Associate- Regulatory Affairs and Intellectual Property (Medical Devices)

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: 6

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

1.	**Qualification Name**	Associate- Regulatory Affairs and Intellectual Property (Medical Devices) Options: 1. Regulated Business Operations	
2.	**Sector/s**	Life Sciences	
3.	**Type of Qualification: ☐ New ☒ Revised ☒ Has Electives/Options** **☐OEM**	**NQR Code & version of existing/previous qualification:** ***QM-05-LS-00253-2023-V1.1-LSSSDC***	**Qualification Name of existing/previous version:** Associate-Regulatory Affairs and Intellectual Property (IVD and Medical Devices)
4.	**a. OEM Name** **b. Qualification Name** (*Wherever applicable)*	NA	
5.	**National Qualification Register (NQR) Code &Version** (*Will be issued after NSQC approval)*	QG-06-LS-04425-2025-V2-LSSSDC	**6. NCrF/NSQF Level:** 6
7.	**Award (Certificate/Diploma/Advance Diploma/ Any Other** *(Wherever applicable specify multiple entry/exits also & provide details in annexure)*	Certificate	
8.	**Brief Description of the Qualification**	Associate- Regulatory Affairs and Intellectual Property (Medical Devices) prepares dossiers and liaison with regulatory bodies in India and relevant overseas markets to support appropriate approvals at various levels of technology readiness during product development, as well as for manufacturing, marketing and import license to ensure regulatory and legal compliance of Medical Devices in targeted markets. The job holder also facilitated in securing quality certification like CE, ISO, IEC, BIS, ICMED etc for the medical devices. The job role holder carries out proper documentation and reporting for dossier preparation and assist in patent filing for intellectual property management of innovations in medical devices.	
9.	**Eligibility Criteria for Entry for Student/Trainee/Learner/Employee**	**a. Entry Qualification & Relevant Experience:**	

S. No.	Academic/Skill Qualification (with Specialization - if applicable)	Required Experience (with Specialization - if applicable)
1.	M. Sc. (Biotechnology)	
2.	MBBS/ BDS/BPT	
3.	B. Tech	Biomedical/biotech/electronics/ mechanical/ mechatronic/ robotics/computer science

		4.	B. Pharma	
		5.	B.Sc	3 years of experience in Medical Device Industry
		6.	Diploma Engineer	2.5 years of experience in Medical Device Industry
		b. Age: As per Government Norms		
10.	**Credits Assigned to this Qualification, Subject to Assessment** *(as per National Credit Framework (NCrF))*	Minimum Credit- 19 Maximum Credit- 21	**11. Common Cost Norm Category (I/II/III)** *(wherever applicable)*: **II**	
12.	**Any Licensing requirements for Undertaking Training on This Qualification** *(wherever applicable)*	NA		
13.	**Training Duration by Modes of Training Delivery** *(Specify **Total Duration** as per selected training delivery modes and as per requirement of the qualification)*	☒ **Offline** ☐**Online** ☒ **Blended**		

Training Delivery Modes	**Theory (Hours)**	**Practical (Hours)**	**OJT Mandatory (Hours)**	**OJT Recommended (Hours)**	**Total (Hours)**
Offline Mode					
Classroom	205:00	365 :00	00:00	00:00	570:00
OR					
Blended Mode	205:00	365 :00	00:00	00:00	570:00
Offline (As part of blended mode)	102:00	365 :00	00:00	00:00	
Online (As part of blended mode)	103:00	00:00	00:00	00:00	

(Refer Blended Learning Annexure for details)

14.	**Aligned to NCO/ISCO Code/s** *(if no code is available mention the same)*	NCO-2015/3359 NCO-2015/2611.1001 Research and Development
15.	**Progression path after attaining the qualification** *(Please show Professional and Academic progression)*	Not avaliable

