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	Drug Regulatory Affairs Chemist (LFS/ Q 0501)
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	Drug Regulatory Affairs Chemist is also known as Dossier Associate falls under Research & Development Occupation. The individual is responsible for making dossiers submitted to regulatory bodies for the various markets and also ensue completion for forms and carry out filling of regulatory forms. The job requires individual to apply knoweldge of life sciences, industry, knowledge of organic chemistry and regulatory affairs and golabl regulatory requirements, and documentation practices. The individual uses the skills like critical and analytical thinking, problem solving, decision making, planning and organizing and communcation skills. The individual is responsible for his/ her work and learning and has some responsibility for other cross functional colleagues work and learning.
Proposed level of the qualification in the NSQF.	Level 5
Anticipated volume of training/learning required to complete the qualification.	300 Hours
Entry requirements / recommendations.	Diploma in Pharmacy/ Mechanical & Chemical Engineering./ Graduate in Science/ B.Pharmacy (Preferable); NO Experience required if hiring company is making only CTD, else minimum 1 year's experience
Progression from the qualification.	**Upward progression:** Manager- Drug Regulatory Affairs **Lateral/ Horizontal progression:** Regulatory Affairs Associate
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 • SFHPHARM23 check documentation and materials • COGLS2 Maintain effective and efficient working relationships • COGPIO3.2 control emergencies • COGLS201 Follow health and safety procedures in life sciences • COGLS301 Maintain health and safety in life sciences

	Switzerland NOS - Australia NOS • Communicate workplace information • 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/N0501 To ensure appropriate licensing, marketing and legal compliance of pharmaceutical and medical products.	Mandatory	100	Level 5
LFS/N0503 To ensure that the products comply with the regulations	Mandatory	50	Level 5
LFS/N0502 To carryout reporting and documentation for dossier preparation	Mandatory	100	Level 5
LFS/N0105: To coordinate with manager and team members for smooth functioning	Mandatory	50	Level 5

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

- Qualifications Pack is attached in Annexure 1

SECTION 1

ASSESSMENT

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

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

Will the assessment body be responsible for RPL assessment?

Only One Given Below:

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

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

RPL arrangements and policies are under development.

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

Assessment Agencies: An assessment agency is selected on the basis of

- Prior experience and understanding of Life Sciences or similar sector.
- Experience in conducting assessments for similar job roles.
- Manpower and Technical capabilities.
- Geographical reach
- Existing Network in the Life Sciences Sector
- Agencies internal policies to maintain Standards, Quality & professional Integrity
- Agencies policy in assessor management

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

- Selection of assessment tool(s) depending on the assessment criteria prescribed in that QP.
- Developing blue print of the question paper, Viva, Demonstration, whatever are selected tools.
- Development of lay-out of Question paper is such that the entire PCs (Performance Criteria) of that QP are covered.
- Score per question maps with the weightage given to that PC, in the assessment criteria and the level of difficulty of the question.
- **SME:** An expert from industry is selected who is called “Subject Matter Expert”. This SME must have over 13-15 years of experience in the industry, on same job role.
- **SME** is screened and approved by LSSSDC. He is 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	Out of	Theory	Practical
LFS/N0501 To ensure appropriate licensing, marketing and legal compliance of pharmaceutical and medical products	PC1. prepare documents, non-conformance reports and corrective action, Preventative action documents for current products and procedures to ensure compliance with applicable regulation	100	7	3	4
	PC2. develop and write clear arguments and explanations for new product licences and licence renewals		7	3	4
	PC3. monitor and set timelines for licence variations and renewal approvals		5	3	2
	PC4. write clear, accessible product labels and patient		5	2	3

	information leaflets				
	PC5. undertake and manage regulatory inspections		6	3	3
	PC6. prepare dossiers/ documents for IND, NDA, ANDA, CTD Submissions and also to support registrations of the new entities		10	5	5
	PC7. liaison with, and make presentations to, regulatory authorities		8	4	4
	PC8. develop and register new medicines, vaccines, diagnostic tests and pharmaceutical products with regulatory authorities like MHRA, MCC, USFDA, TGA, Malaysia, European Union etc in concurrence with the regulations promulgated by a whole range of agencies like the Environmental Protection Agency, Federal Trade Commission, Occupational Safety & Health Administration and Drug Enforcement Administration		7	3	4
	PC9. manage and oversee the laboratory work		5	2	3
	PC10. review company practices and providing advice on changes to systems		5	2	3
	PC11. identify and assess regulatory risks and project issues and make recommendations to regulatory management		7	3	4
	PC12. associating with the marketing personnel to ensure applicability of Regulatory framework		7	3	4

