

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

Phone: +91 11 41042407/ 408, E-mail: info@lssdc.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@lssdc.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. 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	Data Entry Operator/ Documentation Officer- Life Sciences (LFS/ Q 0510)
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	Data Entry Operator- Life Sciences is also known as Documentation Officer and falls under Research & Development Occupation. Job role holder is responsible for receiving the source document from multiple teams, entering the data into computer systems, verifying data and completing the mandated forms associated with the data processing procedure. The Job requires individual to demonstrates Communication skills (English language reading and writing skills) and working knowledge of computer applications. Individual uses skills analytical thinking (Attention to detail), critical thinking, plan and organize, problem solving and decision making. Individual is responsible for his/her own work and learning and is an Independent performer.
Proposed level of the qualification in the NSQF.	Level 4
Anticipated volume of training/learning required to complete the qualification.	130 Hours
Entry requirements / recommendations.	Diploma in Computer Science, Any Graduate (Preferably Life Science)
Progression from the qualification.	Upward progression: Data Validation Associate Lateral/ Horizontal progression: -
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 <ul style="list-style-type: none"> • COGLS203 Use information recording systems in life sciences and related industries • COGLS2 Maintain effective and efficient working relationships in life sciences related work activities Switzerland NOS <ul style="list-style-type: none"> • Refer page no. 222 Unit Group 4132 Australia NOS <ul style="list-style-type: none"> • 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

Formal structure of the qualification

Title of unit or other component (include any identification code used)	Mandatory/ Optional	Estimated size (learning hours)	Level
LFS/N0535 To enter, update and maintain R&D data in the system	Mandatory	70	4
LFS/N0536 Maintain associated data entry terminals	Mandatory	30	4
LFS/N0302 Coordinate with Supervisors and colleagues within and outside the department	Mandatory	30	Common between 4-5 levels

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. Manipal City & Guilds Pvt. Ltd, having its registered office at 4th Floor, above Total Superstore, Sy. No 12/5, Kaikondarahalli, Varthur Hobli, Sarjapur Main Road, Bangalore, Karnataka, PIN- 560034

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 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:

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

ASSESSMENT EVIDENCE

Assessable Outcomes	Assessment Criteria	Total Marks (300)	Out Of	Theory	Skills Practical
LFS/N0535 <u>(To enter, update and maintain R&D data in the system)</u>	PC1. prioritize service requests according to organizational guidelines	100	6	3	3
	PC2. fill and process mandated forms for receiving, processing, or tracking data		6	3	3
	PC3. enter data from source documents (such as patient report, test report etc.) into computer application following standard sequence and coding protocols		14	6	8
	PC4. scan source documents in accordance with specific instructions		8	3	5
	PC5. verify data entered with source documents, checks for compliance with composition codes and style rules and corrects all typographical errors and missing or repeated data		8	2	6

	PC6. maintain files of source documents or other information related to data entered		8	3	5
	PC7. investigate and confirm data that is unclear before entering		8	3	5
	PC8. generate reports of data entry, store completed work in designated locations and perform backup operations		8	3	5
	PC9. update database information to reflect most current source information, such as patient profiles		14	6	8
	PC10. assist in the filing and storage of security and back up data files		14	6	8
	PC11. respond to requests for information and access relevant files		6	2	4
	Total		100	40	60
LFS/N0536 (<u>Maintain associated data entry terminals</u>)	PC1. maintain logbooks or records for data entry job runs on the terminal	100	12	4	8
	PC2. operate the terminal as per the defined organization procedures		18	6	12
	PC3. be attentive for error lights and indicators and highlight the same to the concerned authority		14	6	8
	PC4. correctly load files onto storage media of the system		14	6	8
	PC5. check for network and servers functioning prior to job commencement		16	6	10
	PC6. clear the terminal surrounding at the end of the jobs		10	2	8
	PC7. notify the appropriate authority of malfunctions		16	4	12
	Total		100	34	66
LFS/N0302 (<u>Coordinate with Supervisors and colleagues within</u>)	PC1. understand the work output requirements	100	10	5	5
	PC2. proactively inform supervisor on issues requiring intervention		10	5	5

<u>and outside the department)</u>	PC3. comply with company policy and rule		10	5	5
	PC4. deliver quality work on time and report any anticipated reasons for delays		16	8	8
	PC5. put team over individual goals		10	5	5
	PC6. be able to resolve conflicts		10	5	5
	PC7. learn how to multi-task relevant activities		10	5	5
	PC8. provide guidance and direction to subordinates, including setting performance standards and monitoring performance		12	5	7
	PC9. Impart training to team members/cross-function team members		12	5	7
	Total		100	48	52

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.

