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. AnshulSaxena

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	Clinical Research Associate (LFS/Q0503)
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	Clinical Research Associate also known as Clinical Trial Monitor is a job role under Research and development occupation. The individual is responsible for supporting and monitoring clinical trial activities, carries out reporting and documentation of research activities and coordinates with team members and Contract Research Organization. The job requires individual to use the knowledge of Life Sciences Industry, drug development concepts and process, knowledge of clinical research phases and monitoring and reporting procedures and knowledge of pharmaceutical sciences and medical terminology and human anatomy. The individual uses skills like planning and organizing, critical and analytical thinking, problem solving, customer centricity and decision making. The individual is responsible for own work and learning and has some responsibility of others work and learning.
Proposed level of the qualification in the NSQF.	Level 5
Anticipated volume of training/learning required to complete the qualification.	270 Hours
Entry requirements / recommendations.	B. Pharma preferable/ B. Sc. / Clinical Research certification
Progression from the qualification.	**Upward progression:** • Lead Clinical Research Associate • Clinical Data Validator. **Lateral/ Horizontal progression:** • Clinical Research Coordinator
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 • COGLS217 Drawing blood samples from patients for investigation in life sciences and related industries • 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 • Refer page no.196, Unit Group 3212, page no. 142 Unit Group 2240, page no. 202 Unit Group 3252, page no. 204 Unit Group 3256; 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 • Conduct a clinical measurement • Perform basic clinical procedures • Communicate workplace information • Participate in work teams and groups South Africa NOS • Interact with clients in a health and pharmaceutical environment • 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/N0508 To support clinical trial activities	Mandatory	100	Level 5
LFS/N0509 To carry out reporting and documentation for clinical trials	Mandatory	80	Level 5
LFS/N0101 Maintain a healthy, safe and secure working environment in the life sciences facility	Mandatory	45	Common across level 2-7
LFS/N0510 Co-ordinate with team members and site	Mandatory	45	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?

Not all, only**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 (400)	Out of	Theory	Skills Practical
LFS/N0508(Support Clinical Research Activities)	PC1. monitor that all the clinical trial protocol should be complied with during the research activities	100	14	6	8
	PC2. effectively communicate with clinical research coordinators		12	6	6
	PC3. review Case Report Forms (CRFs)		10	4	6
	PC4. organise investigator's start-up meeting and study site initiation meetings		10	4	6
	PC5. carry out on site visits		16	6	10
	PC6. ensure optimal usage of resources by effective deployment of the same		10	4	6
	PC7. ensure safety and rights of participants		10	8	2
	PC8. record the rate of subject recruitment		6	3	3

	PC9. document the withdrawals of enrolled subjects with reasons on the CRFs		6	2	4
	PC10. record the visits that subjects fail to make and tests that are not conducted		6	2	4
	Total		100	45	55
LFS/N0509(Carry out Reporting and Documentation)	PC1. assist in outlining the purpose and methodology of a trial	100	10	4	6
	PC2. assist in drafting the CRFs		6	2	4
	PC3. assist in presenting trial protocols to a steering committee		6	2	4
	PC4. manage regulatory authority applications and approvals		10	4	6
	PC5. assist in developing and writing trial protocols		10	4	6
	PC6. prepare relevant monitoring reports		10	4	6
	PC7. maintain records of letters of agreement, lab reference ranges and schedule of payment		4	2	2
	PC8. maintain project files including: ethics committee approvals; curricula vitae of investigators and study personnel; consent documents; clinical trial material shipping orders		4	2	2
	PC9. maintain documentation on clinical trial material shipping orders and prepare relevant monitoring reports		4	2	2
	PC10. ensure that adverse events are correctly documented and reported		8	4	4
	PC11. coordinate with the site for obtaining filled documents/CRFs		6	4	2
	PC12. discuss results with a medical statistician, who writes technical trial reports		4	2	2

	PC13. ensure the scientific integrity of the data collected is protected and verified		3	2	1
	PC14. prepare final reports, occasionally manuscripts for publication		6	2	4
	PC15. ensure that unfavourable occurrences are clearly reported and documented		4	2	2
	PC16. archive study documentation, correspondence		2	1	1
	PC17. coordinate with the pharma co-vigilance teams for documenting post-marketing adverse drug reactions		3	2	1
	Total		100	45	55
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 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		10	4	6

	security records legibly and accurately				
	PC9. report any hazards that you are incompetent to deal with to relevant person in line with organizational procedures and warn other people affected		10	4	6
	PC10. follow your company's emergency procedures promptly, calmly, and efficiently		10	5	5
	Total		100	48	52
LFS/N0510 (Coordinate with team members and site)	PC1. work as a team with colleagues and share work to achieve team goals	100	18	8	10
	PC2. provide documented shift handovers to the next person in the shift		20	10	10
	PC3. effectively communicate with team members in case of research related difficulties		18	8	10
	PC4. coordinate with the site team for pre-clinical/clinical trial activities – this may include volunteer management, protocol deployment, sample handling, data management etc.		22	10	12
	PC5. monitor clinical studies process		22	10	12
	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.