	PC13. keep abreast of international legislation, guidelines and customer practices in all countries where the Company sells its products		5	3	2
	PC14. assist scientists and manufacturers on regulatory requirements		5	2	3
	PC 15. provide regulatory related advice to senior management throughoutthe Development of a new product		5	2	3
	PC 16. assist project managing teams of colleagues involved with the development of new products		5	2	3
	Total		**100**	**45**	**55**
LFS/N0503 To ensure that the products comply with the regulations	PC1. ensure that the product is according to standards and regulations	100	10	5	5
	PC2. ensure that GMP and GLP are followed		10	5	5
	PC3. evaluate compliance procedures for new products		10	5	5
	PC4. supervise the work of technicians and other workers to evaluate Accuracy of their results		5	2	3
	PC5. work with technicians, chemists and scientists of other fields as many Scientific research projects involve multiple disciplines		10	5	5
	PC6. present research findings to scientists, non-scientist executives, engineers, Other colleagues, and the public		10	5	5
	PC7. work with specialist computer software to		10	5	5

	undertake studies and research				
	PC8. support continuous process performance evaluation and continuous Process improvement for highest efficiency		5	2	3
	PC9. keep up with new research		5	2	3
	PC10.minimize the risks of cross-contamination, false-positive results and false- negative		10	5	5
	PC11. define alert and action limits		5	2	3
	PC12. support continuous process performance evaluation and continuous Process improvement for highest efficiency		10	5	5
	Total		**100**	**46**	**54**
	PC1. report defects/ problem/ incidents/quality issues/test results as applicable in a timely manner	100	6	3	3
	PC2. report to the appropriate authority as laid down by the company		6	3	3
	PC3. follow reporting procedures as prescribed by the company		6	3	3
	PC4. work with production management and Quality Assurance to provide Feedback regarding quality standards and issues		5	2	3
	PC5. help other R&D lab staff with any other testing required during the developmental work		6	3	3

LFS/N0509 To carry out reporting and documentation to prepare dossiers	PC6.identify documentation to be completed relating to one's role		6	3	3
	PC7.record details accurately inappropriate format		7	3	4
	PC8.accurately document the results of the inspections and testing		6	3	3
	PC9.maintain all controlled document files and test records in a timely and Accurate manner		6	3	3
	PC10.ensure that the final document meets regulatory and compliance requirements		6	3	3
	PC11.make sure documents are available to all appropriate authorities to inspect		5	2	3
	PC12.evaluate problems and make initial recommendations for possible Corrective action to supervise		7	3	4
	PC13.perform review of records and other documentation for compliance to Established procedures and Good Documentation Practices		6	3	3
	PC14.write and update the inspection procedures, protocols and checklists		6	3	3
	PC15.prepare inspection reports as per the inspection activity performed		7	3	4
	PC16.respond to requests for information in an appropriate manner whilst Following organizational procedures		5	2	3
	PC17. inform the appropriate authority of requests for		4	2	2

	information received				
	Total		**100**	**43**	**57**
LFS/N0105 To Coordinate with manager and team members	PC1. receive work instructions from reporting manager	**100**	20	10	10
	PC2. communicate to reporting supervisor about process-flow improvements, quality defects received from previous process		18	8	10
	PC3. communicate any potential hazards or expected process disruptions		13	5	8
	PC4. provide requisite information, documents, clarifications to manager during actual audits		11	5	6
	PC5. work as a team with colleagues and share work as per their or own work load and skills		8	4	4
	PC6. support/assign personnel/team members to support internal and external audit activities as per instructions of superiors/supervisor		8	4	4
	PC7. provide documented shift handovers to the next person in the shift		8	4	4
	PC8. communicate and discuss workflow related difficulties in order to find solutions with mutual agreement		7	3	4
	PC9. provide support in training initiatives		7	3	4
	Total		**100**	**46**	**54**

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.