16.	**Other Indian languages in which the Qualification & Model Curriculum are being submitted**	**Hindi and English**	
17.	**Is similar Qualification(s) available on NQR-if yes, justification for this qualification**	**☐ Yes ☒ No URLs of similar Qualifications:**	
18.	**Is the Job Role Amenable to Persons with Disability**	**☐ Yes ☒ No** **If "Yes", specify the applicable type of Disability:**	
19.	**How Participation of Women will be Encouraged**	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.	
20.	**Are Greening/ Environment Sustainability Aspects Covered** *(Specify the NOS/Module which covers it)*	**☒ Yes ☐ No** **LFS/N0122**	
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:**	**24. Validity Duration: 3 years**	**25. Next Review Date:**

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 NOS** Introduction to the Life sciences Sector and Fundamentals of Regulatory Affairs in IVD and Medical Devices Industry	LFS/N0582 v1	Core	Level 6	1	20	10	-	-	30	50	30	10	10	100	10
2.	**Compulsory NOS** Development of Technical Dossier as per the regulatory guidelines of intended market (India and Global) for medical devices	LFS/N0570 v2.0	Core	Level 6	4	30	90	-	-	120	25	45	20	10	100	10
3.	**Compulsory Module** Submission of Technical Dossier as per the regulatory guidelines	LFS/N0502 v3.0	Core	Level 6	3	30	60	-	-	90	30	50	12	8	100	20
4.	**Compulsory Module** Assist in managing the regulatory affairs for medical devices and In-vitro Diagnostic Devices (IVD)	LFS/N0569 v2.0	Core	Level 6	4	30	90	-	-	120	25	45	20	10	100	20
5.	**Compulsory Module** Assist in intellectual property rights management for life sciences products and assets	LFS/N0571 v2.0	Core	Level 6	2	30	30	-	-	60	30	50	10	10	100	10
6.	**Compulsory Module** Coordinate with Manager, R&D team, other cross-functional teams, external stakeholders and regulatory agencies to manage regulatory affairs operations	LFS/N0567 v2.0	Core	Level 6	2	20	40	-	-	60	25	45	17	13	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)*
7.	**Compulsory Module** Ensure adherence to Environment, health and safety guidelines at workplace by self and subordinates	LFS/N0122 v2.0	Non-Core	Level 6	1	15	15	-	-	30	40	40	10	10	100	10
8.	**Compulsory Module** Employability Skills (60 Hours)	DGT/VSQ/N0102	Core	Level 4	2	30	30	-	-	60	20	30	-	-	50	10
Duration (in Hours) / Total Marks					19	205	365	-	-	570	245	400	119	86	650	100

Option NOS/s: **Regulated Business Operations**

The table lists the modules and their duration corresponding to the Option 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.	Establish own enterprise and perform various entrepreneurial activities to run the business operations in Life Sciences Sector	LFS/N0120 v3.0	Non-Core	Level 6	1	15	15	-	-	30	30	50	12	8	100	30
2.	Maintain the critical business documents as Entrepreneur in Life Sciences Sector	LFS/N0121 v3.0	Non-Core	Level 6	1	15	15	-	-	30	20	55	15	10	100	30
Duration (in Hours) / Total Marks					2	30	30	-	-	60	50	105	27	18	200	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)*	Graduate in B.Pharma OR B.E./B.Tech (with Relevant Subjects) with 6 years relevant industry experience with specialization in Regulatory Affairs and Intellectual Property management for IVD and Medical Devices and 1 year of Training experience on the job assessment/Training experience/Vocational assessment/Academic assessment. OR Post Graduate in M.Pharma or M.Sc (Chemistry) or M.E/M.Tech (with Relevant Subjects) with 4 years relevant industry experience with specialization in Regulatory Affairs and Intellectual Property management for IVD and Medical Devices and 1 year of Training experience on the job assessment/Training experience/Vocational assessment/Academic assessment. Or At least four (4) years of teaching and/or research experience in a relevant academic or research position(Assistant Professor/ Associate Professor/ Professor) with Recognition of Prior Learning Certification in Regulatory Affairs and Intellectual Property management for IVD and Medical Devices "LFS/Q0513, v2.0" post completion of Faculty Development Program of LSSSDC And Certified for Job Role: "Associate- Regulatory Affairs and Intellectual Property (Medical Devices)" in "LFS/Q0513, v2.0" 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, v2.0" with minimum score of 80%.
2.	**Master Trainer's Qualification and experience in the relevant sector (in years)** *(as per NCVET guidelines)*	Graduate in B.Pharma OR B.E./B.Tech (with Relevant Subjects) with 9 years relevant industry experience with specialization in Regulatory Affairs and Intellectual Property management for IVD and Medical Devices and 3 year of Training experience on the job assessment/Training experience/Vocational assessment/Academic assessment. OR Post Graduate in M.Pharma or M.Sc (Chemistry) or M.E/M.Tech (with Relevant Subjects) with 6 years relevant industry experience with specialization in Regulatory Affairs and Intellectual Property management