Data Entry Operator/ Documentation Officer- Life SciencesLFS/ Q 0510					
Process Required	Professional Knowledge	Professional Skills	Core Skills	Responsibility	Level
<p>Job role holder work in familiar, predictable, routine, situation of clear choice. For example:</p> <ul style="list-style-type: none"> - prioritize service requests according to organizational guidelines and fill and process mandated forms for receiving, processing, or tracking data - enter data from source documents (such as patient report, test report etc.) into computer application following standard sequence and coding protocols - verify data entered with source documents, checks for compliance with composition codes and style rules and corrects all typographical errors and missing or repeated data - generate reports of data entry, store completed work in designated locations and 	<p>Job role holder applies factual knowledge of computer and R&D processes. For example:</p> <p>To fill and process mandated forms for receiving, processing, or tracking data applies knowledge of organization and process guidelines, knowledge of critical data and sequence of the data flow and good documentation practices and GCP/GLP/GMP guidelines</p> <p>To enter data from source documents (such as patient report, test report etc.) into computer application applies knowledge of computer system, software, typing and knowledge of other functions and the process flows and organizational SoPs.</p> <p>To carry out</p>	<p>Role holder recalls and demonstrates practical skill, routine and repetitive in narrow range of application, using appropriate rule and tool, using quality concept. For Example:</p> <ul style="list-style-type: none"> - Individual plans, organizes and use analytical and critical thinking while prioritize service requests according to organizational guidelines and fill and process mandated forms for receiving, processing, or tracking data. - While choosing the appropriateness of data entering sequence and setting the data entry terminal for data entry, uses analytical and decision making. <p>The same skills are used while verifying data entered with source documents, and checking for compliance with composition codes</p>	<p>Role holder 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:</p> <ul style="list-style-type: none"> - uses communication skills (listening, speaking, writing) for reporting and documentation, providing the necessary information both upward to supervisor and lateral to cross functional teams. - uses communication skills (reading) to read and interpret images, graphs, diagrams for typical product specifications, job sheets, procedures, computer 	<p>Role holder has responsibility of own work and learning. For Example:</p> <ul style="list-style-type: none"> - prioritize service requests according to organizational guidelines and fill and process mandated forms for receiving, processing, or tracking data - enter data from source documents (such as patient report, test report etc.) into computer application following standard sequence and coding protocols - verify data entered with source documents, checks for compliance with composition codes and style rules and 	Level 4

<p>perform backup operations by assisting in the filing and storage of security and back up data files</p> <ul style="list-style-type: none"> - operate the terminal as per the defined organization procedures, be attentive for error lights and indicators and highlight the same to the concerned authority - check for network and servers functioning prior to job commencement, clear the terminal surrounding at the end of the jobs and notify the appropriate authority of malfunctions - communicate deviations in the process to reporting supervisor - communicate and discuss work flow related difficulties in order to find solutions with mutual agreement 	<p>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).</p> <p>To file and store on security and back up data files, uses the knowledge of storing and back up of the computer files in electronic and magnetic media.</p>	<p>and style rules</p> <ul style="list-style-type: none"> - Decision making skills are also used while deciding to escalate a complex problem as per escalation matrix of organization. - Problem solving skills are used while troubleshooting small issues while carry out the data entry. 	<p>software manuals, reports and other relevant information</p> <ul style="list-style-type: none"> - uses basic arithmetic and algebraic principles to do the simple calculation while setting the data entry parameters - Individual has basic understanding of the Industry, cross functions and own function and understanding of requirements of regulatory bodies like MHRA/FDA etc. 	<p>corrects all typographical errors and missing or repeated data</p> <ul style="list-style-type: none"> - generate reports of data entry, store completed work in designated locations and perform backup operations by assisting in the filing and storage of security and back up data files - operate the terminal as per the defined organization procedures, be attentive for error lights and indicators and highlight the same to the concerned authority - check for network and servers functioning prior to job commencement, clear the terminal surrounding at the end of the jobs and notify the appropriate authority of malfunctions - communicate deviations in the process to reporting supervisor 	
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:

Data entry Operator can move to vertical progression as Data Validation Associate after 3-4 years of experience as data entry operator- Life Sciences.

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