Associate-Clinical Research Management (Pharma, Biologics and Medical devices) Electives: 1. Site management, 2. Study Monitoring, 3. Data management, 4. Biostatistics

QUALIFICATION FILE

☒ Short Term Training (STT) ☐ Long Term Training (LTT) ☒ Apprenticeship

☒ Upskilling ☒ Dual/Flexi Qualification ☒ For ToT ☒ For ToA

☒General ☐ Multi-skill (MS) ☐ Cross Sectoral (CS) ☐Future Skills ☐ OEM

NCrF/NSQF Level: 5.5

Submitted By:

Life Sciences Sector Skill Development Council

14, Palam Marg, Rear 2nd Floor, Vasant Vihar, New Delhi, PIN 110057

Phone: +91 11 41042407/ 408, E-mail: info@lsssdc.in

Table of Contents

Section 1: Basic Details

<table>
<tr><td>1.</td><td>Qualification Name</td><td colspan="2">Associate-Clinical Research Management (Pharma, Biologics and Medical devices)
Electives:
1.Site management
2.Study Monitoring
3.Data management
4.Biostatistics</td></tr>
<tr><td>2.</td><td>Sector/s</td><td colspan="2">Life Sciences</td></tr>
<tr><td>3.</td><td>Type of Qualification: ☐ New ☒ Revised ☒ Has Electives/Options
☐OEM</td><td>NQR Code & version of existing/previous qualification: QM-05-LS-00251-2023-V1.1-LSSSDC</td><td>Qualification Name of existing/previous version:
Associate-Clinical Research Management (Pharma, Biologics and Medical devices)</td></tr>
<tr><td>4.</td><td>a. OEM Name
b. Qualification Name
(Wherever applicable)</td><td colspan="2">NA</td></tr>
<tr><td>5.</td><td>National Qualification Register (NQR) Code &Version
(Will be issued after NSQC approval)</td><td>QG-5.5-LS-00251-2025-V2-LSSSDC</td><td>6. NCrF/NSQF Level: 5.5</td></tr>
<tr><td>7.</td><td>Award (Certificate/Diploma/Advance Diploma/ Any Other (Wherever applicable specify multiple entry/exits also & provide details in annexure)</td><td colspan="2">Certificate</td></tr>
<tr><td>8.</td><td>Brief Description of the Qualification</td><td colspan="2">Associate-Clinical Research Management (Pharma, Biologics and Medical devices Facility) supports clinical trial activities, carries out reporting and documentation for monitoring of research activities to ensure regulatory compliance and current Good Clinical Practices (GLP) as per ICH and coordinates with site staff members, investigators, Site Management Organization and Sponsor. The role holder is expected to assist in the Biostatistics analysis of clinical trial data with the help of artificial intelligence.</td></tr>
<tr><td>9.</td><td>Eligibility Criteria for Entry for Student/Trainee/Learner/Employee</td><td colspan="2">a. Entry Qualification & Relevant Experience:
<table>
<tr><th>S. No.</th><th>Academic/Skill Qualification (with Specialization - if applicable)</th><th>Required Experience (with Specialization - if applicable)</th></tr>
<tr><td>1</td><td>Completed 3rd year of 3-year/ 4-years UG</td><td>Biology, Nursing, Medical Lab Technician, Life Sciences, Biotechnology</td></tr>
<tr><td>2</td><td>Completed 3rd year of B.E/ B. tech. Biotech</td><td></td></tr>
<tr><td>3</td><td>Completed 3rd year B. Pharma</td><td></td></tr>
<tr><td>4</td><td>BAMS/ BDS/ BUMS/ BHMS/ MBBS</td><td></td></tr>
</table></td></tr>
</table>

<table>
<tr><td></td><td></td><td colspan="2">b. Age: 18 years</td></tr>
<tr><td>10.</td><td>Credits Assigned to this Qualification, Subject to Assessment (as per National Credit Framework (NCrF))</td><td>19</td><td>11. Common Cost Norm Category (I/II/III) (wherever applicable): II</td></tr>
<tr><td>12.</td><td>Any Licensing requirements for Undertaking Training on This Qualification (wherever applicable)</td><td colspan="2">NA</td></tr>
<tr><td>13.</td><td>Training Duration by Modes of Training Delivery (Specify Total Duration as per selected training delivery modes and as per requirement of the qualification)</td><td colspan="2">☐Offline ☐Online ☐Blended
<table>
<tr><th>Training Delivery Modes</th><th>Theory (Hours)</th><th>Practical (Hours)</th><th>OJT Mandatory (Hours)</th><th>OJT Recommended (Hours)</th><th>Total (Hours)</th></tr>
<tr><td>Classroom (offline)</td><td>225</td><td>345</td><td></td><td></td><td>570</td></tr>
<tr><td>Online</td><td></td><td></td><td></td><td></td><td></td></tr>
</table>
(Refer Blended Learning Annexure for details)</td></tr>
<tr><td>14.</td><td>Aligned to NCO/ISCO Code/s (if no code is available mention the same)</td><td colspan="2">NCO 2015/3512.0601
Clinical Trials</td></tr>
<tr><td>15.</td><td>Progression path after attaining the qualification (Please show Professional and Academic progression)</td><td colspan="2">Not applicable</td></tr>
<tr><td>16.</td><td>Other Indian languages in which the Qualification & Model Curriculum are being submitted</td><td colspan="2">Hindi and English</td></tr>
<tr><td>17.</td><td>Is similar Qualification(s) available on NQR-if yes, justification for this qualification</td><td colspan="2">☐ Yes ☒ No URLs of similar Qualifications:</td></tr>
<tr><td>18.</td><td>Is the Job Role Amenable to Persons with Disability</td><td colspan="2">☐ Yes ☒ No
If “Yes”, specify the applicable type of Disability:</td></tr>
<tr><td>19.</td><td>How Participation of Women will be Encouraged</td><td colspan="2">Policy measures are needed to promote the inclusion of educated and working women, especially in science and technology fields, where only 14% of women are hired among micro, small, and medium enterprises despite comprising 43% of Science and technology graduates. The conscious efforts are made by LSSSDC to sensitize organizations and hiring manager for bring Women employees on board by LSSSDC through Industry Associations and Large MNCs on governing Board and have received positive responses and assurance from most of employers in life sciences sector to bring Min. 30% share of Women employees and apprentices in the given occupation and job role. LSSSDC shall also be driving a Diversity and Inclusivity Program with Indian Pharmaceutical Alliance for catalyzing the efforts.</td></tr>
<tr><td>20.</td><td>Are Greening/ Environment Sustainability Aspects Covered (Specify the NOS/Module which covers it)</td><td colspan="2">☒ Yes ☐ No</td></tr>
</table>

		LFS/N0119	
21.	**Is Qualification Suitable to be Offered in Schools/Colleges**	**Schools ☐ Yes ☐ No Colleges ☒ Yes ☐ No**	
22.	**Name and Contact Details of Submitting / Awarding Body SPOC** *(In the case of CS or MS, provide details of both Lead AB & Supporting ABs)*	**Name: Mrs. Shivi Chaudhary** **Email: shivi.chaudhary@lsssdc.in** **Contact No.: + 91 11 41042407/ 408, +91 9315747189** **Website: https://www.lsssdc.in/**	
23.	**Final Approval Date by NSQC:** 8 April 2025	**24. Validity Duration: 3 years**	**25. Next Review Date: 8** April 2028

Section 2: Module Summary

NOS/s of Qualifications

(In exceptional cases these could be described as components)

Mandatory NOS/s:

Specify the training duration and assessment criteria at the NOS/ Module level. For further details refer curriculum document.