		for IVD and Medical Devices and 3 year of Training experience on the job assessment/Training experience/Vocational assessment/Academic assessment. And Certified for Job Role: "Associate- Regulatory Affairs and Intellectual Property (Medical Devices)" in "LFS/Q0513, v2.0" 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, v2.0" 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)*	Graduate in B.Pharma OR B.E./B.Tech (with Relevant Subjects) with 6 years relevant industry experience with specialization in Regulatory Affairs and Intellectual Property management for IVD and Medical Devices and 2 years of Training experience on the job assessment/Training experience/Vocational assessment/Academic assessment. OR Post Graduate in M.Pharma or M.Sc (Chemistry) or M.E/M.Tech (with Relevant Subjects) with 4 years relevant industry experience with specialization in Regulatory Affairs and Intellectual Property management for IVD and Medical Devices and 2 years of Training experience on the job assessment/Training experience/Vocational assessment/Academic assessment. OR At least four (4) years of teaching and/or research experience in a relevant academic or research position(Assistant Professor/ Associate Professor/ Professor) with Recognition of Prior Learning Certification in Regulatory Affairs and Intellectual Property management for IVD and Medical Devices "LFS/Q0513, v2.0" post completion of Faculty Development Program of LSSSDC And Certified for Job Role: "Associate- Regulatory Affairs and Intellectual Property (Medical Devices)" in "LFS/Q0513, v1.0" 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, v2.0" with minimum score of 80%.

