

Revised Application Documentation: Version 5 /22 May, 2015

QUALIFICATION FILE – CONTACT DETAILS OF SUBMITTING BODY

Name and address of submitting body:

Life Sciences Sector Skill Development Council

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

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Name and contact details of individual dealing with the submission

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Same as Above

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List of documents submitted in support of the Qualifications File

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

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

QUALIFICATION FILE SUMMARY

Qualification Title	Licensing Manager - Life Sciences (LFS/Q0609)
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	Licensing Manager - Life Sciences falls under Supply Chain occupation. The individual is responsible for managing the work of the licensing team in order to ensure that the appropriate licenses are in place for carrying out the life sciences facility's operations. The role holder liaisons with the licensing authorities to ensure appropriate documents and licenses are available at the time of selling/imports/exports. The job requires individual to use the knowledge of supply chain function in life sciences industry, knowledge of regulatory compliances for licensing and legal language, licensing norms and application procedures and knowledge of required legal documentation, EXIM policy and contracts and tariffs, organizational SoPs. The individual applies skills like Communication skills, Problem solving, analytical thinking, and plan and organize and decision making. The job role holder has responsibility of own work and learning and full responsibility for other's work and learning
Proposed level of the qualification in the NSQF.	Level 6
Anticipated volume of training/learning required to complete the qualification.	250 Hours
Entry requirements / recommendations.	B.Pharma /Graduate in any field / LLB with minimum 5 years of relevant experience
Progression from the qualification.	<p>Upward progression:</p> <ul style="list-style-type: none"> • Logistics and Licensing Head <p>Lateral/ Horizontal progression:</p> <ul style="list-style-type: none"> • Coordination Manager • Manager Tender Business
Planned arrangements for RPL.	RPL arrangements and policies are under development.
International Comparability	<p>While preparing the NOSs, a detailed secondary desk research was conducted. The European, South African and Australian NOSs were referred to. The relevant International NOSs for the job role are listed below for reference:</p> <p>UK NOS</p> <ul style="list-style-type: none"> • COGLS7 Plan and run projects for life science related work activities • COGLS322 Plan, conduct and manage projects, operations or investigations in life sciences and related industries

- SFHPHARM23 check documentation and materials
 - COGLS2 Maintain effective and efficient working relationships
- Switzerland NOS
- Refer page no. 206, Unit Group 3354; 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 NOS
- Review contracts, insurance, risk and liability in the international freight forwarding context
 - Direct ICT in a supply chain
 - Apply knowledge of logistics
 - Participate effectively in a workplace environment
- South Africa NOS
- Act in accordance with ethical and legal codes of pharmaceutical representation and the laws of the country
 - Apply ethical and legally compliant behaviour in pharmaceutical and health environments

Formal structure of the qualification

Title of unit or other component (include any identification code used)	Mandatory/ Optional	Estimated size (learning hours)	Level
LFS/N0622 Regulatory compliance and exchange of information for licensing activities	Mandatory	40	Level 6
LFS/N0613 To provide analytical support for supply chain management	Mandatory	60	Level 6
LFS/N0623 To Manage, coordinate and interact with people to effectively control licensing operations	Mandatory	90	Level 6
LFS/N0102 To carry out reporting and documentation	Mandatory	60	Common across Level 2-6

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. **Confederation of Indian Industry (CII)**, having its headquarters at The Mantosh Sodhi Centre, 23, Institutional Area, Lodi Road, New Delhi, PIN- 110003
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?

Not all, only **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 oriented by both LSSSDC and Assessment agency on – creating question Bank, level of questions, end desired outcome of the assessment.

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

- LSSSDC defines the criteria for profile of an assessor.
- Assessor is a person who is currently working in the same industry on same or higher job role and has minimum 5-7 years of experience.
- Based on this, Assessment agency locates the right people from the Industry and LSSSDC approves them after screening (they are screened on basis of resume and interview).
- Once selected, the assessor is oriented by LSSSDC and Assessment agency on various aspects of the assessment and management of assessment, such as
 - QP and its background.