Clinical Research AssociateLFS/Q0503					
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:- - Monitor that all the clinical trial protocol is being complied with during the research activities - document the withdrawals of enrolled subjects with reasons on the CRFs - record the visits that subjects fail to make and tests that are not conducted - assist in outlining the purpose and methodology of a trial and in drafting the CRFs - maintain project files including: ethics committee approvals; curricula vitae of investigators and study personnel; consent documents; clinical trial material shipping orders	Job role holder requires knowledge of facts, principles, process and general concepts, in a field of Life Sciences Manufacturing. For example:- - Tomonitor and coordinate the clinical trial site applies knowledge of pharmaceutical sciences, clinical trial protocol, functional knowledge of clinical research process and job roles of various stakeholder and team members and required documentation, knowledge of Good Clinical Practice (GCP) and Good Laboratory Practices(GLP) - To coordinate with the pharma co-vigilance teams for documenting post-marketing adverse drug	Job role holder uses a range of cognitive and practical skills required to accomplish tasks and solve problems by selecting and applying basic methods, tools, material and information. For Example:- - uses skills like planning and organizing, critical and analytical thinking and decision making while he/she is monitoring and reviewing the trial documents at clinical trial site. - uses planning and organizing, analytical thinking, problem solving and decision making while he/she coordinates and assist the clinical trial site and clinical research coordinator and other staff for compliance of	Job role holder applies mathematical skill, understanding of social, political systems and some skill of collecting and organizing information, communication. For example:- - While monitoring and coordinating with clinical trial sitehas an understanding of his/her function as well as other peripheral functions like site management, clinical pharmacology, pathology lab, regulatory affairs, pharmacovigilance, quality etc, their scope and responsibilities, applicable regulatory guidelines and tie ups with	Job role holder has responsibility of own work and learning and some responsibility for other's work and learning. For example:- - Monitor that all the clinical trial protocol is being complied with during the research activities - document the withdrawals of enrolled subjects with reasons on the CRFs - record the visits that subjects fail to make and tests that are not conducted - assist in outlining the purpose and methodology of a trial and in drafting the CRFs - maintain project files including: ethics	Level 5

- prepare final reports, occasionally manuscripts for publication and ensure that unfavourable occurrences are clearly reported and documented - coordinate with the pharma co-vigilance teams for documenting post-marketing adverse drug reactions - observe and comply with company's health, safety and security policies and procedures - Coordinate with the site team for pre-clinical/clinical trial activities – this may include volunteer management, protocol deployment, sample handling, data management and obtaining filled documents/CRFs etc.	reactions applies knowledge of adverse reaction management and legal and regulatory requirement and procedures of pharmacovigilance and his/her role 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.	protocol. - Analytical skills are used to understand the clinical trial research. - Analytical thinking and critical thinking, problem solving and decision making skills are used to coordinate with the pharma co-vigilance teams for documenting post-marketing adverse drug reactions. - Uses analytical thinking to understand the quality standards, work expectations and output requirements to be maintained and while understanding the team member's skill, responsibilities, motivational needs. - Decision making skills are also used when he/she makes discretionary judgements while drafting the CRF.	bodies (for example WHO/FDA/DCGI) - While supporting clinical research activities and documenting the monitoring reports and CRFs understands desired quality standards (GCP/GLP/ISO), work expectations and output requirements as per company's SOPs/ guidelines. - Uses collecting and organizing skills, and communication skills (reading, writing, speaking and listening) while carrying out monitoring and site coordination activities - Applies mathematical skills in order to find solutions for research related issues.	committee approvals; curricula vitae of investigators and study personnel; consent documents; clinical trial material shipping orders - prepare final reports, occasionally manuscripts for publication and ensure that unfavourable occurrences are clearly reported and documented - coordinate with the pharma co-vigilance teams for documenting post-marketing adverse drug reactions - observe and comply with company's health, safety and security policies and procedures - Coordinate with the site team for pre-clinical/clinical trial activities – this may include volunteer management, protocol deployment, sample handling, data management and obtaining filled documents.	
Level 5	Level 5	Level 5	Level 5	Level 5	

OTHER EVIDENCE OF LEVEL [This need only be filled in where evidence other than primary outcomes was used to allocate a level] (**Optional)**

Summary of other evidence (if used):

1. Internship Monitoring report available at VTP for each candidate for internship period duly signed by Industry authorized person

SECTION 4

EVIDENCE OF RECOGNITION OR PROGRESSION

What steps have been taken in the design of this or other qualifications to ensure that there is a clear path to other qualifications in this sector?

Horizontal and vertical mobility options have been articulated while developing the standard. For Example:

After 3-4 years of Industry work experience as Clinical Research Associate post qualifying the certification of Clinical Research Associate, candidate has an option to qualify for Lead Clinical Research Associate Job role for a vertical progression.

Clinical Research Associate also has an option to qualify for Clinical Research Coordinator as a lateral progression.

Please attach any documents giving further information about any of the topics above.
Give details of the document(s) here:
• Occupational Map and progression matrix