2.	**Proctor's Qualification and experience in relevant sector (in years)** *(as per NCVET guidelines)*	Graduate in B.Pharma OR B.E./B.Tech (with Relevant Subjects) with 6 years relevant industry experience with specialization in Regulatory Affairs and Intellectual Property management for IVD and Medical Devices and 2 years of Training experience on the job assessment/Training experience/Vocational assessment/Academic assessment. OR Post Graduate in M.Pharma or M.Sc (Chemistry) or M.E/M.Tech (with Relevant Subjects) with 4 years relevant industry experience with specialization in Regulatory Affairs and Intellectual Property management for IVD and Medical Devices and 2 years of Training experience on the job assessment/Training experience/Vocational assessment/Academic assessment. OR At least four (4) years of teaching and/or research experience in a relevant academic or research position(Assistant Professor/ Associate Professor/ Professor) with Recognition of Prior Learning Certification in Regulatory Affairs and Intellectual Property management for IVD and Medical Devices "LFS/Q0513, v2.0" post completion of Faculty Development Program of LSSSDC And Certified for Job Role: "Associate- Regulatory Affairs and Intellectual Property (Medical Devices)'' in "LFS/Q0513, v1.0" with minimum accepted score of 80%. Recommended that the Proctor is certified for the Job Role: "Proctor (VET and Skills)", mapped to the Qualification Pack: "MEP/Q2701, v2.0" with minimum score of 80%.
3.	**Lead Assessor's/Proctor's Qualification and experience in relevant sector (in years)** *(as per NCVET guidelines)*	Graduate in B.Pharma OR B.E./B.Tech (with Relevant Subjects) with 10 years relevant industry experience with specialization in Regulatory Affairs and Intellectual Property management for IVD and Medical Devices and 4 years of Training experience on the job assessment/Training experience/Vocational assessment/Academic assessment. OR Post Graduate in M.Pharma or M.Sc (Chemistry) or M.E/M.Tech (with Relevant Subjects) with 8 years relevant industry experience with specialization in Regulatory Affairs and Intellectual Property management for IVD and Medical Devices and 4 years of Training experience on the job assessment/Training experience/Vocational assessment/Academic assessment. And Certified for Job Role: "Associate- Regulatory Affairs and Intellectual Property (Medical Devices)" in "LFS/Q0513, v1.0" 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, v2.0" 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:** 13
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- Regulatory Affairs and Intellectual Property (Medical Devices) are: ● Operating the Regulatory Systems ● Regulatory Dossier Submission ● IPR Management ● Adhere to health and hygiene protocols ● Adhere to safety and security procedures ● Adhere to emergency procedures ● Coordination with Manager ● Coordination with R&D Team ● Coordination with cross-functional teams ● Coordination with External Stakeholders and Regulatory Agencies ● Sensitivity towards all genders and people with disability ● Regulatory Dossier Preparation ● Regulatory compliance for labelling and inserts ● Regulatory facilitation for Licences and Authorization ● Regulatory facilitation for Miscellaneous Approvals	● Associate- Regulatory Affairs and Intellectual Property (Medical Devices) prepares dossiers to support appropriate licensing, marketing and legal compliance of products and ensure products comply with current regulations. The job role holder carries out proper documentation and reporting for dossier preparation. He/she is also responsible to perform continuous reporting and documentation at every step. All the above performance outcomes are routine and common in all the work assigned to Associate- Regulatory Affairs and Intellectual Property (IVD and Medical Devices), hence they are categorized as familiar and predictable processes where the Associate- Regulatory Affairs and Intellectual Property (Medical Devices)" has a situation of clear choice.	Level 6

	• Regulatory facilitation for Licences and Authorization • Regulatory facilitation for Miscellaneous Approvals • Regulatory facilitation for Post Approval Changes • Regulatory facilitation for US Market • Regulatory facilitation for Indian and Other Market • Ensuring consistent, efficient and quality processes to meet deliverables • Set up enterprise and perform entrepreneurial activities • Maintenance of accounts and ledgers • Comply with legal, regulatory and statutory standards • Infrastructure related documentation • Supply Chain related documentation • Documentation for sales & marketing • Quality audit and client/regulatory inspections related documentation		
Professional Knowledge	Few of the job elements, expected to be performed by Associate- Regulatory Affairs and Intellectual Property (Medical Devices) are: • Operating the Regulatory Systems • Regulatory Dossier Submission • IPR Management • Adhere to health and hygiene protocols • Adhere to safety and security procedures • Adhere to emergency procedures • Coordination with Manager • Coordination with R&D Team • Coordination with cross-functional teams • Coordination with External Stakeholders and Regulatory Agencies	• Associate- Regulatory Affairs and Intellectual Property (Medical Devices) needs to have the factual knowledge of facts, principles, processes and general concepts related to Good Laboratory Practices (GLP), how to routinely perform pre-analysis checks laboratory investigations and analysis, routine Inspection of Instruments, identification of non-conformities and labelling by recalling the work safety guidelines. 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- Regulatory Affairs and Intellectual Property (Medical Devices)	Level 6

	• Sensitivity towards all genders and people with disability • Regulatory Dossier Preparation • Regulatory compliance for labelling and inserts • Regulatory facilitation for Licences and Authorization • Regulatory facilitation for Miscellaneous Approvals • Regulatory facilitation for Licences and Authorization • Regulatory facilitation for Miscellaneous Approvals • Regulatory facilitation for Post Approval Changes • Regulatory facilitation for US Market • Regulatory facilitation for Indian and Other Market • Ensuring consistent, efficient and quality processes to meet deliverables • Set up enterprise and perform entrepreneurial activities • Maintenance of accounts and ledgers • Comply with legal, regulatory and statutory standards • Infrastructure related documentation • Supply Chain related documentation • Documentation for sales & marketing • Quality audit and client/regulatory inspections related documentation		
Professional Skills	Few of the job elements, expected to be performed by Associate- Regulatory Affairs and Intellectual Property (Medical Devices) are: • Regulatory Dossier Preparation • Regulatory compliance for labelling and inserts • Regulatory facilitation for Licences and Authorization	To perform the tasks of Associate- Regulatory Affairs and Intellectual Property (Medical Devices) 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.	Level 6

