

Revised Application Documentation: Version 5 /22 May, 2015

## **QUALIFICATION FILE – CONTACT DETAILS OF SUBMITTING BODY**

### **Name and address of submitting body:**

Life Sciences Sector Skill Development Council

13, Palam Marg, 3<sup>rd</sup> Floor, Vasant Vihar, New Delhi, PIN 110057

Phone: +91 11 41042407/ 408, E-mail: info@lssdc.in

### **Name and contact details of individual dealing with the submission**

**Name:** Mr. Anshul Saxena

**Position in the organisation:** Director- NOS Development & Curriculum Advisory

### **Address if different from above**

Same as Above

**Tel number(s):** +91 11 41042407/ 408, +91 9650433002

**E-mail address:** anshul.saxena@lssdc.in

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

1. Qualifications Pack
2. RFP for development of Occupational Standards detailing the selection process as well
3. Profile of Project Team from Consultant (Inclusive of Industry Expert)
4. LSSDC Protocol for Accreditation of Assessment Agencies and Assessment Guideline Ver 1.00.
5. Sample of Assessors Guide
6. Minutes of meeting of Governing Body
  - a. Composition of National Committee of NOS
  - b. Approval of Occupational Standards by National Committee and Governing Body
7. NSDC Sector Skill Gap Report for Life Sciences Sector is available at <http://nsdcindia.org/sites/default/files/files/Pharmaceuticals.pdf>
8. Occupational Map and Career Progression Map

9. Draft MoU with Industry
10. List of companies and Industry associations participated in the development of these qualification packs
11. List of QP/NOS validating companies ( Under Development)

## QUALIFICATION FILE SUMMARY

<b>Qualification Title</b>	Quality Control Chemist - Packaging (LFS/Q1303)
<b>Body/bodies which will assess candidates</b>	Life Sciences Sector Skills Council
<b>Body/bodies which will award the certificate for the qualification.</b>	Life Sciences Sector Skills Council
<b>Body which will accredit providers to offer the qualification.</b>	Life Sciences Sector Skills Council
<b>Occupation(s) to which the qualification gives access</b>	Quality Control Chemist - Packaging falls under Quality Occupation. Role holder is responsible for monitoring, reviewing and ensuring the adherence of packaging materials as per the quality standards, free from defects and as per the specifications and SOPs. The job requires Individual to have understanding of Pharmaceutical manufacturing, packaging and quality process, concepts and principles. The Individual applies knowledge of pharmaceutical packaging testing techniques, knowledge of instruments and required regulations and standards as per regulatory bodies like FDA/MHRA etc. Organizational SoPs and GMP, GLP. The individual applies skills like decision making, quality centricity, analytical and critical thinking, problem solving and communication skills etc. The role holder is responsible for own work and learning and is responsible for testing and qualifying work done by packaging team.
<b>Proposed level of the qualification in the NSQF.</b>	Level 5
<b>Anticipated volume of training/learning required to complete the qualification.</b>	400 Hours
<b>Entry requirements / recommendations.</b>	B. Sc with Chemistry as major subject, Preferably B. Pharm.
<b>Progression from the qualification.</b>	<p><b>Upward progression:</b></p> <p>Plant QC Manager (Level 6)</p> <p><b>Lateral/ Horizontal progression:</b></p> <p>QC Chemist (Level 5)</p> <p>QC Chemist– Batch Release Testing (Level 5)</p> <p>QA Chemist (Level 5)</p> <p>QMS Specialist (Level 5)</p> <p>Stability Specialist (Level 5)</p>
<b>Planned arrangements for RPL.</b>	RPL arrangements and policies are under development.
<b>International Comparability</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>• COGPI03.6 maintaining product quality</li> <li>• SFHPHARM23 check documentation and materials</li> <li>• SKSPI25 Mix, store and manage processing chemistry</li> </ul>

- COGLS2 Maintain effective and efficient working relationships
  - COGLS15 Improve product(s) and process quality within life
  - COGLS206 Preparing reagents in life sciences and related industries
  - COGLS212 Carry out testing using manual or automated equipment
  - COGLS215 Carry out sampling operations in life sciences
  - COGLS202 Maintain effective and efficient working relationships in life Sciences and related industries
  - COGPI03.2 control emergencies
  - COGLS201 Follow health and safety procedures in life sciences
  - COGLS301 Maintain health and safety in life sciences
- Switzerland NOS
- Refer page no. 196 Unit Group 3212, page no. 123 Unit Group 2113, page no. 190 Unit Group 3141
- Australia NOS
- Apply sampling procedures
  - Communicate workplace information
  - Operate a separation process using chromatography
  - Participate in OHS processes
  - Perform basic tests
  - Participate in work teams and groups
- South Africa NOS
- Act in accordance with ethical and legal codes of pharmaceutical representation and the laws of the country

