NSDA Reference
To be added by NSDA

QUALIFICATION FILE – CONTACT DETAILS OF SUBMITTING BODY

Name and address of submitting body:

Life Sciences Sector Skill Development Council

13, Palam Marg, 3rd Floor, Vasant Vihar, New Delhi, PIN 110057

Phone: +91 11 41042407/ 408, E-mail: info@lsssdc.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@lsssdc.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. LSSSDC 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

Qualification Title	Quality Control Biologist (LFS/Q 2301)
Body/bodies which will assess candidates	Life Sciences Sector Skills Council
Body/bodies which will award the certificate for the qualification.	Life Sciences Sector Skills Council
Body which will accredit providers to offer the qualification.	Life Sciences Sector Skills Council
Occupation(s) to which the qualification gives access	Quality Control Biologist falls under Quality Occupation. The role holder is responsible for conducting qualitative and quantitative analysis to ensure specified quality of the manufactured bio pharmaceutical products. The job requires Individual to have understanding of Biopharmaceutical manfuacturing and quality process, concepts and principles. The Individual applies knowledge of bipharmaceutical testing techniques, knowledge of instruements and required regulations and standards as per regulatoru bodies like FDA/MHRA etc. Organizational SoPs and 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 some work done by junior lab staff and their learning.
Proposed level of the qualification in the NSQF.	Level 5
Anticipated volume of training/learning required to complete the qualification.	460 Hours
Entry requirements / recommendations.	Graduate in Science (Biology / Biochemistry specialization), Preferably B. Pharm
Progression from the qualification.	**Upward progression:** QC Plant Manager (Level 6) **Lateral/ Horizontal progression:** Quality Assurance Chemist (Level 5) Quality Management System In charge (Level 5)
Planned arrangements for RPL.	RPL arrangements and policies are under development.
International Comparability	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: UK NOS • COGLS213 Preparing biological specimens or samples for investigations in life sciences and related industries • COGLS216 Operating in a clean room or aseptic facility in life sciences and related industries • COGLS318 Maintaining cell lines in life sciences and related industries • COGLS329 Culturing or fermenting cells for life sciences and related industries • COGLS314 Analysis of samples using high performance liquid

	• COGLS315 Analysis of samples using spectroscopy in life sciences • COGLS328 Analysis of samples using gas chromatography in life sciences • COGPIO3.6 maintaining product quality • SFHPHARM23 check documentation and materials • 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 • COGPIO3.2 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 • Apply the principles of asepsis and sterility in a healthcare environment

Formal structure of the qualification

Title of unit or other component (include any identification code used)	Mandatory/ Optional	Estimated size (learning hours)	Level
LFS/N0803 Analyze bio-pharmaceuticals in lab while ensuring compliance with Good Manufacturing Practices(GMP) and Good Laboratory Practices (GLP)	Mandatory	100	5
LFS/N0101 Maintain a healthy, safe and secure working environment in the life sciences facility	Mandatory	45	Commom across 2-7 levels
LFS/N0302 Coordinate with Supervisors and colleagues within and outside the department	Mandatory	40	5
LFS/N0103 To ensure cleanliness in the work area	Mandatory	25	Common across 2-6 levels
LFS/N0314 To carry out reporting and documentation to meet quality standards	Mandatory	75	Common across 3-6 levels
LFS/N0320 To carry out quality checks in the quality	Mandatory	175	5

control process			

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 the 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)
- Assesor 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:

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

ASSESSMENT EVIDENCE

Assessable Outcome	Assessment Criteria	Total Marks (600)	Out Of	Theory	Skills Practical
LFS/N0338 (Analyze bio pharmaceutical in lab while ensuring compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP))	PC1. prepare the required buffer, solvent solutions and microbial media for running bio-analytical quality tests	100	3	1	2
	PC2. prepare and work on assays to carry out quality control procedures on biopharmaceutical products		6	3	3
	PC3. perform all the test activities and validations satisfactorily, including procedures such as cell culture, protein purifications etc.		5	2	3
	PC4. train the line staff effectively to perform tests		6	3	3
	PC5. manage manpower efficiently to undertake the needed tests		6	3	3
	PC6. ensure that all work meets		6	3	3

	applicable QA/QC guidelines				
	PC7. review the data given by analysts and ensure that it is as per the SOP		6	3	3
	PC8. adhere to quality conformance standards and norms		6	3	3
	PC9. review and update test methods and procedures according to SOP		5	3	2
	PC10. prepare reports for document findings and recommendations on time		5	2	3
	PC11. conduct all the analysis on time and as per procedure		6	2	4
	PC12. coordinate effectively with personnel in other disciplines to integrate findings and recommendations		6	3	3
	PC13. identify causes for out-of-spec products and then recommend changes to improve the product's quality		4	2	2
	PC14. analyse root cause of deviations and take corrective actions		6	3	3
	PC15. participate in laboratory investigations when required		4	1	3
	PC16. regular documentation of all the activities		4	2	2
	PC17. evaluate assay performance, develop and implement assay optimization plans		2	1	1
	PC18. conduct regular checks for positioning of all equipment and instrument tags		4	2	2
	PC19. conduct regular checks on equipment and instrument conditions and document calibrations		4	2	2
	PC20. ensure precision in instrument calibrations to minimize source of		6	3	3

	errors				
	Total		100	47	53
LFS/N0101 (Maintain a healthy, safe and secure working environment in the life sciences facility)	PC1. observe and comply with your company's current health, safety and security policies and procedures	100	10	5	5
	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	52