***Th.**-Theory **Pr.**-Practical **OJT**-On the Job **Man.**-Mandatory Training **Rec.**-Recommended **Proj.**-Project*

S. No	NOS/Module Name	NOS/Module Code & Version *(if applicable)*	Core/ Non-Core	NCrF/NSQF Level	Credits as per NCrF	Training Duration (Hours)					Assessment Marks					
						Th.	Pr.	OJT-Man.	OJT-Rec.	Total	Th.	Pr.	Proj.	Viva	Total	Weightage (%) *(if applicable)*
1.	**Compulsory Module** Introduction to life sciences industry and basic of Clinical trial occupation	LFS/N3507, v1	Core	Level-5.5	1	30	-	-	-	30	50	30	10	10	100	10
2.	**Compulsory Module** Ensure environment sustainability and sensitivity towards all genders and people with disability	LFS/N0119, v3.0	Non-Core	Level-5.5	1	15	15	-	-	30	30	50	10	10	100	10
3.	**Compulsory Module**	LFS/N3506, v1	Core	Level-5.5	1	15	15	-	-	30	20	50	10	10	100	10

S. No	NOS/Module Name	NOS/Module Code & Version *(if applicable)*	Core/ Non-Core	NCrF/NS QF Level	Credits as per NCrF	Training Duration (Hours)					Assessment Marks					
						Th.	Pr.	OJT-Man.	OJT-Rec.	Total	Th.	Pr.	Proj.	Viva	Total	Weightage (%) *(if applicable)*
	Carry out management activities related for clinical trial															
4.	**Compulsory Module** Employability Skills (90 Hours)	DGT/VSQ/N0103	Core	Level-5	3	45	45	-	-	90	20	30	-	-	50	10
Duration (in Hours) / Total Marks					6	105	75	-	-	180	50	80	10	10	150	40

Elective NOS/s 1: **Site Management**

The table lists the modules and their duration corresponding to the Elective NOS of the QP

S. No	NOS/Module Name	NOS/Module Code & Version *(if applicable)*	Core/ Non-Core	NCrF/NS QF Level	Credits as per NCrF	Training Duration (Hours)					Assessment Marks					
						Th.	Pr.	OJT-Man.	OJT-Rec.	Total	Th.	Pr.	Proj.	Viva	Total	Weightage (%) *(if applicable)*
1.	Perform site management activities at clinical research site	LFS/N3503, v3	Core	Level-5.5	7	60	150	-	-	210	25	50	13	12	100	30
2.	Carry out reporting and documentation for site coordination activities as per regulatory standards	LFS/N3504, v3	Core	Level-5.5	6	60	120	-	-	180	25	45	10	20	100	30
Duration (in Hours) / Total Marks					13	120	270	-	-	390	50	95	23	32	200	60

Elective NOS/s 2: **Study Monitoring**

The table lists the modules and their duration corresponding to the Elective NOS of the QP

S. No	NOS/Module Name	NOS/Module Code & Version *(if applicable)*	Core/ Non-Core	NCrF/NSQF Level	Credits as per NCrF	Training Duration (Hours)					Assessment Marks					
						Th.	Pr.	OJT-Man.	OJT-Rec.	Total	Th.	Pr.	Proj.	Viva	Total	Weightage (%) *(if applicable)*
1.	Monitor the clinical trial site to ensure that ICH GCP guidelines, study protocol and applicable regulations are followed	LFS/N3501, v3	Core	Level-5.5	7	60	150	-	-	210	25	50	15	10	100	30
2.	Carry out reporting and documentation for site monitoring activities as per regulatory standards	LFS/N3502, v3	Core	Level-5.5	6	60	120	-	-	180	25	45	15	15	100	30
Duration (in Hours) / Total Marks					13	120	270	-	-	390	50	95	30	25	200	60

Elective NOS/s 3: **Data management**

The table lists the modules and their duration corresponding to the Elective NOS of the QP

S. No	NOS/Module Name	NOS/Module Code & Version *(if applicable)*	Core/ Non-Core	NCrF/NSQF Level	Credits as per NCrF	Training Duration (Hours)					Assessment Marks					
						Th.	Pr.	OJT-Man.	OJT-Rec.	Total	Th.	Pr.	Proj.	Viva	Total	Weightage (%) *(if applicable)*
1.	Provide support for clinical data management activities	LFS/N3505, v3	Core	Level-5.5	13	120	270	-	-	390	25	50	10	15	100	60
Duration (in Hours) / Total Marks					13	120	270	-	-	390	25	50	10	15	100	60

Elective NOS/s 4: **Biostatistics**

The table lists the modules and their duration corresponding to the Elective NOS of the QP

S. No	NOS/Module Name	NOS/Module Code & Version *(if applicable)*	Core/ Non-Core	NCrF/NSQF Level	Credits as per NCrF	Training Duration (Hours)					Assessment Marks					
						Th.	Pr.	OJT-Man.	OJT-Rec.	Total	Th.	Pr.	Proj.	Viva	Total	Weightage (%) *(if applicable)*
1.	Provide support in data through Biostatical analysis	LFS/N3508, v1	Core	Level-5.5	4	30	90	-	-	120	25	50	10	15	100	20
2.	Provide support in PK & PD through Biostatistics analysis	LFS/N3509, v1	Core	Level-5.5	4	30	90	-	-	120	25	50	10	15	100	20
3.	Provide algorithm support for Biostatistics activities	LFS/N3510, v1	Core	Level-5.5	4	45	75	-	-	120	25	50	10	15	100	10
4.	Apply AI/ML Models in biostatistical analysis	LFS/N3511, v1	Core	Level-5.5	1	15	15			30	25	50	10	15	100	10
Duration (in Hours) / Total Marks					13	120	270	-	-	390	75	150	30	45	100	60

Assessment - Minimum Qualifying Percentage

*Please specify **any one** of the following:*

Minimum Pass Percentage – Aggregate at qualification level: 70 % *(Every Trainee should score a specified minimum aggregate passing percentage at qualification level to successfully clear the assessment.)*

Minimum Pass Percentage – NOS/Module-wise: 70 % *(Every Trainee should score a specified minimum passing percentage in each mandatory and selected elective NOS/Module to successfully clear the assessment.)*

Section 3: Training Related

1.	**Trainer's Qualification and experience in the relevant sector (in years)** *(as per NCVET guidelines)*	B.Sc (Biology/Nursing/Medical Lab Technician/Life Sciences/Biotechnology) with 7 year relevant industry experience with specialization in Associate- Clinical Research Management (Pharma, Biologics and Medical Devices). OR Graduate in B.Pharmacy/B.Tech (Biotechnology)/BAMS/BDS/BUMS/BHMS with 6 years relevant industry experience with specialization in Associate- Clinical Research Management (Pharma, Biologics and Medical Devices). OR

		Post Graduate in M.Pharmacy/M.Tech (Biotechnology)/MBBS/M.Sc (Biology/Nursing/Medical Lab Technician/Life Sciences/Biotechnology) with 4 years relevant industry experience with specialization in Associate- Clinical Research Management (Pharma, Biologics and Medical Devices). OR Vocation Qualification Associate-Clinical Research Management at NSQF Level 5, mapped to QP "LFS/Q3501 v1 with 4 years relevant industry experience with specialization in Associate- Clinical Research Management (Pharma, Biologics and Medical Devices). and Certified for Job Role: "Associate - Clinical Research Management (Pharma, Biologics and Medical devices)" mapped to QP: "LFS/Q3501, v3" with minimum accepted score of 80%. Recommended that the Trainer is certified for the Job Role: "Trainer (VET and Skills)", mapped to the Qualification Pack: "MEP/2601, v3.0" with minimum score of 80%.
2.	**Master Trainer's Qualification and experience in the relevant sector (in years)** *(as per NCVET guidelines)*	B.Sc (Biology/Nursing/Medical Lab Technician/Life Sciences/Biotechnology) with 10 year relevant industry experience with specialization in Associate- Clinical Research Management (Pharma, Biologics and Medical Devices). OR Graduate in B.Pharmacy/B.Tech (Biotechnology)/BAMS/BDS/BUMS/BHMS with 9 years relevant industry experience with specialization in Associate- Clinical Research Management (Pharma, Biologics and Medical Devices). OR Post Graduate in M.Pharmacy/M.Tech (Biotechnology)/MBBS/M.Sc (Biology/Nursing/Medical Lab Technician/Life Sciences/Biotechnology) with 6 years relevant industry experience with specialization in Associate- Clinical Research Management (Pharma, Biologics and Medical Devices). OR Vocation Qualification Associate-Clinical Research Management at NSQF Level 5, mapped to QP "LFS/Q3501 v1 with 6 years relevant industry experience with specialization in Associate- Clinical Research Management (Pharma, Biologics and Medical Devices). and Certified for Job Role: "Associate - Clinical Research Management (Pharma, Biologics and Medical devices)" mapped to QP: "LFS/Q3501, v3" with minimum accepted score of 80%. Recommended that the Master Trainer is certified for the Job Role: "Master Trainer (VET and Skills)", mapped to the Qualification Pack: "MEP/2601, v3.0" with minimum score of 80%.
3.	**Tools and Equipment Required for Training**	☐Yes ☐No (*If "Yes", details to be provided in Annexure)*
4.	**In Case of Revised Qualification, Details of Any Upskilling Required for Trainer**	