#### Formal structure of the qualification

Title of unit or other component (include any identification code used)	Mandatory/ Optional	Estimated size (learning hours)	Level
LFS/N0323 To inspect and monitor the packaging process and ensure that all SOPs are followed to adhere to quality measures and standards	Mandatory	100	5
LFS/N0324 To inspect and ensure that the labeling requirements are met	Mandatory	30	5
LFS/N0314 To carry out reporting and documentation to meet quality standards	Mandatory	75	Common across 3-6 levels
LFS/N0103 To ensure cleanliness in the work area	Mandatory	25	Common across 2-6 levels
LFS/N0101 Maintain a healthy, safe and secure working environment in the life sciences facility	Mandatory	45	Common across 2-7 levels
LFS/N0320 To carry out quality checks in the quality control process	Mandatory	125	5

Please attach any document giving further detail about the structure of the qualification – eg a Curriculum or Qualification Pack.

Give details of the document here:

- Qualifications Pack is attached in Annexure 1

## **SECTION 1**

### **ASSESSMENT**

#### **Name of assessment body:**

If there will be more than one assessment body for this qualification, give details.

1. Induslynk Training Services Pvt. Ltd (Mettl), having its registered office at 1004, Tower 4, The Palms, South City-1, Gurgaon, Haryana, PIN- 122001
2. Aspiring Minds Assessment Private Limited, having its registered office at 24, Pusa Road, New Delhi, PIN-110005

#### **Will the assessment body be responsible for RPL assessment?**

Only One Given Below:

Induslynk Training Services Pvt. Ltd (Mettl), having its registered office at 1004, Tower 4, The Palms, South City-1, Gurgaon, Haryana, PIN- 122001

Give details of how RPL assessment for the qualification will be carried out and quality assured.

RPL arrangements and policies are under development.

**Describe the overall assessment strategy and specific arrangements which have been put in place to ensure that assessment is always valid, consistent and fair and show that these are in line with the requirements of the NSQF:**

**Assessment Agencies:** An assessment 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

**Assessment development:** The assessment development is done with close monitoring and support of LSSSDC at every stage.

Steps for assessment development:

- Selection of assessment tool(s) depending on the assessment criteria prescribed in that QP.
- Developing blue print of the question paper, Viva, Demonstration, whatever are selected tools.
- Development of lay-out of Question paper is such that the entire PCs (Performance Criteria) of that QP 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.
- **SME:** An expert from industry is selected who is called "Subject Matter Expert". This SME must have over 13-15 years of experience in the industry, on same job role.
- **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.

**Assessor:** The Assessors are engaged to conduct the assessments. The selection takes place as follows

- LSSSDC 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.
- Based on this, Assessment agency locates the right people from the Industry and LSSSDC approves them after screening (they are screened on basis of resume and interview).

- Once selected, the assessor is oriented by LSSSDC and Assessment agency on various aspects of the assessment and management of assessment, such as
  - QP 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, VTP credentials, mark sheet management.
  - Confidentiality management.
- Assessment agency signs the agreement letter with the Assessor.
- LSSSDC certifies the Assessor.

#### **Assessment process:**

- Assessment date is decided with common agreement of VTP and assessment agency.
- Assessment agency ensures the availability of required infrastructure, tools for the assessment.
- Assessor is provided with location details of the VTP. He contacts VTP a day prior to the assessment to ensure that all the aspects are well managed.
- The trainees are scheduled in such a way that an assessor shall not assess more than 20 candidates in a day.
- Assessor and a representative from Assessment agency are present on the day of assessment to manage the process at assessment location.
- They carry an identity card and letter from the council authorising to conduct the assessment.
- Assessor ensures authenticity of Trainee's identity by verifying the documents (any document issued by GOI, such as Ration card, Adhar Card, Driving Licence, Passport, election card etc)
- Assessor maintains the records of attendance, verified documents, Score sheets, answer sheets and whatever applicable.
- Assessor collects evidences of the assessment in best possible way (videos, pictures, voice recordings etc)
- Assessor maintains complete confidentiality of the score, compiles the data and document and sends it to assessment agency.
- The assessment agency after processing the results and putting them in standard format hands over to LSSSDC within 7 days of assessment.
- LSSSDC cross checks and validates the data and declares the result to VTP.
- Passed candidates are provided with certificate

**Assessment tools:** Assessment tools for a QP are decided on the basis of composition of knowledge and skill in that particular QP. 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.