LFS/N0302 (Coordinate with Supervisors and colleagues within and outside the department)	PC1. understand the work output requirements	100	10	5	5
	PC2. proactively inform supervisor on issues requiring intervention		10	5	5
	PC3. comply with company policy and rule		10	5	5
	PC4. deliver quality work on time and report any anticipated reasons for delays		16	8	8
	PC5. put team over individual goals		10	5	5
	PC6. be able to resolve conflicts		10	5	5
	PC7. learn how to multi-task relevant activities		10	5	5
	PC8. provide guidance and direction to subordinates, including setting performance standards and monitoring performance		12	5	7
	PC9. impart training to team members/cross-function team members		12	5	7
	Total		100	48	52
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
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		4	2	2

	corrective 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		5	2	3

	out				
	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 work area, type of soiling and surface		4	2	2
	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		5	2	3

	thoroughly				
	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
				100	

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 2nd 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 BiologistLFS/ Q 2301					
Process Required	**Professional Knowledge**	**Professional Skills**	**Core Skills**	**Responsibility**	**Level**
The role holder requires well developed skill, with clear choice of procedures in familiar context to perform job. For example:- - performs all the routine quality check activities like developing assay etc for biopharmaceutical products as per organizational SoPs and the regulatory guidelines like WHO, MHRA, FDA, DCGI etc; - conduct analysis and documentation as per approved written procedure, analyse root cause of deviations, assesses Out of Specification (OOS) incidents - evaluate assay performance, develop and	The role holder requires knowledge of facts, principles, process and general concepts, in a field of Life Sciences Manufacturing and Quality Systems. For example:- - To conductroutine quality check activities for biopharma productapplies knowledge of biopharmaceutical industry, basic concepts of biopharmaceutical manufacturing and biochemical analysis processes and tools (for example –ELISA, enzyme assays, invitro studies etc), basics of microbiology (water testing etc) and biology/ biotechnology, basic statistical analysis tools and organizational SoPs and norms related to Good Laboratory	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:- - while performing quality checks and writing analysis records and recommendations, individual uses skills like planning and organizing, analytical thinking, critical thinking, customer centricity and decision making. - Analytical thinking and critical thinking and decision making skills are usedto choose the appropriate safety gears like head gear, masks, etc.and to identify and correct any hazards that he/she can deal with.	The role holder applies mathematical skill, understanding of social, political systems and some skill of collecting and organizing information, communication. For example:- - While conducting the quality checks activities like buffering, 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/ISO), work expectations and output requirements as	Responsibility of own work and learning and some responsibility for other's work and learning. For example:- - has responsibility to conduct quality checks as per SoPs for biopharmaceutical products. - 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 - has responsibility for checking the quality in the work done by cross functional teams being testing and	Level 5

implement assay optimization plans - uses appropriate safety gears like head gear, masks, gloves etc.as mentioned in the EHS guidelines - 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 - identify and recommend opportunities for improving health, safety, and security to the designated person as notified by company in SoPs - interacts within and cross functional team tocommunicate and discuss work flow related difficulties in order to find solutions with mutual agreement while ensuring adherence to the laid down guidelines.	Practices (GLP) (like environment condition, instrument upkeep) and Good Documentation Practices (GDP), Quality Management System (like ISO) and current regulations guidelines (like FDA, MHRA etc.) - To report hazards and breaches and limits of individual for dealing with hazards applies knowledge of biological substances, required precaution and safety measures, types of health and safety hazards and breaches at the workplace. - To coordinate with manager and team members (both within and cross functional) applies knowledge of escalation SoPs, work flow in organization, problem solving tools like (root cause analysis) and quality principles like Quality by design etc, and company's tie-ups with bodies like DCGI, FDA, etc.	- 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. - Uses customer centricity and analytical thinking to understand the quality standards, work expectations and output requirements to be maintained. - Decision making skills are also used when he/she makes discretionary judgements while responding to information requests, documents, clarifications and providing necessary information to superiors and production and quality assurance teams. - Uses organize and planning, analytical thinking and critical thinking skills while interacting within and cross functional team to collect sample. - The problem solving skills are used in communicating and discussing issues identified in samples and in order to find solutions with	per company's SOPs/ guidelines and tie up arrangements with applicable regulatory body (like FDA etc) - uses collecting and organizing skills, and communication skills (reading, writing, speaking and listening) while collecting sampling and any specific information like acceptance criteria of sample (product/ intermediate), while communicating sample analysis results, writing narrative of analysis. - 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. - Applies mathematical skills for assessment of OOS and to compile and analyze data as well as to discuss results/ issues.	analysing the samples. - Also responsible that junior staff under him/her is following company's emergency procedures promptly, calmly, and efficiently at the lab area. - responsible for the assignedquality check/ control tasks by the supervisor as well as follow up and guide the junior staff for their work with respect to any quality norm like SOPs, ISO/GLP guidelines. - He/ she is also responsible jointly to discuss issues and results of sample analysis in order to find solutions with mutual agreement. - Individual is responsible for training junior staff as per requirements coming out of the trend analysis or as per guidelines of WHO/FDA/MHRA etc.	

		mutual agreement.			
Level 5	Level 5	Level 5	Level 5	Level 5	

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 Biologist post qualifying the certification of Quality Control Biologist, 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 Biologist.

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