Section 4: Assessment Related

1.	**Assessor's Qualification and experience in relevant sector (in years)** *(as per NCVET guidelines)*	B.Sc (Biology/Nursing/Medical Lab Technician/Life Sciences/Biotechnology) with 7 years relevant industry experience with specialization in Associate- Clinical Research Management (Pharma, Biologics and Medical Devices) and 1 year of Training/Assessment experience with specialization in Teaching Assessment/ Inhouse Training. OR Graduate in B.Pharmacy/B.Tech (Biotechnology)/BAMS/BDS/BUMS/BHMS with 6 years relevant industry experience with specialization in Associate- Clinical Research Management (Pharma, Biologics and Medical Devices) and 1 year of Training/Assessment experience with specialization in Teaching Assessment/Inhouse Training. OR Post Graduate in M.Pharmacy/M.Tech (Biotechnology)/MBBS/M.Sc (Biology/Nursing/Medical Lab Technician/Life Sciences/Biotechnology) with 4 years relevant industry experience with specialization in Associate- Clinical Research Management (Pharma, Biologics and Medical Devices) and 1 year of Training/Assessment experience with specialization in Teaching Assessment/Inhouse Training. OR Vocation Qualification Associate-Clinical Research Management at NSQF Level 5, mapped to QP "LFS/Q3501 v1 with 4 years relevant industry experience with specialization in Associate- Clinical Research Management (Pharma, Biologics and Medical Devices) and 1 year of Training/Assessment experience with specialization in Teaching Assessment/Inhouse Training. And Associate - Clinical Research Management (Pharma, Biologics and Medical devices) mapped to the Qualification Pack: "LFS/Q3501, v3. " with minimum accepted score of 80%. Recommended that the Assessor is certified for the Job Role: "Assessor (VET and Skills)", mapped to the Qualification Pack: "MEP/Q2701, v3.0" with minimum score of 80%.
2.	**Proctor's Qualification and experience in relevant sector (in years)** *(as per NCVET guidelines)*	B.Sc (Biology/Nursing/Medical Lab Technician/Life Sciences/Biotechnology) with 7 years relevant industry experience with specialization in Associate- Clinical Research Management (Pharma, Biologics and Medical Devices) and 1 year of Training/Assessment experience with specialization in Teaching Assessment/ Inhouse Training. OR Graduate in B.Pharmacy/B.Tech (Biotechnology)/BAMS/BDS/BUMS/BHMS with 6 years relevant industry experience with specialization in Associate- Clinical Research Management (Pharma, Biologics and Medical Devices) and 1 year of Training/Assessment experience with specialization in Teaching Assessment/Inhouse Training. OR

		Post Graduate in M.Pharmacy/M.Tech (Biotechnology)/MBBS/M.Sc (Biology/Nursing/Medical Lab Technician/Life Sciences/Biotechnology) with 4 years relevant industry experience with specialization in Associate- Clinical Research Management (Pharma, Biologics and Medical Devices) and 1 year of Training/Assessment experience with specialization in Teaching Assessment/Inhouse Training. OR Vocation Qualification Associate-Clinical Research Management at NSQF Level 5, mapped to QP "LFS/Q3501 v1 with 4 years relevant industry experience with specialization in Associate- Clinical Research Management (Pharma, Biologics and Medical Devices) and 1 year of Training/Assessment experience with specialization in Teaching Assessment/Inhouse Training. And Associate - Clinical Research Management (Pharma, Biologics and Medical devices) mapped to the Qualification Pack: "LFS/Q3501, v3. " with minimum accepted score of 80%.
3.	**Lead Assessor's/Proctor's Qualification and experience in relevant sector (in years)** *(as per NCVET guidelines)*	B.Sc (Biology/Nursing/Medical Lab Technician/Life Sciences/Biotechnology) with 10 years relevant industry experience with specialization in Associate- Clinical Research Management (Pharma, Biologics and Medical Devices) and 3 year of Training/Assessment experience with specialization in Teaching Assessment/ Inhouse Training. OR Graduate in B.Pharmacy/B.Tech (Biotechnology)/BAMS/BDS/BUMS/BHMS with 9 years relevant industry experience with specialization in Associate- Clinical Research Management (Pharma, Biologics and Medical Devices) and 3 year of Training/Assessment experience with specialization in Teaching Assessment/Inhouse Training. OR Post Graduate in M.Pharmacy/M.Tech (Biotechnology)/MBBS/M.Sc (Biology/Nursing/Medical Lab Technician/Life Sciences/Biotechnology) with 6 years relevant industry experience with specialization in Associate- Clinical Research Management (Pharma, Biologics and Medical Devices) and 3 year of Training/Assessment experience with specialization in Teaching Assessment/Inhouse Training. OR Vocation Qualification Associate-Clinical Research Management at NSQF Level 5, mapped to QP "LFS/Q3501 v1 with 6 years relevant industry experience with specialization in Associate- Clinical Research Management (Pharma, Biologics and Medical Devices) and 3 year of Training/Assessment experience with specialization in Teaching Assessment/Inhouse Training. And Associate - Clinical Research Management (Pharma, Biologics and Medical devices) mapped to the Qualification Pack: "LFS/Q3501, v3. " with minimum accepted score of 80%. Recommended that the Lead Assessor is certified for the Job Role: "Lead Assessor (VET and Skills)", mapped to the Qualification Pack: "MEP/Q2701, v3.0" with minimum score of 80%.

4.	**Assessment Mode** *(Specify the assessment mode)*	**Offline and Online**
5.	**Tools and Equipment Required for Assessment**	☒ Same as for training ☐ Yes ☐ No *(details to be provided in Annexure-if it is different for Assessment)*

Section 5: Evidence of the need for the Qualification

Provide Annexure/Supporting documents name.

1.	**Latest Skill Gap Study (not older than 2 years) (Yes/No):** Yes
2.	**Latest Market Research Reports or any other source (not older than 2 years) (Yes/No):** Yes
3.	**Government /Industry initiatives/ requirement (Yes/No):** No
4.	**A number of Industry validations provided:** 12
5.	**Estimated nos. of persons to be trained and employed:** 1500
6.	**Evidence of Concurrence/Consultation with Line Ministry/State Departments:** *No* If "No", why:

Section 6: Annexure & Supporting Documents Check List

Specify Annexure Name / Supporting document file name

1.	**Annexure:** NCrF/NSQF level justification based on NCrF level/NSQF descriptors *(Mandatory)*	Yes
2.	**Annexure:** List of tools and equipment relevant for qualification *(Mandatory, except in case of online course)*	Yes
3.	**Annexure:** Detailed Assessment Criteria *(Mandatory)*	Yes
4.	**Annexure:** Assessment Strategy *(Mandatory)*	Yes
5.	**Annexure:** Blended Learning *(Mandatory, in case the selected Mode of delivery is "Blended Learning")*	Yes
6.	**Annexure:** Multiple Entry-Exit Details *(Mandatory, in case of qualification has multiple Entry-Exit)*	Yes
7.	**Annexure:** Acronym and Glossary *(Optional)*	Yes
8.	**Supporting Document:** Model Curriculum *(Mandatory – Public view)*	Yes

9.	**Supporting Document:** Career Progression *(Mandatory - Public view)*	Yes
10.	**Supporting Document:** Occupational Map *(Mandatory)*	Yes
11.	**Supporting Document:** Assessment SOP *(Mandatory)*	Yes
12.	**Any other document you wish to submit:**	