- Training on Assessment methodology and how to use Assessment tools. Scoring system. (as per the attached assessment guide)
- Maintain integrity at the assessment site.
- Crisis handling and support system available for the same.
- Scope of his authorities
- Administrative responsibilities.
- Required documentation of Trainee credentials, VTP credentials, mark sheet management.
- Confidentiality management.
- Assessment agency signs the agreement letter with the Assessor.
- LSSSDC certifies the Assessor.

Assessment process:

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

Assessment tools: Assessment tools for a QP are decided on the basis of composition of knowledge and skill in that particular QP. All assessments shall have at least two tools unless indicated otherwise. All assessments carry time allotment required per trainee, within which the assessment should be completed.

Written test:

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

Tools – Pen and Paper in form of OMR sheet, computer or tab based online or offline.

Method – objective type questions, match the columns, fill in the blanks, tick the odd man out, choose the correct option, choose the best answer, True or false, Identify the object, tool or machinery, arrange in proper sequence.

Analysis – Question paper is divided in sections. Each Section intends to assess a particular knowledge field of the trainee. Thus section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated marks gives the overall rating of the trainee.

Viva

Scope – Is used to test the knowledge and understanding and breadth of awareness about the subject. Some personality traits and generic skills (such as – promptness, sharpness, communication skills, depth of knowledge, comprehension, presentation, patience etc) can also be tested required for the QP.

Tools – Direct dialogue between assessor and Trainee.

Method – Direct questions open and close ended questions, situation based questions, analytical questions, and decision making based questions. Different questions are included to test relevant PCs from the QP

Analysis – Assessor is provided with spectrum of ready answers to be expected from trainee. This reduces effect of subjectivity of the assessor. Comparative quality of trainees with in a batch or different institutes can

be gauged.

Practical Test

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

Tools – Demonstration, role play.

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

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

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

Give details of the document(s) here:

- 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	Practical
LFS/N0622 (Regulatory compliance and exchange of information for licensing activities)	PC1. manage and evaluate all regulations and legislations for licensing activities	100	10	5	5
	PC2. ensure appropriate implementation and prepare strategies for various business groups		10	5	5
	PC3. maintain knowledge on all compliance trends and recommend changes for all company processes.		10	5	5
	PC4. design all company strategies for all businesses and resolve all compliance issues and perform research for all product competition		10	5	5
	PC5. prepare all reports for all product forms and manage all communications with licensors and perform audit		12	6	6
	PC6. evaluate all licensing agreements for all license partners and assist to transmit all reports and maintain database and reconcile the same		12	6	6

	PC7. maintain and update all distribution lists and manage all correspondence with licensed partners.		6	3	3
	PC8. review SAP periodic reports to carry out the departmental checks in compliance with rules and regulations and other statutory requirements		5	2	3
	PC9. review updates on cost impacts, cost estimates, stock management, feasibility analysis to carry out the departmental functions in compliance with rules and regulations and other statutory requirements		5	2	3
	PC10. identify variation from the regulatory guidelines and correction of the same		5	2	3
	PC11. comply with organization's policies, procedures, guidelines		5	2	3
	PC12. maintain confidentiality of strategic information		5	2	3
	PC13. communicate information to all relevant people in timely manner		5	2	3
	Total		100	47	53
LFS/N0613 (To provide analytical support for supply chain management)	PC1. analyze and recommend improvements to all internal procedures and implement same	100	15	7	8
	PC2. establish role and responsibilities in providing analytical support for Supply chain management process		15	5	10
	PC3. obtain confirmation from relevant employees and define the objective of the study		10	5	5
	PC4. access suitable sources of data		15	7	8
	PC5. sort and collate relevant data for the analysis		15	5	10
	PC6. usage of appropriate analysis methods and procedures		15	5	10
	PC7. identify potential and actual glitches and the causes for the same		15	7	8
	Total		100	41	59

