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	Clean Room Engineer/ Technician (LFS/ Q 0218)
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	Clean Room Engineer is also known as Clean Room Technician falls under Manufacturing Occupation. The Individual is responsible for performing activities towards decontamination, infection control, preparation/assembly, sterilization and distribution of equipment and supplies in sterile processing environment. The job requires individual to apply knowledge ofmanufacturing facility and clear room operations, functional knowledge of sterilization equipment's, like sterilizer, etc. and knowledge of decontamination and sterilization process. The individual uses skills like analytical and critical thinking, planning and organizing, problem solving, decision making and communication skills. The individual is responsible for his/her own work and learning.
Proposed level of the qualification in the NSQF.	Level 4
Anticipated volume of training/learning required to complete the qualification.	270 Hours
Entry requirements / recommendations.	Diploma/ D.Pharma/ B.Sc/ Graduation in any field
Progression from the qualification.	**Upward progression:** Production Chemist – Life Sciences (Level 5) Production Supervisor- Life Sciences (Level 5) **Lateral/ Horizontal progression:** Production Operator- Life Sciences (Level 4)
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** • COGLS216 Operating in a clean room or aseptic facility in life sciences and related industries • COGPIO1.8 Work in aseptic or clean room conditions in processing industries operations • COGDO30 Control room operations in downstream operations • COGPACK44 work effectively in a team

- COGPIO2.15 identify and deal with industry hazards
- COGPIO3.2 control emergencies
- SFHPHARM23 check documentation and materials
- COGLS201 Follow health and safety procedures in life sciences
- COGLS301 Maintain health and safety in life sciences

Switzerland NOS

- Refer page no. 266 Unit Group 5329; 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

- Maintain 'clean room' environments
- 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

- 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/N0243:To participate in decontamination, inspection, cleaning and sterilization of all manufacturing equipment	Mandatory	150	Level 4
LFS/N0245:To carry out reporting and documentation for sterilization records	Mandatory	30	Level 4
LFS/N0103: To ensure cleanliness in the work area	Mandatory	30	Common across level 2-6
LFS/N0246: Co-ordinate with manager and team members to carry out sterilization activities	Mandatory	30	Level 4

LFS/N0101: Maintain a healthy, safe and secure working environment in the life sciences facility	Mandatory	30	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 (500)	Out of	Theory	Skills Practical
LFS/N0243 (To participate in decontamination, inspection, cleaning and sterilization of all manufacturing equipment)	PC1. demonstrate efficient skills in decontamination, inspection, cleaning and sterilization of all manufacturing equipment, instruments and supplies using various types of autoclaves	100	14	6	8
	PC2. when sterilized, follow set procedures for putting back pieces of equipment together		10	4	6
	PC3. participate and monitor process of building accurate and timely assembling of case carts for emergent / urgent and elective cases		4	2	2
	PC4. use chemicals in the appropriate fashion, taking into consideration the intended use and function of the chemicals including knowledge of the		10	4	6

	appropriate Personal Protection Equipment (PPE)				
	PC5. assist with support for overseeing all activities of the Sterile Processing department to ensure flow of the highest level of operations by identification of issues and problem solving in the timely manner including timely reporting to the supervisor		14	6	8
	PC6. follow safety instructions, and policies and procedures, external and internal to the Sterile Processing function and provides compliance		10	4	6
	PC7. improve manufacturing efficiency by analysing and planning work flow, space requirements, and equipment layout		8	4	4
	PC8. assure product and process quality by designing testing methods; testing finished- product and process capabilities; establishing standards; confirming manufacturing processes		8	4	4
	PC9. validate sterilizer test parameters monitoring such as bowie dick test, biologicals, and other forms of sterilization testing		8	4	4
	PC10. respond appropriately to sterilization that does not pass testing		14	6	8
	Total		100	44	56
LFS/N0245 (To carry out reporting and documentation for sterilization records)	PC1. complete appropriate documentation records prior to sterilization, read and initials and incubates biologicals	100	14	6	8
	PC2. assist with maintaining manufacturing department's		14	6	8

	sterilization records				
	PC3. follow reporting procedures as prescribed by the company		14	6	8
	PC4. prepare comprehensive summaries of sterilization information and other document necessary for regulatory submission		14	6	8
	PC5. maintain, update and archive study related files and documents		8	4	4
	PC6. identify documentation to be completed relating to one's role and record details accurately, in the appropriate format and meeting regulatory and compliance requirements		16	6	10
	PC7. perform review of records and other documentation for compliance to established procedures and good documentation practices		10	4	6
	PC8. respond to requests for information in an appropriate manner whilst following organizational procedures		6	3	3
	PC9. 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		5	2	3

	working condition				
	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. ensure that there is no oily substance on the floor to avoid slippage		4	2	2
	PC11. ensure that no scrap material is lying around		4	2	2
	PC12. maintain and store housekeeping equipment and supplies		4	2	2
	PC13. follow workplace procedures to deal with any accidental damage caused during the cleaning process		4	2	2
	PC14. ensure that, on completion of the work, the area is left clean and dry and meets requirements		4	2	2
	PC15. return the equipment, materials and personal		4	2	2