Annexure: Evidence of Level

NCrF/NSQF Level Descriptors	Key requirements of the job role/ outcome of the qualification	How the job role/ outcomes relate to the NCrF/NSQF level descriptor	NCrF/NSQF Level
Process	Few of the job elements, expected to be performed by Associate-Clinical Research Management (Pharma, Biologics and Medical devices Facility) • Environment sustainability • Sensitivity towards all genders and people with disability • Monitor clinical trials • Pre research activities • Research process activities • Post research activities • Manage clinical trial site activities • Coordination and communication with team members • Coordinating with vendors and site staff • Recording and reporting for site management activities for Clinical Trial/ Bioavailability-Bioequivalence (BA-BE) Study • Monitor participants during a clinical trial for safety and rights of participants • Recording and reporting for site management activities for Clinical Trial/ Bioavailability-Bioequivalence (BA-BE) Study • Information security • Designing eCRF • Validation of clinical data	Associate-Clinical Research Management (Pharma, Biologics and Medical devices Facility) supports clinical trial activities, carries out reporting and documentation for monitoring of research activities to ensure regulatory compliance and Good Clinical Practices (GCP) as per ICH and coordinates with site staff members, investigators, SMO and Sponsor/CRO. All the above performance outcomes are routine and common in all the work assigned to Associate-Clinical Research, hence they are categorized as familiar and predictable processes where the Associate-Clinical Research has a situation of clear choice.	Level 5.5

Professional Knowledge	Few of the job elements, expected to be performed by Associate-Clinical Research Management (Pharma, Biologics and Medical devices Facility): • Manage clinical trial site activities • Coordination and communication with team members • Coordinating with vendors and site staff • Recording and reporting for site management activities for Clinical Trial/ Bioavailability-Bioequivalence (BA-BE) Study • Monitor participants during a clinical trial for safety and rights of participants • Environment sustainability • Sensitivity towards all genders and people with disability • Monitor clinical trials	To perform the tasks given, Associate-Clinical Research Management (Pharma, Biologics and Medical devices Facility) needs to have the factual knowledge of facts, principles, processes and general concepts related to Good Manufacturing a Practices (GMP) and Good Clinical Practices (GCP). The job holder should also be efficient to coordinate with Manager, colleagues and auditors to meet the communication needs to fulfil work requirements of Associate-Clinical Research Management (Pharma, Biologics and Medical devices Facility).	Level 5.5
Professional Skills	Few of the job elements, expected to be performed by Associate- Associate-Clinical Research Management (Pharma, Biologics and Medical devices Facility): • Environment sustainability • Monitor clinical trials • Pre research activities • Research process activities • Post research activities • Manage clinical trial site activities • Coordination and communication with team members • Coordinating with vendors and site staff	To perform the tasks of Associate-Clinical Research Management (Pharma, Biologics and Medical devices Facility) the job holder utilizes professional skills like good communication and interpersonal skills, good analytical, reasoning skills, attention to details, critical thinking, and excellent organizational skills. For routine job activities and tasks the Associate-Clinical Research Management (Pharma, Biologics and Medical devices Facility) uses the planning and organizing skills. The job holder demonstrates analytical and critical thinking skills while performing tasks. The scope of utilization of all above professional skills remains limited to routine and repetitive and for a narrow range of applications	Level 5.5
Core Skills	Few of the job elements, expected to be performed by Associate-Clinical Research Management (Pharma, Biologics and Medical devices Facility): • Clinical site management • Clinical data management • Conduct training program and events on EHS standards • Managing environment sustainability programs	To perform the given tasks, Associate-Clinical Research Management (Pharma, Biologics and Medical devices Facility) uses organizing information, communication and problem solving skills. For reporting and documentation proposed, he/she applies the basics of arithmetic and algebraic principles and organizational skills. For coordination related tasks and ensuring compliance to organizational SOPs and regulatory	Level 5.5

	• Ensure adherence to health and hygiene protocols • Manage and coordination with the supervisor and teams • Respond to audit queries • Sensitivity towards all genders and people with disability	requirements, the job holder is expected to have a basic understanding of the social-political and natural environment at the place of work/ organization he/she is working for.	
Responsibility	Few of the job elements, expected to be performed by Associate-Clinical Research Management (Pharma, Biologics and Medical devices Facility): • Environment sustainability • Sensitivity towards all genders and people with disability • Monitor clinical trials • Pre research activities • Research process activities • Post research activities • Manage clinical trial site activities • Coordination and communication with team members • Coordinating with vendors and site staff • Recording and reporting for site management activities for Clinical Trial/ Bioavailability-Bioequivalence (BA-BE) Study • Monitor participants during a clinical trial for safety and rights of participants • Recording and reporting for site management activities for Clinical Trial/ Bioavailability-Bioequivalence (BA-BE) Study • Information security	Associate-Clinical Research Management (Pharma, Biologics and Medical devices Facility) has responsibility for his/her work and learning and supports juniors and cross functional teams and in case of a scenario/situation of no clear choice, he is expected to take guidance from the supervisor.	Level 5.5

Annexure: Tools and Equipment (Lab Set-Up)

List of Tools and Equipment

Batch Size:

S. No.	Tool / Equipment Name	Specification	Quantity for specified Batch size
1.	Black & White Printer	As per standards	1
2.	Indian Drug Formulary	As per standards	1
3.	US Pharmacopia National Formulary (USP-41- NF-36)	As per standards	1
4.	Indian Pharmacopia 2018, 8th Edition/ IP 2018	As per standards	1
5.	Stedman's Medical Dictionary e-subscription	As per standards	1

Classroom Aids

The aids required to conduct sessions in the classroom are:

1. Whiteboard
2. Marker Pen
3. Computer or Laptop attached to LCD projector.
4. Computer speaker (wireless)
5. Pencil
6. Whiteboard duster
7. Microphone: collar/podium (for instructor)
8. Laser pointer
9. Internet (cable/wi-fi)
10. Scanner
11. Flip charts

Annexure: Industry Validations Summary

Provide the summary information of all the industry validations in the table. This is not required for OEM qualifications.

S. No	Organization Name	Representative Name	Designation	Contact Address	Contact Phone No	E-mail ID	LinkedIn Profile *(if available)*
1.	Aegis Lifesciences Private Limited	Mr. Piyush Patel	Quality Head	215/216 Mahagujarat Ind.Estate, Ahmedabad ,India 382213	9898791189	qc@aegis-lifesciences.com	
2.	Machscape Innovations Pvt. Ltd.	PRAVESH JAIN	DIRECTOR	Mangla Plaza, opp. Lodha School Pali, Rajasthan 306401, India.	97721 99777	pravesh.jain78977@gmail.com	
3.	Ayukriyam Innovations	Prabhu Balasubramanian	Chief Operating Officer		8903349663	ayukriyam@gmail.com	
4.	Syngene International	Sormishtha Gosh				Sormishtha.Ghosal@syngeneintl.com	
5.	Cadila pharmaceutical Limited	Dr. Arani Chatterjee	Joint President CRO		6357080635	arani.chatterjee@cadilapharma.com	
6.	OSTIC PHARMA PVT LTD	Dr. Vinay Saini	Director		9987253095	drvinays14@gmail.com	
7.	International Institute of Health Management Research (IIHMR) Delhi	Dr Sutapa . P . Neogi	Director	Plot No.3, Sector-18-A, Dwarka, New Delhi-110075	9910028889	sutapa@iihmrdelhi.ed.in	
8.	Trivitron healthcare private limited	Rajeev Kumar Singh	RA Manager	Ground Floor, Wing A, Old No. 25, New No.15,Abhiramapuram, IVth Street, Chennai, Tamil Nadu. 600018, India	9971321391	rk.singh@trivitron.com	
9.	Norwich Clinical Services	Praveen Maddi	Deputy Head		8105801765	Praveen.maddi@norwichclinical.com	
10.	Innovare Labs Private Limited	Ravi	Assistant manger	Plot No. 23A-23B, Lalam Koduru(V),	7569279497	hr@innovarelabs.com	

				APSEZ, Denotified Area, Atchutapuram, Rambili Mandal, Anakapalli.			
11.	CMS Laboratories India Private Limited	Guntuku Jagadeeswara Rao	Managing Director	47-10-50, Dwaraka Nagar, 4th Lane, 3rd Floor, Above Union Bank,Visakhapatnam	8919168131	jdguntuku@gmail.com	
12.	Vasista Life Sciences Private Limited	PRASAD	HR	Plot No 27B1,B2, B13, B14, Atchutapuram, Gurjapalem, Andhra Pradesh 531011	7337345638	hr@vasista.co.in	
13.	Synaptics Labs Pvt Ltd	KISHORE REDDY	Senior Manager		9440002968	hr@synapticslabs.com	
14.	Gramin Shiksha Private Limited	Rinku Manchanda	Director	Gali No. 1, Near Janki Children Hospital, Rishi Nagar Hisar – 125001 Haryana	9996311114	graminshiksha.rk@gmail.com	
15.	Maharashtra vocational education training center	Dhanet v Chawan	Ownee		8380823149	Infoskillindia2018@gmail.com	
16.	Pushpanchal Foundation	Mr. CHARLOTTN G. NOHA	OPERATIONS HEAD	Plot No:- 16, Maharana Nagar 1, Zingabai Takli, Godhani Road, Nagpur-440030.	8956161906	pushpanchalfoundation@gmail.com	

