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	Bio Process Engineer (LFS/ Q 0219)
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	Bio Process Engineer falls under Manufacturing Occupation. The Job role holder is responsible for providing technical support in the operational implementation and performance aspects of biochemical drug substance manufacturing plants. The role holder supports design, development, and evaluation of biological and health systems and products, such as artificial organs, prostheses, instrumentation, medical information systems, and health management and care delivery systems. The individual is required to apply knowledge of design or commissioning of a mammalian cell-based biopharmaceutical manufacturing plant, functional knowledge of production equipment and knowledge of bioprocess technology transfer and/or scale-up technology manufacturing and upstream mammalian cell culture. The individual uses skills like analytical thinking, critical thinking, planning and organizing, communication skills, problem solving and decision making skills. Bio process engineer has responsibility of own work and learning and some responsibility for other's work and learning.
Proposed level of the qualification in the NSQF.	Level 5
Anticipated volume of training/learning required to complete the qualification.	425 Hours
Entry requirements / recommendations.	Bachelor's degree in biotechnology/biochemical/ chemical preferable or biological science or applied science or a closely related field
Progression from the qualification.	**Upward progression:** Production Plant Manager (Level 6) **Lateral/ Horizontal progression:** Production Planning Engineer (Level 5) Research Associate- Product Development/ Technical (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
- SFHPHARM23 check documentation and materials
- COGLS2 Maintain effective and efficient working relationships
- COGLS15 Improve product(s) and process quality within life
- COGPIO1.8 Work in aseptic or clean room conditions in processing industries operations
- COGPACK44 work effectively in a team
- COGLS206 Preparing reagents in life sciences and related industries
- 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 3213, page no. 190 Unit Group 3141; ; International Standard Classification of Occupations ILO Geneva, ISCO–08 Volume I (http://www.ilo.org/wcmsp5/groups/public/---dgreports/---dcomm/---publ/documents/publication/wcms_172572.pdf)

Australia

- Operate a terminal sterilisation process
- Clean equipment in place
- Clean and sanitize equipment
- Apply quality standards
- Communicate workplace information
- Participate in OHS processes
- Participate in work teams and groups

South Africa NOS

- Weigh raw materials in large scale pharmaceutical manufacturing
- Apply the principles of asepsis and sterility in a healthcare environment
- 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/N0247: To provide operational support for daily manufacturing activities	Mandatory	50	Level 5
LFS/N0248: To support R&D	Mandatory	80	Level 5

capabilities			
LFS/N0249: To assist in development and execution technical transfer plans, process transfer and validation protocols	Mandatory	100	Level 5
LFS/N0250: To carry out reporting and documentation for bioprocessing activities	Mandatory	75	Level 5
LFS/N0103: To ensure cleanliness in the work area	Mandatory	30	Common across Level 2-6
LFS/N0251: To coordinate with manager and team members to carry out bioprocessing activities	Mandatory	45	Level 5
LFS/N0101: Maintain a healthy, safe and secure working environment in the life sciences facility	Mandatory	45	Common across Level 2-7

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:

Aspiring Minds Assessment Private Limited, having its registered office at 24, Pusa Road, New Delhi, PIN-110005

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 (700)	Out Of	Theory	Skills Practical
LFS/N0247 (To provide operational support for daily manufacturing activities)	PC1. provide technical support for the evaluation of raw material to ensure manufacturing processes are robust, safe and adequate	100	6	2	4
	PC2. assist improvements in raw material testing regimes to ensure the critical functional attributes are evaluated		3	1	2
	PC3. provide support to Manufacturing to meet production demands		6	2	4
	PC4. operate small-scale cell culture areas and systems by operating cleaning, set up, and maintaining batch reefed fermenters; inoculating and maintaining spinner seed cultures using aseptic techniques, maintaining cellbanks; and performing general seed		9	3	6

	lab operation				
	PC5. operate large scale column chromatography systems		3	1	2
	PC6. comply with safety requirements, GMP, SOP and manufacturing		6	2	4
	PC7. assist in use of automation to perform production operations		3	1	2
	PC8. participate in continuous operational improvement in the manufacturing process		4	2	2
	PC9. apply the concepts in commercial-scale drug substance manufacturing		3	1	2
	PC10. anticipate potential problems and takes preventative action		3	1	2
	PC11. provide day-to-day bioprocess engineering support to upstream / downstream manufacturing operations.		6	2	4
	PC12. support and participate in commissioning and start-up activities of biotech unit operations and equipment.		6	2	4
	PC13. initiate and implement facility and equipment upgrades to improve plant productivity and throughput.		6	2	4
	PC14. facilitate the introduction of new products with associated new unit operations and equipment and ensure the bio-processing at the site stays current with emerging processing and equipment innovations.		6	2	4
	PC15. assemble and prepare equipment for production		4	2	2
	PC16. prepare solutions for the production process		4	2	2