	protective equipment that were used to the right places making sure they are clean, safe and securely stored				
	PC16. dispose the waste garnered from the activity in an appropriate manner		4	2	2
	PC17. dispose of used and un-used solutions according to manufacturer's instructions, and clean the equipment thoroughly		4	2	2
	PC18. maintain schedules and records for housekeeping duty		4	2	2
	PC19. replenish any necessary supplies or consumables		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/N0246 (Co-ordinate with manager and team members to carry out sterilization activities)	PC1. receive work instructions from reporting manager	100	6	2	4
	PC2. communicate to reporting supervisor about process-flow improvements, quality defects received from sterilization and decontamination processes		18	8	10
	PC3. investigate, bring to the Manager's attention and suggest possible solutions to		18	8	10

	problems arising within the Department resulting from faulty equipment, dated SOP or human error				
	PC4. communicate any potential hazards or expected process disruptions		18	8	10
	PC5. provide requisite information, documents, clarifications to manager during actual audits		10	4	6
	PC6. Collaborate with the manufacturing department in updating sterilization procedures and policies		7	3	4
	PC7. work as a team with colleagues and share work as per their your own work load and skills		3	1	2
	PC8. support/assign personnel/team members to support internal and external audit activities as per instructions of superiors/supervisor		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	42	58
LFS/N0101(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	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

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.

Clean Room Engineer/ Technician LFS/ Q 0218					
Process Required	**Professional Knowledge**	**Professional Skills**	**Core Skills**	**Responsibility**	**Level**
Clean room engineer work in familiar, predictable, routine, situation of clear choice. For example: - Ensures Decontamination, inspection, cleaning and sterilization of equipment and Validate sterilizer test parameters as per SoPs and Good Manufacturing Practices (GMP) Guidelines - Assists all activities of the sterile processing department to ensure flow of the highest level of operations by identification of issues and problem solving in the timely manner including timely reporting to the supervisor - Report problems / incidents / quality issues and test results and record and document of sterilization records - Ensure health and	Clean room engineer applies factual knowledge of life sciences manufacturing. For example: To Ensures Decontamination, inspection, cleaning and sterilization of equipment applies knowledge of manufacturing facility and clear room operations, functional knowledge of sterilization equipment's, like sterilizer, etc. and knowledge of decontamination and sterilization process Tovalidate sterilizer test parameters applies knowledge of sterilizer test parameters such as bowie dick test, biologicals, and other forms of sterilization testing knowledge of chemicals and basic chemistry concepts and organizational	Clean room engineer recalls and demonstrates practical skill, routine and repetitive in narrow range of application, using appropriate rule and tool, using quality concept. For Example: - Individual plans, organizes and use analytical and critical thinking while ensuring Decontamination, inspection, cleaning and sterilization of equipment as per GMP and SoPs. - While validate sterilizer test parameters, uses analytical and decision making. The same skills are used while handling and reporting a hazard/ breach or while managing the emergency as per EHS guidelines. - Decision making skills are also used while deciding to escalate a complex problem as per escalation matrix	Clean room engineer uses language to communicate written and oral with required clarity, skill to basic arithmetic and algebraic principles, basic understanding of social, political and natural environment. For Example: - uses communication skills (listening, speaking, writing) for reporting and documentation, providing the necessary information both upward to production supervisor and downward to manufacturing assistants. - uses communication skills (reading) to	Clean room engineer has responsibility of own work and learning. For Example: - Ensures Decontamination, inspection, cleaning and sterilization of equipment and Validate sterilizer test parameters as per SoPs and Good Manufacturing Practices (GMP) Guidelines - Assists all activities of the sterile processing department to ensure flow of the highest level of operations by identification of issues and problem solving in the timely manner including timely reporting to the supervisor	Level 4

safety at shop floor as per SoPs, EHS and regulatory guidelines like FDA/MHRA etc and as per norms (environment condition, cross contamination guidelines etc) of Good Manufacturing Practices (GMP) and Good Documentation Practices (GDP) - Co-ordinate with manager and team members to carry out sterilization activities	SoPs. To carry out reporting and documentation applies knowledge of documentation formats, SoPs and Good Documentation Practices (GDP) and knowledge of computer tools like (Lab Management Information system and Microsoft Office etc). 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.	of organization. - Problem solving skills are used while troubleshooting small issues while carry out the sterilization as well as while setting and reassembling the machines post sterilization as per the SoPs and sterilization guidelines.	read and interpret images, graphs, diagrams for sterilization and decontaminatio n parameters, job sheets, procedures, basic machine control panels, and safety information - uses basis arithmetic and algebraic principles to do the simple calculation while validating the sterilization parameters - Individual has basic understanding of the Industry, cross functions and own function, understanding of requirements of regulatory bodies like MHRA/FDA etc. and understand the legislative requirement for EHS procedures.	- Report problems / incidents / quality issues and test results and record and document of sterilization records Co-ordinate with manager and team members to carry out sterilization activities	
Level 4	Level 4	Level 4	Level 4	Level 4	

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 Clean Room Engineer/ Technician post qualifying the certification of Clean Room Engineer/ Technician, candidate has an option to qualify for Production Supervisor/ In charge- Life Sciences Job role for a vertical 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