<p>LFS/N0623 (To manage, coordinate and interact with people to effectively control licensing operations)</p>	P1. lead the demand planning team through all stages of the process ensuring accurate and actionable volume plans for new service launches.	100	10	5	5
	P2. convey organizational strategy to the team		5	2	3
	P3. ensure that the team is onboard with the organizational strategies		5	2	3
	P4. communicate departmental objectives and provide leadership direction to achieve goals		5	2	3
	PC5. manage and support recruitment		5	2	3
	PC6. delineation of individual roles, appropriate delegation of responsibility		5	2	3
	PC7. lead a team of demand planners responsible for integrating POU data into enterprise wide forecasts driving purchasing decisions		5	2	3
	PC8. set KRA's for direct reports, monitor overall team's KRA's, conduct performance appraisal, ensure clarity		5	2	3
	PC9. facilitate the development of subordinates through constant on and off the job learning, job rotation etc.		5	2	3
	PC10. guide, motivate and develop the sub-ordinates.		5	2	3
	PC11. oversee staff deployment and drive motivation levels of the team		5	2	3
	PC12. monitor staff welfare and facilitate complaint resolution		5	2	3
	PC13. manage efficiency levels and drive timely delivery of all operational targets		5	2	3
	PC14. compliance manager- Collaborate with compliance manager and prepare presentations to be presented in all meeting and committees		5	2	3

	PC15. coordinate with senior management and forecast all weekly revenue for same and resolve all complex issues with help from legal and finance teams		5	2	3
	PC16. quality Head – Collaborate to ensure the effectiveness of existing processes and to incorporate improvements		5	2	3
	PC17. department Heads- SAP Cell, Stores, Dispatch, PPC (Production, Planning & Control), Support- Materials, Total Cost Management Control – Collaborate to gather critical information, facts and data from the business		5	2	3
	PC18. stay in touch with ground reality to ensure effective implementation of key business decisions, to ensure availability for reviews, and discuss implementation plans		5	2	3
	PC19. suppliers, contractors and vendors - For continuous evaluation and maintaining long term relationships with the vendors and contractors and ensuring all company policies and procedures are followed		5	2	3
	Total		100	41	59
LFS/N0102 (To carry out reporting and documentation)	PC1. report data/problems/incidents as applicable in a timely manner	100	10	5	5
	PC2. report to the appropriate authority as laid down by the company		10	5	5
	PC3. follow reporting procedures as prescribed by the company		10	5	5
	PC4. identify documentation to be completed relating to one's role		10	5	5
	PC5. record details accurately in an appropriate format		10	5	5
	PC6. complete all documentation within stipulated time according to company procedure		10	5	5
	PC7. ensure that the final document meets regulatory and compliance requirements		10	5	5

	PC8. make sure documents are available to all appropriate authorities to inspect		10	5	5
	PC9. respond to requests for information in an appropriate manner whilst following organizational procedures		10	5	5
	PC10. inform the appropriate authority of requests for information received		10	4	6
	Total		100	49	51

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.