	PC17. trouble shoot equipment and process problems		4	2	2
	PC18. operate systems that clean and sterilize tanks and filtration systems		6	2	4
	PC19. operate fermenters, centrifuges, other harvest systems and protein purifications units		6	2	4
	PC20. interact with internal and external business partners to remain updated on emerging technologies to best position the operations team with a competitive advantage in delivering products of the highest quality at the lowest cost		3	1	2
	PC21. develop recommendations for improvements to existing commercial-scale manufacturing processes to ensure reliability, robustness, and regulatory compliance		3	1	2
	Total		100	36	64
LFS/N0248 (To support research and development capabilities)	PC1. establish process development scale-up to extend the company's research and development capabilities	100	10	4	6
	PC2. optimize growth and productivity parameters of suspension cell lines and assist, as needed, in the hands-on experiments to define these variables		10	4	6
	PC3. conduct research, along with life scientists, chemists, and medical scientists, on the engineering aspects of the biological systems of humans and animals.		16	6	10
	PC4. diagnose and interpret bioelectric data, using signal processing techniques.		10	4	6
	PC5. design and develop medical diagnostic and clinical instrumentation, equipment, and procedures, using the principles of engineering and bio		14	6	8

	behavioural sciences.				
	PC6. develop models or computer simulations of human bio behavioural systems to obtain data for measuring or controlling life processes.		14	6	8
	PC7. assist in design, development, and evaluation of biological and health systems and products, such as artificial organs, prostheses, instrumentation, medical information systems, and health management and care delivery systems		14	6	8
	PC8. participate in the creation, development and design of the organization's novel technologies by interfacing with vector design, downstream and analytical teams		6	2	4
	PC9. research new materials to be used for products, such as implanted artificial organs.		6	2	4
	Total		100	40	60
LFS/N0249 (To develop and execute technical transfer plans, process transfer and validation protocols)	PC1. contribute technical support to develop and execute technical transfer plans (including transfers of existing products or new products under development). This includes preparation of process transfer protocols, process validation protocols, and supporting regulatory documents.	100	24	8	16
	PC2. provide technical guidance to R&D cell-line development and media optimization functions to ensure manufacturing suitability and regulatory compliance of proposed strategies while maximizing process yields and/or reducing cost of goods		20	8	12
	PC3. serve as the global biologics operations technical support on capital projects related to manufacturing processes and equipment and as a bioprocessing functional area subject matter expert on the internal mammalian cell culture manufacturing		20	8	12

	PC4. assist in design and execution of test protocols to optimize unit operations		20	8	12
	PC5. assist in processing data to manufacturing performance management meetings to establish and monitor process metrics, extract key learnings, and develop continuous		16	6	10
	Total		100	38	62
LFS/N0250 (To carry out reporting and documentation for bioprocessing activities)	PC1. support the team in technical transfer of data, processes and technical specifications to CMOs for the implementation of large-scale manufacturing operations for clinical and commercial development of targeted product	100	12	6	6
	PC2. follow reporting procedures as prescribed by the company		10	4	6
	PC3. identify and report defects/ anomalies to the appropriate authority		12	6	6
	PC4. prepare comprehensive summaries of bioprocessing information and other document necessary for regulatory submission		16	6	10
	PC5. maintain, update and archive study related files and documents		8	4	4
	PC6. identify documentation to be completed relating to one's role		6	2	4
	PC7. record details accurately in appropriate format		6	2	4
	PC8. ensure that the final document meets regulatory and compliance requirements		10	4	6
	PC9. perform review of records and other documentation for compliance to established procedures and good documentation practices		10	4	6
	PC10. respond to requests for information in an appropriate manner whilst following organizational		6	3	3

	procedures				
	PC11. inform the appropriate authority of requests for information received		4	2	2
	Total		100	43	57
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 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		4	2	2

	work				
	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/N0251 (To coordinate with manager and team members to carry out bioprocessing	PC1. receive work instructions from reporting manager	100	6	2	4
	PC2. communicate to reporting supervisor about process-flow improvements, quality defects		18	8	10

activities)	received from manufacturing activities				
	PC3. investigate, bring to the Manager's attention and suggest possible solutions to problems arising within the Department resulting from faulty equipment, dated SOP or human error		18	8	10
	PC4. communicate any potential hazards or expected process disruptions		15	5	10
	PC5. provide requisite information, documents, clarifications to manager during actual audits		10	4	6
	PC6. collaborate with the manufacturing department in updating manufacturing procedures and policies		10	4	6
	PC7. work as a team with colleagues and share work as per their or own workload and skills		3	1	2
	PC8. support/assign personnel/team members to support internal and external audit activities as per instructions of superior(s)		8	4	4
	PC9. provide documented shift handovers to the next person in the shift		6	2	4
	PC10. communicate and discuss work flow related difficulties in order to find solutions with mutual agreement		6	2	4
	Total		100	40	60
LFS/N0101 (To maintain a healthy, safe and secure working environment)	PC1. observe and comply with your company's current health, safety and security policies and procedures	100	5	5	10
	PC2. while carrying out work, use appropriate safety gears like head gear, masks, gloves and other accessories as mentioned in the guidelines		5	5	10
	PC3. report any identified breaches in health, safety, and security policies and		5	5	10