Annexure: Training & Employment Details

Training and Employment Projections:

Year	Total Candidates		Women		People with Disability	
	Estimated Training #	Estimated Employment Opportunities	Estimated Training #	Estimated Employment Opportunities	Estimated Training #	Estimated Employment Opportunities
2025	500	-	500	-	-	-
2026	500	-	500	-	-	-
2027	500	-	500	-	-	-

Data to be provided year-wise for the next 3 years

Training, Assessment, Certification, and Placement Data for previous versions of qualifications:

Qualification Version	Year	Total Candidates				Women				People with Disability			
		Trained	Assessed	Certified	Placed	Trained	Assessed	Certified	Placed	Trained	Assessed	Certified	Placed
V1.0&v2.0	2022-2023	162	54	54									
V1.0&v2.0	2023-2024	137	49	45									
V1.0&v2.0	2024-2025	496	27	22									

Applicable for revised qualifications only, data to be provided year-wise for the past 3 years.

List Schemes in which the previous version of Qualification was implemented:

1. NAPS
2. Self-Financed- Higher Education-PCI Embedded
3. Self-Financed- Higher Education-STT
4. Self-Financed-STT

Content availability for previous versions of qualifications:

☒Participant Handbook ☒ Facilitator Guide ☐ Digital Content ☐ Qualification Handbook ☐ Any Other:

Languages in which Content is available: English

Annexure: Blended Learning

Blended Learning Estimated Ratio & Recommended Tools:

Refer to NCVET "Guidelines for Blended Learning for Vocational Education, Training & Skilling" available at:
https://ncvet.gov.in/sites/default/files/Guidelines%20for%20Blended%20Learning%20for%20Vocational%20Education,%20Training%20&%20Skilling.pdf

S. No.	Select the Components of the Qualification	List Recommended Tools – for all Selected Components	Offline: Online Ratio
1	☐Theory/ Lectures - Imparting theoretical and conceptual knowledge	LMS Portal- LSSSDC Daksh Portal will be utilized with online content/virtual lectures	50:50
2	☐Imparting Soft Skills, Life Skills, and Employability Skills /Mentorship to Learners	LMS Portal- LSSSDC Daksh Portal will be utilized with online content/virtual lectures	50:50
3	☐Showing Practical Demonstrations to the learners	LMS Portal- LSSSDC Daksh Portal will be utilized with online content/virtual lectures / Skill labs	100:00
4	☐Imparting Practical Hands-on Skills/ Lab Work/ workshop/ shop floor training	Skill Labs	100:00
5	☐Tutorials/ Assignments/ Drill/ Practice	LMS Portal- LSSSDC Daksh Portal will be utilized with online content/virtual lectures / Field Visits	50:50
6	☐Proctored Monitoring/ Assessment/ Evaluation/ Examinations	Parakh	00:100
7	☐On the Job Training (OJT)/ Project Work Internship/ Apprenticeship Training	Offline	00:100

Annexure: Detailed Assessment Criteria

Detailed assessment criteria for each NOS/Module are as follows:

NOS/Module Name	Assessment Criteria for Performance Criteria/Learning Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
1.LFS/N3507 V1.0: Introduction to life sciences industry and Clinical trial occupation	Life sciences industry and clinical trial occupation	60		20	20
	PC1. Identifies major players, key products, and innovations in the life sciences industry.				
	PC2. Explain the key regulations and legislations governing clinical research in India (e.g., NDCT Rules 2019, Schedule Y, Indian GCP, ICH-GCP) and compares them with global standards.				
	PC3. Follow key regulations and legislations governing clinical research				
	PC4. Identify the workflow and key responsibilities in clinical trial roles				
	PC5. Explain the importance subject/patient confidentiality and consent.				

	PC6. Explains the impact of errors or negligence by unskilled personnel on clinical trials and public health.				
	PC7. Demonstrates the ability to identify gaps in compliance in a clinical trial				
	Total Marks	**60**		**20**	**20**
2. LFS/N0119 v3: Ensure environment sustainability and sensitivity towards all genders and people with disability	*Environment sustainability*	***15***	***25***	***5***	***5***
	PC 1. ensure energy conservation by switching off the machine and equipment post operations				
	PC 2. identify ways to optimize the usage of electricity/energy in various tasks/activities/processes				
	PC 3. ensure energy conservation by optimizing the machine/ equipment performance				
	PC 4. identify recyclable and non-recyclable, and hazardous waste generated				
	PC 5. segregate waste into different categories to achieve minimum pollution of land , air and water				
	PC 6. check for water leakage in plant/ work area and take corrective actions				
	Sensitivity towards all genders and people with disability	***15***	***25***	***5***	***5***
	PC 7. respect all genders, religions, and caste				
	PC 8. empathize with the people with disability				
	PC 9. offer support or help to a person with a disability only when asked				
	PC 10. ensure to adhere to the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act				
	PC 11. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee				
	Total Marks	**30**	**50**	**10**	**10**
3. LFS/N3506 Ver1: Carry out management activities related for clinical trial	*Planning, Development, and Compliance*	**10**	**20**	**5**	**5**
	PC1. Develop and implement comprehensive plans for the initiation, execution, and completion of clinical trials, ensuring alignment with project goals and timelines.				
	PC2. Monitor progress and make adjustments as necessary to meet milestones and deadlines.				
	PC3. Contribute to the creation and refinement of study protocols, ensuring they clearly define the methodology, objectives, and participant selection criteria.				
	PC4. Ensure the protocol aligns with scientific and regulatory standards, addressing all critical study requirements.				

	PC5. Identify and evaluate potential clinical trial sites based on patient demographics, facilities, and regulatory compliance.				
	PC6. Ensure site readiness and capability to meet trial requirements, including recruitment capacity and adherence to protocols.				
	Financial Management, Data Integrity, and Quality Assurance	**15**	**25**	**10**	**10**
	PC7. Manage the financial aspects of the clinical trial, ensuring adherence to the allocated budget.				
	PC8. Make informed decisions to optimize resource utilization while maintaining cost-effectiveness.				
	PC9. Oversee data collection and management processes to ensure accuracy, completeness, and compliance with regulatory standards.				
	PC10. Implement measures to prevent data discrepancies and ensure data quality throughout the trial.				
	PC11. Proactively identify and address challenges that may arise during the trial, ensuring patient safety and the integrity of the study.				
	PC12. Make timely and informed decisions to resolve issues effectively and maintain trial integrity.				
	Total Marks	25	45	15	15
4. DGT/VSQ/N0103 V1.0: Employability Skills (90 Hours)	*Introduction to Employability Skills*	***1***	***1***		
	PC 1. understand the significance of employability skills in meeting the current job market requirement and future of work.				
	PC 2. identify and explore learning and employability relevant portals				
	PC 3. research about the different industries, job market trends, latest skills required and the available opportunities				
	Constitutional values – Citizenship	***1***	***1***		
	PC 4. recognize the significance of constitutional values, including civic rights and duties, citizenship, responsibility towards society etc. and personal values and ethics such as honesty, integrity, caring and respecting others, etc.				
	PC 5. follow environmentally sustainable practices				
	Becoming a Professional in the 21st Century	***1***	***3***		
	PC 6. recognize the significance of 21st Century Skills for employment				
	PC 7. practice the 21st Century Skills such as Self-Awareness, Behavior Skills, time management, critical and adaptive thinking, problem-				

	solving, creative thinking, social and cultural awareness, emotional awareness, learning to learn for continuous learning etc. in personal and professional life				
	PC 8. adopt a continuous learning mindset for personal and professional development				
	Basic English Skills	***3***	***4***		
	PC 9. use basic English for everyday conversation in different contexts, in person and over the telephone				
	PC 10. read and understand routine information, notes, instructions, mails, letters etc. written in English				
	PC 11. write short messages, notes, letters, e-mails etc. in English				
	Career Development & Goal Setting	***1***	***2***		
	PC 12. identify career goals based on the skills, interests, knowledge, and personal attributes				
	PC 13. prepare a career development plan with short- and long-term goals.				
	Communication Skills	***2***	***2***		
	PC 14. follow verbal and non-verbal communication etiquette while communicating in professional and public settings				
	PC 15. use active listening techniques for effective communication				
	PC 16. communicate in writing using appropriate style and format based on formal or informal requirements				
	PC 17. work collaboratively with others in a team				
	Diversity & Inclusion	***1***	***1***		
	PC 18. communicate and behave appropriately with all genders and PwD				
	PC 19. escalate any issues related to sexual harassment at workplace according to POSH Act				
	Financial and Legal Literacy	***2***	***3***		
	PC 20. identify and select reliable institutions for various financial products and services such as bank account, debit and credit cards, loans, insurance etc.				
	PC 21. carry out offline and online financial transactions, safely and securely, using various methods and check the entries in the passbook				