Drug Regulatory Affairs ChemistLFS/ Q 0501					
Process Required	**Professional Knowledge**	**Professional Skills**	**Core Skills**	**Responsibility**	**Level**
Job role holder requires well developed skill, with clear choice of procedures in familiar context to perform job. For example:- - prepare documents, non-conformance reports and corrective action preventative action documents for current products and procedures to ensure compliance with applicable regulation - prepare dossiers/ documents for IND, NDA, ANDA, CTD Submissions and also to support registrations of the new entities - develop and register new medicines, vaccines, diagnostic tests and pharmaceutical products with regulatory authorities like MHRA, MCC, USFDA, TGA, Malaysia, European Union	Job role holder requires knowledge of facts, principles, process and general concepts, in a field of Life Sciences Research and development. For example:- - Toprepare dossiers/ documents for IND, NDA, ANDA, CTD Submissions applies knowledge of life sciences manufacturing, R&D, regulatory affair, EHS and legal requirement of the global market etc. Toprepare documents, non-conformance reports and corrective action preventative action documents for current products and procedures applies knowledge of advance chemistry technology, in house research literature, knowledge of	The role holderuses 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 is prepare dossiers/ documents for IND, NDA, ANDA, CTD Submissions - uses planning and organizing, analytical thinking, problem solving and decision making while he/she prepare documents, non-conformance reports and corrective action preventative action documents for current products and procedures. - Analytical skills are used to	The role holder applies mathematical skill, understanding of social, political systems and some skill of collecting and organizing information, communication. For example:- - While developing and compiling dossiers/ documents for IND, NDA, ANDA, CTD Submissions has an understanding of his/her function as well as other peripheral functions like analytical, R&D, manufacturing, EHS, stores, their scope and responsibilities, applicable regulatory guidelines and tie ups with bodies (for example WHO/FDA/DCGI) - While supporting new	The role holder has responsibility of own work and learning and some responsibility for other's work and learning. For example:- - prepare documents, non-conformance reports and corrective action preventative action documents for current products and procedures to ensure compliance with applicable regulation - prepare dossiers/ documents for IND, NDA, ANDA, CTD Submissions and also to support registrations of the new entities - develop and register new medicines, vaccines, and	Level 5

etc in concurrence with the regulations promulgated by a whole range of agencies like the Environmental Protection Agency, Federal Trade Commission, Occupational Safety & Health Administration and Drug Enforcement Administration - assist scientists, medical writers and manufacturing group, on regulatory requirements and in evaluating compliance procedures for new products - supervise the work of biological technicians and other workers to evaluate accuracy of their results - identify documentation to be completed relating to one's role for dossier preparation - provide requisite information, documents, clarifications to manager during actual audits	regulatory compliance requirement, understanding of product life cycle 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 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.	support R&D activities. - Analytical thinking and critical thinking and decision making skills are used to identify and correct procedures for regulatory compliance for new product development. - 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.	product development and documentation understands desired regulatory and quality standards (GMP/GLP/ISO), work expectations and output requirements as per company's SOPs/ guidelines and global market regulatory and legal requirement. - Uses collecting and organizing skills, and communication skills (reading, writing, speaking and listening) while developing and compiling dossiers/ documents for IND, NDA, ANDA, CTD Submissions - Communication skills are used to interact with multiple stakeholders in assisting them to fill / complete their part in the dossier. - Applies mathematical skills in order to find solutions for research and regulatory related issues.	pharmaceutical products with regulatory authorities like MHRA, Malaysia, European Union etc in concurrence with the regulations promulgated by a whole range of agencies like the Environmental Protection Agency, Federal Trade Commission, Occupational Safety & Health Administration and Drug Enforcement Administration - assist scientists, medical writers and manufacturing group, on regulatory requirements and in evaluating compliance procedures for new products - supervise the work of biological technicians and other workers to evaluate accuracy of their results - identify documentation to be completed relating to one's role for dossier preparation	
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:

Drug Regulatory Affairs Chemist has an option to qualify for Regulatory Affairs Associate as lateral progression.

Similarly, after 4-5 years of experience as Drug Regulatory Affairs Chemist, the job role holder can qualify for Drug Regulatory Affairs Manager job role

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