	procedures to the designated person				
	PC4. responsible for maintaining discipline at the storage area		5	5	10
	PC5. identify and correct any hazards that you can deal with safely, competently and within the limits of your authority		5	5	10
	PC6. adhere and comply to storage and handling guidelines for hazardous material		5	5	10
	PC7. identify and recommend opportunities for improving health, safety, and security to the designated person		5	5	10
	PC8. complete any health, safety and security records legibly and accurately		4	6	10
	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		4	6	10
	PC10. follow your company's emergency procedures promptly, calmly, and efficiently		5	5	10
	Total	100	48	52	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.

Bio Process Engineer - Life Sciences LFS/ Q 0219					
Process Required	**Professional Knowledge**	**Professional Skills**	**Core Skills**	**Responsibility**	**Level**
Bio process engineer requires well developed skill, with clear choice of procedures in familiar context to perform job. For example:- - Provide technical support for evaluation of raw materials - Operate small-scale cell culture areas and systems by operating cleaning, set up, and maintaining batch reefed fermenters; inoculating and maintaining spinner seed cultures using aseptic techniques, maintaining cell banks; and performing general seed lab operation - operate systems that clean and sterilize tanks and filtration systems and operates fermenters,	Bio process engineer requires knowledge of facts, principles, process and general concepts, in a field of Life Sciences Manufacturing. For example:- To develop and execute technical transfer plans applies knowledge of design or commissioning of a mammalian cell-based biopharmaceutical manufacturing plant, functional knowledge of production equipment anf knowledge of bioprocess technology transfer and/or scale-up technology manufacturing and upstream mammalian cell culture To operate small-scale cell culture areas and systems applies knowledge of downstream biopharmaceutica	Bio process engineer 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:- - uses skills like planning and organizing, critical thinking and decision making while he/she provide operation support for daily manufacturing activities - uses planning and organizing, analytical thinking, problem solving and decision making while he/she assist in development and execution technical transfer plans, process transfer and validation protocols. - Analytical skills are used to support R&D activities.	The role holder applies mathematical skill, understanding of social, political systems and some skill of collecting and organizing information, communication. For example:- - While supporting the daily manufacturing activities and assist in development and execution technical transfer plans has an understanding of his/her function as well as other peripheral functions like production, quality control, engineering, EHS, their scope and responsibilities, applicable regulatory guidelines and tie ups with bodies (for example	Bio process engineer has responsibility of own work and learning and some responsibility for other's work and learning. For example:- - Provide technical support for evaluation of raw materials - Operate small-scale cell culture areas and systems by operating cleaning, set up, and maintaining batch reefed fermenters; inoculating and maintaining spinner seed cultures using aseptic techniques, maintaining cell banks; and performing general seed lab operation - operate systems that clean and sterilize tanks and filtration	Level 5

centrifuges, other harvest systems and protein purifications units - contribute for technical support to develop and execute technical transfer plans (including transfer of existing products or new products under development), which includes preparation of process transfer protocols, process validation protocols, and supporting regulatory documents	l unit operations involved with bioreactor design and control, SIP/CIP, filtration etc and organizational SoPs. To carry out reporting and documentation applies knowledge of documentation formats, SoPs and Good Documentation Practices (GDP) and knowledge of entering, transcribing, recording, storing, or maintaining information in written or electronic/magnetic form To report hazards and breaches applies knowledge of required precaution and safety measures, types of health and safety hazards and breaches and organization SoPs for EHS.	- Analytical thinking and critical thinking and decision making skills are used to identify and correct any hazards that he/she can deal with safely, competently and within the limits of their authority. - Uses analytical thinking to understand the quality standards, work expectations and output requirements to be maintained and while understanding the team member's skill, responsibilities, motivational needs. - Decision making skills are also used when he/she makes discretionary judgements while deciding on technology transfer and processes.	WHO/FDA/DCGI) - While supporting production activities and documenting understands desired quality standards (GMP/GLP/ISO), work expectations and output requirements as per company's SOPs/ guidelines. - Uses collecting and organizing skills, and communication skills (reading, writing, speaking and listening) while development and execution technical transfer plans and supporting production activities - Communication skills are used to report hazards to the relevant person in line with organizational procedures and warn other people who may be affected and while managing the shift operations - Applies mathematical skills in order to find solutions for production related issues.	systems and operates fermenters, centrifuges, other harvest systems and protein purifications units - contribute for technical support to develop and execute technical transfer plans (including transfer of existing products or new products under development), which includes preparation of process transfer protocols, process validation protocols, and supporting regulatory documents	
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 5 years of Industry work experience as Bio Process Engineer post qualifying the certification of Bio Process Engineer, candidate has an option to qualify for Production Plant Manager Job role for a vertical progression.

Similarly can qualify for Production Planning Engineer job role for lateral progression.

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