	PC 22. identify common components of salary and compute income, expenses, taxes, investments etc				
	PC 23. identify relevant rights and laws and use legal aids to fight against legal exploitation				
	Essential Digital Skills	***3***	***5***		
	PC 24. operate digital devices and carry out basic internet operations securely and safely				
	PC 25. carry out basic internet operations by connecting to the internet safely and securely, using the mobile data or other available networks through Bluetooth, Wi-Fi, etc.				
	PC 26. display responsible online behavior while using various social media platforms				
	PC 27. create a personal email account, send and process received messages as per requirement				
	PC 28. carry out basic procedures in documents, spreadsheets and presentations using respective and appropriate applications				
	PC 29. utilize virtual collaboration tools to work effectively				
	Entrepreneurship	***2***	***3***		
	PC 30. identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research				
	PC 31. develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion				
	PC 32. identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity				
	Customer Service	***1***	***2***		
	PC 33. identify different types of customers and ways to communicate with them				
	PC 34. identify and respond to customer requests and needs in a professional manner				
	PC 35. use appropriate tools to collect customer feedback				
	PC 36. follow appropriate hygiene and grooming standards				
	Getting ready for apprenticeship & Jobs	***2***	***3***		
	PC 37. create a professional Curriculum vitae (Résumé)				

	PC 38. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively				
	PC 39. apply to identified job openings using offline /online methods as per requirement				
	PC 40. answer questions politely, with clarity and confidence, during recruitment and selection				
	PC 41. identify apprenticeship opportunities and register for it as per guidelines and requirements				
	Total Marks	**20**	**30**	**-**	**-**
5. LFS/N3501 v3: Monitor the clinical trial site to ensure that ICH GCP guidelines, study protocol and applicable regulations are followed	*Monitor clinical trials*	***15***	***30***	***10***	***5***
	PC 1. organize investigator's start-up meeting and study site initiation meetings				
	PC 2. carry out clinical trials as per ICH GCP guidelines, study protocol, and applicable regulations				
	PC 3. communicate effectively with principal investigator, co-investigator, and clinical research coordinators to gather relevant information				
	PC 4. review and assess the clinical trial process				
	PC 5. ensure to study procedures that are consistently carried out by the study team across all participants				
	PC 6. ensure that principal investigator is submitting documents to the ethics committee in a timely manner				
	PC 7. perform source data verification, review source documents, informed consent procedures and forms for evaluating the participant's eligibility and assessing the protection of participant's rights				
	PC 8. Review safety/ efficacy related aspects of the participants, investigational product compliance by participants, and review case report forms (CRFs)				
	PC 9. conduct site monitor to ensure that all investigational products are stored, and drug accountability is maintained as per SOP				
	PC 10. ensure optimal usage of resources by effective deployment of the same				

	Monitor participants during a clinical trial for safety and rights of participants	***10***	***20***	***5***	***5***
	PC 11. ensure safety and rights of participants during all phases of clinical trials				
	PC 12. review safety events and ensure that drug- related Adverse Events (AE) are identified and promptly reported to all concerned stakeholders and ethics committee within prescribed timelines and as per SOPs				
	PC 13. record and review the rate of subject recruitment, visits that subjects fail to make, and tests that are not conducted				
	PC 14. ensure documentation exists at the site to follow up with the participant for any missing test/ procedure and recommend participant enrolment and retention plan with the principal investigator and co- investigator				
	PC 15. ensure the documentation of the withdrawals of enrolled subjects with reasons on the CRFs by the site coordinators and principal investigators				
	PC 16. identify anomalies in study conduct from a misconduct or fraud perspective				
	Total Marks	**25**	**50**	**15**	**10**
6. LFS/N3502 v3: Carry out reporting and documentation for site monitoring activities as per regulatory standards	*Pre research activities*	***10***	***15***	***5***	***5***
	PC 1. outline the purpose and methodology of a trial				
	PC 2. develop, draft, and write the Trial Protocols				
	PC 3. present trial protocols to a steering committee				
	PC 4. generate regulatory authority applications and approvals				
	PC 5. identify, select and evaluate trial sites and investigators and provide inputs in investigator grants and agreements				
	Research process activities	***10***	***15***	***5***	***5***
	PC 6. develop training materials for site for site initiations				
	PC 7. prepare follow up letters to principal investigator, complete site monitoring documentation				
	PC 8. prepare site monitoring visit reports, maintain records of communication with site staff and investigator, letters of agreement, lab reference ranges and schedule of payment				

	PC 9. maintain project files including : ethics committee approvals; curriculum vitae of investigators and study personnel; Investigator's Undertaking etc.				
	Post research activities	***5***	***15***	***5***	***5***
	PC 10. provide inputs to medical/ scientific teams as well as bio-statistician, who analyses technical trial data and writes technical trial reports				
	PC 11. provide support in preparing final reports, occasionally manuscripts for publication				
	PC 12. archive study documentation, and trial related correspondence				
	Total Marks	**25**	**45**	**15**	**15**
7. LFS/N3503 v3: Perform site management activities at clinical research site	*Manage clinical trial site activities*	***10***	***20***	***5***	***5***
	PC 1. observe study processes wherever necessary, to confirm adherence to study protocol and cGCP				
	PC 2. review study documents and may observe study processes to confirm adherence to cGCP				
	PC 3. schedule site initiation visits				
	PC 4. review source documentation and data collection form				
	PC 5. identify unreported events recorded in source documentation				
	PC 6. perform IP counts for stock and returned supply against dispensing logs				
	Coordination and communication with team members	***10***	***20***	***5***	***5***
	PC 7. work as a team with colleagues and share work as per their or own work load and skills				
	PC 8. provide documented shift handovers to the next person in the shift or during transition from one project to other project				
	PC 9. effectively communicate with team members in case of research related difficulties				
	PC 10. escalate issues to manager or designated personnel in cases where support is required				
	Coordinating with vendors and site staff	***5***	***10***	***3***	***2***
	PC 11. coordinate with the site/ CRO team for clinical research (in phase 1 or BA/ BE studies				

	PC 12. coordinate with principal investigator, site manager, vendor, clinical research coordinator for clinical trial (in phase 2- phase 4 trial)				
	PC 13. coordinate and follow up with site investigator, subject enrolment, trial performance, quality of study conduct, feedback during site monitoring, technical discussions about compliance to protocol				
	PC 14. coordinate for internal or external quality audits, coordinating responses from the Principal Investigator(PI)				
	PC 15. collect essential documents as per cGCP/ regulatory requirements, impart training to site staff				
	Total Marks	**25**	**50**	**13**	**12**
8. LFS/N3504 v3: Carry out reporting and documentation for site coordination activities as per regulatory standards	*Recording and reporting for site management activities for Clinical Trial/ Bioavailability- Bioequivalence (BA-BE) Study*	***15***	***25***	***5***	***10***
	PC 1. maintain documentation on clinical trial material shipping orders and prepare relevant reports				
	PC 2. ensure Patient Information Sheet, Informed Consent Form, Patient Diaries, CRFs, development of regulatory dossier for regulatory and ethics committee submissions				
	PC 3. ensure that adverse events are correctly documented and reported				
	PC 4. assists the Principal Investigator in submission of accurate and timely closeout documents to applicable federal agencies				
	PC 5. obtain filled documents/CRFs from the cross functional site teams				
	PC 6. collect data as required by the protocol				
	Information security	***10***	***20***	***5***	***10***
	PC 7. ensure that unfavorable occurrences (e.g. protocol deviations) are clearly reported and documented				
	PC 8. coordinate with the pharmaco-vigilance teams for documenting post-marketing adverse drug reactions				
	PC 9. respond to requests for information in an appropriate manner whilst following organizational procedures				
	PC 10. make sure documents are available to all appropriate authorities to inspect/ audit				
	Total Marks	**25**	**45**	**10**	**20**