#### **Written test:**

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

Tools – Pen and Paper in form of OMR sheet, 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.

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 marks gives the overall rating of the trainee.

#### **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 QP.

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 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.

**Practical Test**

Scope – Is used to test primarily the Skill component of the QP. Trainee’s expertise in handling and managing the tools and situation is tested.

Tools – Demonstration, role play.

Method – A situation is narrated or created in front of the trainee and he is asked to react to it. The selected situations are based on real situations. They are predefined and provided to assessor. Assessor is provided with spectrum of reactions to be expected from trainee. Based on these guidelines the assessor fills the score sheet.

Analysis –Practical tests are analysed on knowledge and skill component.

Please attach any documents giving further information about assessment and/or RPL.

Give details of the document(s) here:

- LSSDC Protocol for Accreditation of Assessment Agencies and Assessment Guideline Ver1.00
- Sample of Assessors Guide

**ASSESSMENT EVIDENCE**

<b>Assessable Outcomes</b>	<b>Assessment Criteria</b>	<b>Total Marks (600)</b>	<b>Out Of</b>	<b>Theory</b>	<b>Skills Practical</b>
LFS/N0323  (To inspect and monitor the packaging process and ensure that all SOPs are followed to adhere to quality measures and standards)	PC1.comply with dress code, safety requirements and personal hygiene procedures prior to entering the packaging/pre-packaging area	100	6	3	3
	PC2.ensure that all the equipment are of desired quality and in standard working condition		6	3	3
	PC3. identify, clean, prepare and set packaging/pre-packaging machinery and identify any defects or malfunctioning		6	3	3
	PC4. conduct area / line clearance checks to make sure that no remnants from previous batch are available on the line / area		6	3	3
	PC5.obtain relevant documentation and check product specifications		6	3	3
	PC6.reconcile and verify pre-packaging materials under supervision of an authorized		6	3	3

	person				
	PC7.maintain the work area according to housekeeping standards		4	2	2
	PC8.conduct pre-start checks on machinery used for packaging process and ensure that any detectors / cameras / alarms on the equipment / line are in working condition and are challenged before start of activity as appropriate		6	3	3
	PC9.set up appropriate equipment or apparatus for testing correctly		6	3	3
	PC10.calibrate the testing equipment periodically as per SOP		5	2	3
	PC11.identify defective equipment/apparatus and steps to be taken		4	2	2
	PC12.verify the equipment accuracy by running the reference		5	2	3
	PC13.complete packaging documentation according to standard operating procedures		5	2	3
	PC14.note discrepancies in labels and documentation		5	2	3
	PC15.monitor packaging quality and packaging appearance to confirm that specifications are met		6	3	3
	PC16.ensure use of qualitative durable dosage boxes		4	1	3
	PC17.handle the products carefully specially requiring attention e.g. cytotoxic and its spill management, refrigerated and frozen items, light sensitive material and flammables		4	2	2
	PC18.careful consideration to be given to sterilization related products		5	2	3
	PC19.carry out disposal of waste and left over tested material safely as per SOP		3	1	2
	PC20.dispose all materials used in the experiment safely as per Health and Safety management system of the company		2	1	1
	Total		100	46	54

LFS/N0324  (To inspect and ensure that the labeling requirements are met)	PC1.ensure all products are clearly identified by labels, and remain permanently attached to the containers under all storage conditions	100	20	10	10
	PC2.ensure appearance of label on its package if the final container is not suitable for labelling		20	10	10
	PC3.ensure compliance to relevant national regulations and international agreements for labels of radiopharmaceutical products		20	10	10
	PC4.cross-check proper mentioning of dosages and storage conditions		20	10	10
	PC5.ensure leaflet in the package should contain the specific product information and indications for use		20	10	10
	Total		100	50	50
LFS/N0314  (To carry out reporting and documentation to meet quality standards)	PC1.report defects/problem/incidents/quality issues/test results as applicable in a timely manner	100	10	5	5
	PC2.report to the appropriate authority as laid down by the company		3	1	2
	PC3.follow reporting procedures as prescribed by the company		4	2	2
	PC4.work with production management and Quality Assurance to provide feedback regarding quality standards and issues		4	2	2
	PC5.help other R&D lab staff with any other testing required during the developmental work		4	2	2
	PC6.identify documentation to be completed relating to one's role		7	3	4
	PC7.record details accurately in appropriate format		6	3	3
	PC8.accurately document the results of the inspections and testing		8	4	4
	PC9.maintain all controlled document files and test records in a timely and accurate manner		10	5	5
	PC10.ensure that the final document meets regulatory and compliance requirements		7	2	5
	PC11.make sure documents are available to all appropriate authorities to inspect		5	2	3
	PC12.evaluate problems and make initial recommendations for possible corrective		4	2	2