Licensing Manager - Life SciencesLFS/Q0609					
Process Required	Professional Knowledge	Professional Skills	Core Skills	Responsibility	Level
<p>The job demands wide range of specialized technical skill, clarity of knowledge and practice in broad range of activity involving standard/ non standard practices For example:</p> <ul style="list-style-type: none"> - identify and evaluate all regulations and legislations needs for licensing activities - prepare required reports for all product forms and manage all communications with licensors and perform audit - evaluate the relevant licensing agreements for all license partners and assist to transmit all reports for maintaining database and reconciling the same - review updates on cost impacts, cost estimates, stock management, feasibility analysis to carry out the 	<p>The role holder uses factual and theoretical knowledge in broad context within a field of work or study. For example:</p> <ul style="list-style-type: none"> - To identify and evaluate all regulations and legislations needs and prepare required reports for all product formsuses the knowledge of supply chain function in life sciences industry, regulatory and licensing requirements, contracts, laws and acts, NAPPA guidelines and EXIM policy - to facilitate the development of subordinates through constant on and off the job learning, job rotation etc. uses the knowledge of their motivational needs, responsibilities in organizationa and skill needs, 	<p>The role holder uses a range of cognitive and practical skills required to generate solutions to specific problems in a field of work/ study. For Example:</p> <ul style="list-style-type: none"> - To identify and evaluate all regulations and legislations needs uses the skills like analytical and critical thinking, plan and organizing communication and decision making skills. - to and prepare required reports for all product formsuses skills like plan and organize, analytical thinking, problem solving and decision making - to facilitate the development of subordinates through constant on and off the job learning, job rotation etc. uses the skills like communication, analytical and 	<p>The role holder is required to be reasonably good in mathematical calculation, understanding of social political and reasonably good in data collecting organizing information and logical communication. For Example:</p> <ul style="list-style-type: none"> - To review updates on cost impacts, cost estimates, stock management, feasibility analysis individual is required to use complex mathematical calculation and logical reasoning. The mathematical skills are also being used while prepare required reports for all product forms. - To identify and evaluate all regulations and legislations uses understanding of local/ state/ 	<p>The job role holder has responsibility of own work and learning and full responsibility for other's work and learning. For example:-</p> <ul style="list-style-type: none"> - identify and evaluate all regulations and legislations needs for licensing activities - prepare required reports for all product forms and manage all communication s with licensors and perform audit - evaluate the relevant licensing agreements for all license partners and assist to transmit all reports for maintaining database and reconciling the same - review 	Level 6

<p>departmental functions in compliance with rules and regulations and other statutory requirements</p> <ul style="list-style-type: none"> - establish protocol for sharing of regulatory/statutory-related information for licensing to prevent risk issues - establish role and responsibilities in providing analytical support for supply chain management process - facilitate the development of subordinates through constant on and off the job learning, job rotation etc. - coordinate with suppliers, contractors and vendors, for continuous evaluation and maintaining long term relationships and ensuring all company policies and procedures are followed 	<p>escalation matrix.</p> <ul style="list-style-type: none"> - To interact with suppliers, contractors and vendors applies knowledge of suppliers, contractors and vendors, the relevant service level agreements, terms, organizational SoPs and reports, knowledge of different market players and their suppliers, contractors and vendors. 	<p>critical thinking and decision making.</p> <ul style="list-style-type: none"> - To interact with vendors and contractors uses analytical and critical thinking, problem solving and communication skills - To review updates on cost impacts, cost estimates, stock management, feasibility analysis to carry out the departmental functions in compliance with rules and regulations and other statutory requirements, uses the skills like plan and organize, analytical thinking, decision making 	<p>national/ global laws, regulations, and understanding of trends, govt tariffs, contracts, EXIM and NAPPA policies etc.</p> <ul style="list-style-type: none"> - In all data collection and coordination activities data is collected, organized from multiple stakeholder and the logical communication in both written and oral communication is made between multiple stakeholders. - While facilitating the subordinate development role holder has good understanding of all sub functions of supply chain and motivational and skilling needs of the subordinates. 	<p>updates on cost impacts, cost estimates, stock management, feasibility analysis to carry out the departmental functions in compliance with rules and regulations and other statutory requirements</p> <ul style="list-style-type: none"> - establish protocol for sharing of regulatory/statutory-related information for licensing to prevent risk issues - establish role and responsibilities in providing analytical support for supply chain management process - facilitate the development of subordinates through constant on and off the job learning, job rotation etc. - coordinate with suppliers, contractors and vendors, for continuous evaluation and maintaining long term relationships 	
Level 6	Level 6	Level 6	Level 6	Level 6	

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:

Licensing Manager- Life Sciences can qualify for Logistics and Licencing Head job role as vertical progression after an experience of 5 years as Licensing Manager- Life Sciences.

The job holder also have option to move as lateral progression for job role of Coordination Manager

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