9. LFS/N3505 v3: Provide support for clinical data management activities	*Designing eCRF*	***15***	***30***	***5***	***10***
	PC 1. assess database design requirements relevant to data capture tool, data extraction, processing, and reporting				
	PC 2. eCRF design and edit check programming based on protocol requirements				
	PC 3. manage the design specification, development, testing, and validation of electronic case report forms, edit checks standards, and dataset extraction				
	PC 4. make recommendations to management concerning complex technical issues and provide solutions				
	PC 5. manage multiple studies and projects simultaneously and deliver on the timelines				
	PC 6. provide support in the fixing of any issues or changes to eCRF and edit checks encountered during system testing, User Acceptance Testing (UAT), and deployment testing				
	PC 7. generate and maintain functional specifications for the eCRF edit checks				
	PC 8. generate data listings to support data review				
	PC 9. import external data in the EDC based on the data transfer agreement developed in collaboration with the clinical data manager				
	PC 10. develop the eCRF completion guidelines				
	Validation of clinical data	***10***	***20***	***5***	***5***
	PC 11. prepare and update annotation list, data validation plan, edit check specifications, and database/ data entry screens as per study requirements				
	PC 12. perform query management activities per study requirements including the manual queries raised by the data entry team and medical coder				
	PC 13. fill the data in 2 CRF(s) for data base testing				
	PC 14. validate the external data after uploading it into the database				
	PC 15. update self-evident correction queries in self-evident correction form per study requirements				

	PC 16. update reports and trackers on regular basis or as per study requirements				
	Total Marks	**25**	**50**	**10**	**15**
10. LFS/N3508, v1: Provide support in data through Biostatistical analysis	*Data Preparation and Refinement for Statistical Analysis*	***15***	***30***	***5***	***10***
	PC1. Define the format, structure, and statistical requirements of the research/ clinical dataset to ensure compatibility with analytical methods.				
	PC2. Establish indexing strategies and organize variables systematically for efficient statistical computation.				
	PC3. Identify and classify data types (continuous, categorical, ordinal, etc.) for each variable to ensure appropriate statistical treatment.				
	PC4. detect and impute missing values using statistical techniques such as mean/mode imputation, regression, or multiple imputation methods.				
	PC5. identify and correct incorrect data types to prevent analytical errors in statistical modelling.				
	PC6. sort and segment data into meaningful subsets to facilitate hypothesis testing and subgroup analysis.				
	PC7. perform necessary transformations (e.g., normalization, standardization, log transformation) to meet statistical assumptions.				
	PC8. identify redundant data points and apply data normalization techniques to reduce bias and improve model accuracy.				
	PC9. validate pre-processed data using statistical diagnostics, such as descriptive statistics and outlier detection methods.				
	PC10. ensure compliance with data privacy regulations (e.g., HIPAA, GDPR) while maintaining data integrity for analysis.				
	Data Visualization for Statistical Analysis	***10***	***20***	***5***	***5***
	PC11. identify statistical objectives, such as trend analysis, hypothesis testing, or predictive modelling, to guide data visualization.				
	PC12. define the purpose, scope, and target audience for statistical reporting of results.				
	PC13. determine the optimal delivery mode and format (e.g., interactive dashboards, statistical reports, APIs) for conveying insights.				
	PC14. summarize key statistical findings from the research/ clinical dataset into a structured and meaningful narrative.				

	PC15. select appropriate visualization techniques (e.g., box plots, histograms, kaplan-meier survival curves, forest plots) to represent statistical results effectively.				
	PC16. present statistical outputs using standardized templates and consistent language for clarity and reproducibility.				
	PC17. validate visualizations by cross-referencing with statistical outputs and stakeholder feedback.				
	PC18. publish validated visualizations in agreed formats for dissemination across research, regulatory, and industry platforms.				
		25	**50**	**10**	**15**
11. LFS/N3509, v1 : Provide support in PK & PD through Biostatistics analysis	*Support in PK & PD studies*	***15***	***30***	***5***	***10***
	PC1. ensure appropriate design with unbiased randomization, allocation concealment, and blinding.				
	PC2. justify sample size and effect size based on literature, ensuring statistical and clinical relevance.				
	PC3. Provide statistical input in planning interim analyses with clear stopping rules for safety and efficacy oversight				
	PC4. provide statistical expertise for manuscripts, and regulatory documents with accurate and consistent methodologies.				
	PC5. provide statistical consulting to ensure compliance with regulatory requirements for analysis and interpretation.				
	Support in Data Management, Imputation, and Reporting Tools	***10***	***20***	***5***	***5***
	PC6. Ensure report and diaries capture necessary data clearly and in line with study objectives.				
	PC7. Perform calculations such as Cmax and AUC to analyze pharmacodynamic and pharmacokinetic data.				
	PC8. Develop a Statistical Analysis Plan (SAP) with justified data imputation methods and handling of missing data.				
	PC9. Utilize various software tools like Vinolin and Phoenix for statistical analysis.				
	PC10. Statistical models should be appropriate for the study design and objectives, and their assumptions should be checked and justified.				
	PC11. Ensure accurate Tables, listings, and figures should be clear, concise, and properly formatted.				
	PC12. Ensure that TLF generation is automated or done via reproducible programming practices to reduce error risk.				
		25	**50**	**10**	**15**
	Algorithm Creation for Statistical Analysis	***15***	***30***	***5***	***10***

12. LFS/N3510, v1: Provide algorithm support for Biostatistics activities	PC1. Define the mathematical foundation and statistical principles for developing algorithms tailored to research/clinical data analysis.				
	PC2. Design and prototype new statistical algorithms to handle research/clinical -specific challenges, such as adaptive research designs, missing data imputation, and longitudinal data analysis.				
	PC3. Develop machine learning and artificial intelligence-based models to enhance predictive analytics, patient stratification, and biomarker discovery in research/clinical.				
	PC4. Optimize algorithm efficiency by implementing computational techniques such as parallel processing, cloud computing, and memory-efficient data handling.				
	PC5. Validate algorithm performance through benchmarking against existing statistical models and research/clinical datasets, ensuring accuracy, reproducibility, and regulatory compliance.				
	Statistical Analysis using available and customized algorithm	***10***	***20***	***5***	***5***
	PC6. Refine and implement statistical algorithms, programming codes, and analytical methodologies to manage, process, and analyze research/clinical data effectively.				
	PC7. Apply statistical programming languages (e.g., SAS, R, Python) and mathematical modeling techniques to design and implement methods for analyzing research/clinical endpoints, patient demographics, and treatment outcomes.				
	PC8. Utilize biostatistical methods such as survival analysis, mixed-effects models, and propensity score matching to derive meaningful research /clinical insights.				
	PC9. Perform quality control and sensitivity analysis to validate the robustness of statistical models used in research/clinical.				
	PC10. Communicate algorithmic refinements, customizations, and validation results to the development team and regulatory stakeholders to ensure compliance with research/clinical protocols and guidelines (e.g., ICH E9, FDA, EMA).				
	Total Marks	**25**	**50**	**10**	**15**
13. LFS/N3511, v1: Apply AI/ML Models in biostatistical analysis	*Apply AI/ML Models*	**25**	**50**	**10**	**15**
	PC1. describe various ways AI/ML improves predictions in clinical research.				
	PC2. explain ML-based stratification techniques with relevant applications.				
	PC3. Identify and explain various clustering techniques with correct mention of data types.				