	action to supervise				
	PC13.perform review of records and other documentation for compliance to established procedures and Good Documentation Practices		8	4	4
	PC14.write and update the inspection procedures, protocols and checklists		6	2	4
	PC15.prepare inspection reports as per the inspection activity performed		6	2	4
	PC16.respond to requests for information in an appropriate manner whilst following organizational procedures		4	2	2
	PC17.inform the appropriate authority of requests for information received		4	2	2
	Total		100	45	55
LFS/N0103 (To ensure cleanliness in the work area)	PC1.inspect the area while taking into account various surfaces	100	4	2	2
	PC2.identify the material requirements for cleaning the areas inspected, by considering risk, time, efficiency and type of stain		5	2	3
	PC3.ensure that the cleaning equipment is in proper working condition		5	2	3
	PC4.select the suitable alternatives for cleaning the areas in case the appropriate equipment and materials are not available and inform the appropriate person		4	2	2
	PC5.plan the sequence for cleaning the area to avoid re-soiling clean areas and surfaces		4	2	2
	PC6.inform the affected people about the cleaning activity		4	2	2
	PC7.display the appropriate signage for the work being conducted		4	2	2
	PC8.ensure that there is adequate ventilation for the work being carried out		5	2	3
	PC9.wear the personal protective equipment required for the cleaning method and materials being used		4	2	2
	PC10.use the correct cleaning method for the		4	2	2

	work area, type of soiling and surface				
	PC11.deal with accidental damage, if any, caused while carrying out the work		4	2	2
	PC12.report to the appropriate person any difficulties in carrying out your work		4	2	2
	PC13.identify and report to the appropriate person any additional cleaning required that is outside one's responsibility or skill		4	2	2
	PC14.ensure that there is no oily substance on the floor to avoid slippage		4	2	2
	PC15.ensure that no scrap material is lying around		4	2	2
	PC16.maintain and store housekeeping equipment and supplies		4	2	2
	PC17.follow workplace procedures to deal with any accidental damage caused during the cleaning process		4	2	2
	PC18.ensure that, on completion of the work, the area is left clean and dry and meets requirements		4	2	2
	PC19.return the equipment, materials and personal protective equipment that were used to the right places making sure they are clean, safe and securely stored		5	2	3
	PC20.dispose the waste garnered from the activity in an appropriate manner		5	2	3
	PC21.dispose of used and un-used solutions according to manufacturer's instructions, and clean the equipment thoroughly		5	2	3
	PC22.maintain schedules and records for housekeeping duty		5	2	3
	PC23.replenish any necessary supplies or consumables		5	2	3
	Total		100	46	54
LFS/N0101 (Maintain a healthy, safe	PC1. observe and comply with your company's current health, safety and security policies and procedures	100	10	5	5

and secure working environment in the life sciences facility)	PC2. while carrying out work, use appropriate safety gears like head gear, masks, gloves and other accessories as mentioned in the guidelines		10	5	5
	PC3. report any identified breaches in health, safety, and security policies and procedures to the designated person		10	5	5
	PC4. responsible for maintaining discipline at the shop-floor/ production area		10	5	5
	PC5. identify and correct any hazards that you can deal with safely, competently and within the limits of your authority		10	5	5
	PC6. adhere and comply to storage and handling guidelines for hazardous material		10	5	5
	PC7. identify and recommend opportunities for improving health, safety, and security to the designated person		10	5	5
	PC8. complete any health, safety and security records legibly and accurately		10	4	6
	PC9. report any hazards that you are not competent to deal with to the relevant person in line with organizational procedures and warn other people who may be affected		10	4	6
	PC10. follow your company's emergency procedures promptly, calmly, and efficiently		10	5	5
		Total		100	48
LFS/N0320 (To carry out quality checks in the quality control process)	PC1. ensure that total range of checks are regularly and consistently performed	100	16	8	8
	PC2. use appropriate measuring instruments, equipment, tools, accessories etc. ,as required		13	5	8
	PC3. ensure the status and accuracy of instruments used for measurement		10	5	5
	PC4. identify non-conformities to quality assurance standards		13	5	8
	PC5. identify potential causes of non-conformities to quality assurance standards		13	5	8
	PC6. identify impact on final product due to non-conformance to company standards		16	8	8

