, Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) uses organizing information, communication and problem solving skills.</p> <p>For reporting and documentation proposed, he/she applies the basics of arithmetic and algebraic principles and organizational skills.</p> <p>For coordination related tasks and ensuring compliance to organizational SOPs and regulatory requirements, the job holder is expected to have a basic understanding of the social-political and natural environment at the place of</p>	<b>5</b>

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		work/ organization he/she is working for.	
<b>Responsibility</b>	<p>Few of the job elements, expected to be performed by Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) are:</p> <ul style="list-style-type: none"> <li>• Perform quality checks</li> <li>• Identification of Non-conformities</li> <li>• Coordination with Manager</li> <li>• Coordination with colleagues and auditors</li> <li>• Sensitivity towards all genders and people with disability</li> <li>• Recording and Reporting</li> <li>• Documentation compliance with GDP, GLP and GMP</li> <li>• Data Integrity</li> </ul>	Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) has responsibility for his/her work and learning and supports to Junior QA Chemist and cross functional Teams. And in case of a scenario/situation of no clear choice, he is expected to take guidance from the Head of Quality Department.	<b>5</b>

### SECTION 3

#### EVIDENCE OF NEED

**26** What evidence is there that the qualification is needed? What is the industry relevance of this qualification and what is the basis of this?

**Need of the qualification**

LSSSDC has prepared a skill gap report forecasting the need for this job role both on a short-term and long-term basis.  
Additionally, all the industries that have validated the qualification have expressed the need for this qualification considering the futuristic need.

**Industry Relevance**

Experts from following companies have consented for relevance of this qualification with Industry need.

S.No	Name of Organization
1	Anglo French Drugs and Industries Ltd.
2	Arbro Pharmaceuticals Private Limited
3	Belco Pharma
4	Blue Cross Laboratories Pvt Ltd.
5	Drugfarm Laboratories
6	Emcure Pharmaceuticals Ltd
7	Group Pharmaceuticals Ltd
8	Intas Pharmaceuticals Ltd.
9	Kumar Organic Products Limited
10	Lupin Ltd
11	Macleods Pharmaceuticals Ltd.
12	Medorah Meditek Pvt Ltd.
13	Micro Labs Limited
14	Modgal Pharmaceuticals Pvt. Ltd.
15	Nakoda Chemicals Limited
16	Neuland Laboratories Limited
17	Prerana Bio-Innovations Research Pvt. Ltd.
18	Pure & Cure Healthcare Pvt.Ltd
19	Smruti Organics Limited
20	Sun Pharmaceutical Industries Ltd.
21	Unimarck Healthcare Ltd.

**Usage of qualification**

LSSSDC would submit periodic details (directly/Via NSDC) of the employment generated (wherever applicable) and realize under training in the

	<p>Qualifications post-approval of NSQC and implementation of the qualification.</p> <p><b>Estimated uptake</b> LSSSDC has prepared a skill gap report forecasting the year wise estimated uptake. The forecasted uptake is given as annexure-4.</p>
<b>27</b>	<p><b>Recommendation from the concerned Line Ministry of the Government/Regulatory Body. To be supported by documentary evidences</b></p>
	<p>We have requested a recommendation from the Ministry of Health and Family Welfare as well as Department of Biotechnology for the job role of Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) (copy of request letter is enclosed in Annexure 5).</p> <p>We have received a recommendation from Department of Biotechnology for the job role Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device)</p> <p>The response from the Ministry of Health and Family Welfare is awaited and will be submitted sooner we receive it.</p>
<b>28</b>	<p><b>What steps were taken to ensure that the qualification(s) does (do) not duplicate already existing or planned qualifications in the NSQF? Give justification for presenting a duplicate qualification</b></p> <p>Before submission of the qualification to NSQC we have checked the availability of Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) with other councils on the portal of NSDC and we found no other qualification matching with the submitted job role. We have revalidated the first version of NSQC approved Qualification of Quality Assurance Chemist from Life Sciences Sector Skill Development Council. Hence no duplication is found of the submitted jobrole. While performing the functional analysis approved by industry we identified skill gap in some competencies and NOSs which have been rewritten and revalidated from industries. The validation mails and inputs received from industries are attached in(annexure 6) as one of the evidence. Hence following NOS have been newly drafted for the revised Qualification of Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) And dgt mandatory employability skills is also added:</p> <ol style="list-style-type: none"> <li>1. LFS/N0341 v2.0: Perform quality checks in the manufacturing/production units in compliance with regulatory guidelines</li> <li>2. LFS/N0345 v2.0: Perform reporting and documentation to meet regulatory standards</li> <li>3. LFS/N0346 v2.0: Coordinate with Supervisor, team members, cross-functional teams and auditors</li> <li>4. LFS/N0110 v2.0: Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab</li> <li>5. DGT NOS DGT/VSQ/N0103v1.0: Employability Skills (90 Hours)</li> </ol>

29	<p><b>What arrangements are in place to monitor and review the qualification(s)? What data will be used and at what point will the qualification(s) be revised or updated? Specify the review process here</b></p> <p>Workshops with Industry Associations of Employers are part of a continuous awareness drive and will be utilized as a channel to get continual feedback from Industry.</p> <p>LSSSDC will be engaged with Training Providers and Authorised educational institutions, who are imparting training as per qualification guidelines, to gather feedback in implementation</p> <p>Monitoring of candidate Assessment Result will be carried out</p> <p>Employer feedback will be sought post placement of trainee's batch</p> <p>A formal review is scheduled in a three-year time frame</p>
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#### **SECTION 4**

#### **EVIDENCE OF PROGRESSION**

30	<p><b>What steps have been taken in the design of this or other qualifications to ensure that there is a clear path to other qualifications in this sector?</b></p> <p><b><i>Show the career map here to reflect the clear progression</i></b></p> <p>Mobility options to other qualifications are enabled through the alignment of educational qualifications and prior work experience stated as a requirement in the respective qualifications. For Example:</p> <p>After 3-4 years of Industry work experience Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) post-qualifying the certification Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) (Level-5), a candidate has an option to qualify for various job roles as an upward progression such as :</p> <ol style="list-style-type: none"> <li>1. Specialist - Quality Assurance (Level 6)</li> <li>2. Quality Assurance Manager (Food Processing Sector) Level 6 as cross sector progression</li> </ol> <p>Also a qualified Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) has option to move for horizontal progression across Sector in Cross Sectoral in Process Industries like Food Processing / Bio Agri Fertilizers/Pesticide/Chemical Manufacturers</p>
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