	PC4. outline the process and ML techniques used in biomarker discovery.				
	PC5. List and describe various algorithms with mention of their predictive strengths and use cases.				
	PC6. List ethical concerns and key regulatory frameworks with examples.				
	PC7. Explain various features that improve model performance				
	PC8. Utilize explainable AI tools (e.g., SHAP, LIME) to interpret predictions and ensure transparency.				
	Total Marks	**25**	**50**	**10**	**15**
Grand Total		175	320	73	82

Annexure: Assessment Strategy

This section includes the processes involved in identifying, gathering, and interpreting information to evaluate the Candidate on the required competencies of the program.

Mention the detailed assessment strategy in the provided template.

1. Assessment System Overview:

The assessment for the Training will be conducted toward the end of the training duration. The assessment of the qualification shall be carried out by NCVET approved assessment agencies empaneled by LSSSDC after a defined evaluation process. For Execution of the assessment for training for the qualification, LSSSDC will be engaging more than one NCVET approved assessment agency/ body.

1.1 Criteria of selection of assessment body/agency:

The assessment body/agency is selected based on:

- 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 and practices in assessor management
- NCVET approval

1.2 Assessment tool development for assessment of Training:

For the Training assessment, the assessment instrument development is done by the selected assessment body with close monitoring and support of LSSSDC at every stage.

1.2.1 Digital Written test for knowledge assessment:
Scope – Is used to test the knowledge component of the Qualification/ Micro Credential/ NOS.
Tools –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, case study, scenario-based responses.
Analysis – Question paper is divided into sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section-wise calculation of marks gives a clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.

1.2.2 Digital Written test for skill assessment:
Scope – Is used to test primarily the Skill component of the Qualification/ Micro Credential/ NOS. Trainee's expertise in handling and managing the situation is tested.
Tools – computer or tab based online or offline questions

Method – A situation is narrated or created in the question posed to the trainee and he is asked objective type questions to select the correct reaction to the situation. The selected situations are based on real situations.
Analysis – Question paper is divided into sections. Each Section intends to assess a particular skill field of the trainee. Thus, section-wise calculation of marks gives a clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.

1.3 Steps for assessment tool development:

- The selection of assessment tool(s) is done as per the assessment criteria prescribed in Qualification/ Micro Credential/ NOS.
- For Associate-Clinical Research Management assessment, a blueprint of the question paper is part of the assessment tool for training in manufacturing operation.
- Development of layout of Question paper is such that the entire PCs (Performance Criteria) of that Qualification/ Micro Credential/ NOS 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 is screened and approved by LSSSDC. He/she is oriented by both LSSSDC and Assessment agency on – creating question Bank, level of questions, end the desired outcome of the assessment.

1.4 Execution of Training Assessment/ RPL Assessment:

- Once the assessment date for training is decided with common agreement of Industry/ Vocational Training Centre and LSSSDC, LSSSDC allocates the batch to an NCVET approved and LSSSDC empaneled assessment body/agency.
- Assessment agency ensures
    - the availability of required infrastructure
    - the availability of validated assessment tools for the assessment of training for the assigned qualification
    - the availability of assessor as per assessor eligibility criteria of the qualification
- Assessment agencies send the assessment confirmation to VTP/TC looping SSC
- Assessment agency deploys LSSSDC certified assessor for executing the assessment
- LSSSDC monitors the assessment process & records
- The assessment is executed in two possible ways depending on the choice of the industry:

1.4.1 Tab based assessment using physical proctoring
1.4.2 Smartphone-based assessment using e-proctoring

1.4.1 Tab-based assessment using physical proctoring

- A representative from the Assessment agency is present on the day of assessment to executing the assessment at the venue in case of physical proctoring.
- The assessment agency representative carries an identity card and letter from the council authorizing to conduct the assessment.
- Assessment agency representative ensures the authenticity of Trainee's identity by verifying the documents (any document issued by GOI, such as Ration card, Aadhaar Card, Driving License, Passport, Election card, etc)
- The assessment agency representative maintains the records of attendance, verified documents, and tablet instruments used in the assessment.
- Assessment agency representative collects evidence of the assessment in the best possible way (videos, pictures, voice recordings, etc)

- Assessment agency representative transfers the assessment scores from tab to assessment agency server, using a secure, encrypted web-based program.
- The assessment agency after processing the results and putting them in standard format hands over to LSSSDC within 7 days of assessment.

1.4.2 Smartphone-based assessment using e-proctoring

- All trainees enrolled in the batch due for assessment, are registered on an assessment tool application using their unique mobile number and e-mail ID along with a Govt. ID issued proof.
- An assessment link is sent to the mail ID of each trainee with a defined expiry date of the link.
- Trainee at any location can click on the link using his/her smartphone or a web camera-enabled computer system
- Using the unique credentials and Govt ID number, the trainee logs in for the start of assessment and completes the assessment.
- The authenticity of Trainee's identity is done by assessment application by verifying the documents (any document issued by GOI, such as Ration card, Aadhaar Card, Driving License, Passport, election card, etc.) and a live photo capture
- A live video of the candidate during the assessment is captured to collect the evidence of the assessment

- Once the assessment is complete, the assessment application automatically assessment scores to the assessment agency server, using a secure, encrypted web-based program.
- The assessment agency after processing the results and putting them in standard format hands over to LSSSDC within 7 days of assessment.

2. Testing Environment:

- The Centre/ location of the assessment is pre decided and geo tagged in case of physical assessment
- The assessment of LSSSDC qualifications is 99% done in digital environment while 1% pen and paper is used ONLY in business exigencies
- Based on the size of batch the assessment duration/ no. of required assessors is decided to ensure detailed assessment without any negative impact on quality of assessment
- The system driven automated assessment management system ensures uniform time allocation to each student, unique logins for each student and automated randomization of questions for developing multiple sets of question paper for single batch.
- Identity check of the student is mandated

3. Assessment Quality Assurance levels/Framework:

- Question bank is created by the Subject Matter Experts (SME) of Assessment Agency are verified by the other SME of LSSSDC
- All Questions are mapped to the specified assessment criteria
- Assessor eligibility criteria are structured to ensure quality and knowledge credentials of an assessor like-wise the trainer's quality and knowledge credentials.
- Eligible Assessor must be certified by LSSSDC for the respective and relevant qualification
- The tools used for assessment are validated for relevance and feasibility for skill assessment of the qualification in consideration

4. Types of evidence or evidence-gathering protocol:

- Time-stamped & geotagged reporting of the assessor from assessment location

- ID Proof of the students
- Educational qualification of students
- Certificate of Trainer
- In case of Physical assessment, geotagged photographs of the students undergoing assessment
- While students are undergoing assessment on the digital assessment platform the system captures random photos of the student which is audited by LSSSDC

5. Method of verification or validation:

- Surprise visit to the assessment location
- ID Proof of the students for identity verification
- Educational qualification verification of students for validation of entry level criteria
- Certificate of Trainer to verify the credential of vocational educator
- Random photos taken by the digital system are verified during audit by the assessment team

6. Method for assessment documentation, archiving, and access

- Hard copies and digital copies (whichever is applicable) of the assessment evidences are stored with assessment agency team for 5 years
- Assessment transcripts are stored in the server space of assessment agency for 5 years
- Assessment question banks and validation records are stored with assessment agency and LSSSDC digitally
- Assessment records are archived with assessment agency archive server after 5 years for another 5 years
- Access of assessment records are controlled with restricted access to concerned department and stakeholders and is shared on demand after due approval of Head of Assessment and Certification-LSSSDC

Annexure: Acronym and Glossary

Acronym

Acronym	Description
AA	Assessment Agency
AB	Awarding Body
ISCO	International Standard Classification of Occupations
NCO	National Classification of Occupations
NCrF	National Credit Framework
NOS	National Occupational Standard(s)
NQR	National Qualification Register
NSQF	National Skills Qualifications Framework
OJT	On the Job Training

Glossary

Term	Description
National Occupational Standards (NOS)	NOS defines the measurable performance outcomes required from an individual engaged in a particular task. They list down what an individual performing that task should know and also do.
Qualification	A formal outcome of an assessment and validation process is obtained when a the competent body determines that an individual has achieved learning outcomes to given standards
Qualification File	A Qualification File is a template designed to capture necessary information about a Qualification from the perspective of NSQF compliance. The Qualification File will be normally submitted by the awarding body for the qualification.
Sector	A grouping of professional activities on the basis of their main economic function, product, service, or technology.
Long Term Training	Long-term skilling means any vocational training program undertaken for a year and above. https://ncvet.gov.in/sites/default/files/NCVET.pdf