	PC7.evaluating the need for action to ensure that problems do not recur		6	3	3
	PC8.suggest corrective action to address problem		7	3	4
	PC9.review effectiveness of corrective action		6	3	3
	Total		100	45	55

## **SECTION 2**

### **EVIDENCE OF NEED**

**What evidence is there that the qualification is needed?**

While collecting data from the industry for development of the occupational map, we also took inputs on the list of unique roles and the roles to be prioritized, w.r.t. workforce volume and skilling needs. These inputs have been used for subsequent qualification packs development.

**What is the estimated uptake of this qualification and what is the basis of this estimate?**

Skills Gap analysis Reports for industry demand and secondary research data is the basis, though these do not lend to accurate demand projection. The link to NSDC Human Resource & Skills Requirement in Life Sciences Sector is <http://nsdcindia.org/sites/default/files/files/Pharmaceuticals.pdf>

- Feedback from industry for demand though again sample size may not lend to accurate figures
- Training duration, and current and potential training capacity envisaged
- An LMIS development initiative is being put in place to be more precise regarding the demand and supply

**What steps were taken to ensure that the qualification(s) does/do not duplicate already existing or planned qualifications in the NSQF?**

The NSDC list of Approved and Under-development QPs has been checked for overlap

Quality team of NSDC has done the 2<sup>nd</sup> level check before QRC presentation

The QP is under Industry validation and post completing the validation exercise, the QP will be resubmitted for QRC approval as per laid down protocol of NSDC.

**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?**

Workshops with Industry Associations of Employers are part of continuous awareness drive and will be utilized as a channel to get a continual feedback from Industry

The Qualification has been uploaded on SSC website for public with a request for feedback on qualification to be sent to an identified mail address

SSC will be engaged with Training Providers and Authorised educational institutions, who are imparting trainings as per QP guidelines, to gather feedback in implementation

Monitoring of candidate Assessment Result will be carried out

Employer feedback will be sought post placement of trainee's batch

A formal review is scheduled in two year time frame

Please attach any documents giving further information about any of the topics above.

Give details of the document(s) here:

- NSDC Human Resource & Skills Requirement in Life Sciences Sector is <http://nsdcindia.org/sites/default/files/files/Pharmaceuticals.pdf>

## SECTION 3

### SUMMARY EVIDENCE OF LEVEL

#### Summary of Direct Evidence:

Generic NOS is/are linked to the overall authority attached to the job role.

Quality Control Chemist - PackagingLFS/Q1303					
Process Required	Professional Knowledge	Professional Skills	Core Skills	Responsibility	Level
<p>The role holder requires well developed skill, with clear choice of procedures in familiar context to perform job. For example:-</p> <ul style="list-style-type: none"> <li>- performs inspection and quality check for packaging and labelling activities like pre-packaging inspection, reconciliation and verification of packaging materials, monitoring packaging to be as per organizational SoPs and the regulatory guidelines like FDA, DCGI etc;</li> <li>- ensures that the labelling requirements are met appropriately like Printing of correct dosages, date of manufacture and</li> </ul>	<p>The role holder requires knowledge of facts, principles, process and general concepts, in a field of Life Sciences Manufacturing and Quality Systems. For example:-</p> <ul style="list-style-type: none"> <li>- To conduct inspection for packaging and labelling activities applies knowledge of pharmaceutical industry, basic concepts of pharmaceutical manufacturing and packaging processes and tools, analytical chemistry, basic statistical analysis tools and organizational SoPs and norms related to Good Manufacturing Practices (labelling guidelines etc) Good Laboratory Practices (GLP) (like environment condition, instrument</li> </ul>	<p>The role holder uses a range of cognitive and practical skills required to accomplish tasks and solve problems by selecting and applying basic methods, tools, material and information. For Example:-</p> <ul style="list-style-type: none"> <li>- while performing inspections and writing analysis records and recommendations, individual uses skills like planning and organizing, analytical thinking, critical thinking, customer centricity and decision making.</li> <li>- Analytical thinking and critical thinking and decision making skills are used to choose the appropriate safety gears like head gear, masks, etc., in selecting the testing tools and to identify and correct any hazards that</li> </ul>	<p>The role holder applies mathematical skill, understanding of social, political systems and some skill of collecting and organizing information, communication. For example:-</p> <ul style="list-style-type: none"> <li>- While conducting the quality check activities in packaging process for pharmaceutical products, like, inspection, analysis and documentation has an understanding of production, and quality assurance function in addition to quality control function, applicable regulatory guidelines (for example FDA/DCGI), laws and Acts, desired quality standards (GLP/I</li> </ul>	<p>Responsibility of own work and learning and some responsibility for other's work and learning. For example:-</p> <ul style="list-style-type: none"> <li>- has responsibility to conduct quality checks and inspection in packaging process as per SoPs for pharmaceutical products.</li> <li>- Individual is responsible of own safety while carrying out work, for using appropriate safety gears like head gear, masks, etc. as mentioned in the guidelines and while following emergency procedures</li> <li>- has responsibility for checking the quality in the work done by</li> </ul>	Level 5

<p>expiry.</p> <ul style="list-style-type: none"> <li>- conduct analysis using techniques/inspection methods used to identify defects and documentation as per approved written procedure, analyse root cause of deviations etc</li> <li>- uses appropriate safety gears like head gear, masks, gloves etc.as mentioned in the EHS guidelines</li> <li>- follows the company's emergency procedures to identify and correct any hazards that he/she can deal with safely, competently and within the limits of his/her authority</li> <li>- identify and recommend opportunities for improving health, safety, and security to the designated person as notified by company in SoPs</li> </ul>	<p>upkeep) and Good Documentation Practices (GDP), Quality Management System (like ISO) and current regulations guidelines (like FDA, MHRA etc.)</p> <ul style="list-style-type: none"> <li>- To report hazards and breaches and limits of individual for dealing with hazards applies knowledge of biological substances, required precaution and safety measures, hazards and breaches, types of health and safety hazards and breaches at the workplace.</li> </ul>	<p>he/she can deal with.</p> <ul style="list-style-type: none"> <li>- Customer centricity and decision making skills are utilized to observe and identify and recommend opportunities for improving health, safety, and security to the designated person as per SoPs.</li> <li>- Uses customer centricity and analytical thinking to understand the quality standards, work expectations and output requirements to be maintained.</li> <li>- Decision making skills are also used when he/she makes discretionary judgements for accepting or rejecting the packaging.</li> <li>- The problem solving skills are used in communicating and discussing issues identified in samples and in order to find solutions with mutual agreement.</li> </ul>	<p>SO), work expectations and output requirements as per company's SOPs/ guidelines and tie up arrangements with applicable regulatory body (like FDA etc)</p> <ul style="list-style-type: none"> <li>- uses collecting and organizing skills, and communication skills (reading, writing, speaking and listening) while inspecting and collecting specific information like packaging specifications, while communicating sample analysis results, writing narrative of analysis.</li> <li>- Communication skills are used to report hazards to the relevant person in line with organizational procedures and warn other people who may be affectedand while training the staff.</li> <li>- Applies mathematical skills for assessment of defects and to compile and analyze data as well as to discuss results/ issues.</li> </ul>	<p>packaging team and analysing the samples.</p> <ul style="list-style-type: none"> <li>- He/ she is also responsible jointly to discuss issues and results of sample analysis in order to find solutions with mutual agreement.</li> </ul>	
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Level 5	Level 5	Level 5	Level 5	Level 5	
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**OTHER EVIDENCE OF LEVEL** [This need only be filled in where evidence other than primary outcomes was used to allocate a level] (**Optional**)

**Summary of other evidence (if used):**

1. Internship Monitoring report available at VTP for each candidate for internship period duly signed by Industry authorized person

## **SECTION 4**

### **EVIDENCE OF RECOGNITION OR PROGRESSION**

**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?**

Horizontal and vertical mobility options have been articulated while developing the standard. For Example:

After 2 years of Industry work experience as Quality Control Chemist – Packaging post qualifying the certification of Quality Control Chemist- Packaging, candidate has an option to qualify for Quality Assurance Chemist Job role for a lateral progression.

Similarly can move vertically as Quality Control Plant Manager after 5 years of industrial work experience as Quality Control Chemist- Packaging.

Please attach any documents giving further information about any of the topics above.

Give details of the document(s) here:

- Occupational Map and progression matrix