	• Regulatory facilitation for Miscellaneous Approvals • Regulatory facilitation for Licences and Authorization • Regulatory facilitation for Miscellaneous Approvals • Regulatory facilitation for Post Approval Changes • Regulatory facilitation for US Market • Regulatory facilitation for Indian and Other Market • Ensuring consistent, efficient and quality processes to meet deliverables • Set up enterprise and perform entrepreneurial activities • Maintenance of accounts and ledgers • Comply with legal, regulatory and statutory standards • Infrastructure related documentation • Supply Chain related documentation • Documentation for sales & marketing • Quality audit and client/regulatory inspections related documentation	For routine job activities and tasks, the Associate- Regulatory Affairs and Intellectual Property (Medical Devices) uses the planning and organizing skills. The scope of utilization of all above professional skills remains limited to routine and repetitive and for a narrow range of applications	
Core Skills	Few of the job elements, expected to be performed by Associate- Regulatory Affairs and Intellectual Property (Medical Devices) are: • Regulatory Dossier Preparation • Regulatory compliance for labelling and inserts • Regulatory facilitation for Licences and Authorization • Regulatory facilitation for Miscellaneous Approvals • Regulatory facilitation for Licences and Authorization • Regulatory facilitation for Miscellaneous Approvals • Regulatory facilitation for Post Approval Changes • Regulatory facilitation for US Market	To perform the tasks, Associate- Regulatory Affairs and Intellectual Property (Medical Devices) 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 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.	Level 6

	• Regulatory facilitation for Indian and Other Market • Ensuring consistent, efficient and quality processes to meet deliverables • Set up enterprise and perform entrepreneurial activities • Maintenance of accounts and ledgers • Comply with legal, regulatory and statutory standards • Infrastructure related documentation • Supply Chain related documentation • Documentation for sales & marketing • Quality audit and client/regulatory inspections related documentation		
Responsibility	Few of the job elements, expected to be performed by Associate- Regulatory Affairs and Intellectual Property (Medical Devices) are: • Operating the Regulatory Systems • Regulatory Dossier Submission • IPR Management • Adhere to health and hygiene protocols • Adhere to safety and security procedures • Adhere to emergency procedures • Coordination with Manager • Coordination with R&D Team • Coordination with cross-functional teams • Coordination with External Stakeholders and Regulatory Agencies • Regulatory Dossier Preparation • Regulatory compliance for labelling and inserts • Regulatory facilitation for Licences and Authorization • Regulatory facilitation for Miscellaneous Approvals • Regulatory facilitation for Licences and Authorization • Regulatory facilitation for Miscellaneous Approvals • Regulatory facilitation for Post Approval Changes • Regulatory facilitation for US Market	Associate- Regulatory Affairs and Intellectual Property (Medical Devices) has responsibility for his/her work and learning and supports to Biologist- Quality & Research and Chemist - IP/QA and cross functional Teams. And in case of a scenario/situation of no clear choice, he is expected to take guidance from the Head of Quality Department.	Level 6

	• Regulatory facilitation for Indian and Other Market • Ensuring consistent, efficient and quality processes to meet deliverables • Set up enterprise and perform entrepreneurial activities • Maintenance of accounts and ledgers • Comply with legal, regulatory and statutory standards • Infrastructure related documentation • Supply Chain related documentation • Documentation for sales & marketing • Quality audit and client/regulatory inspections related documentation		

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.	e-CTD Express Software License	Can be dummy version	1
2.	vNeeS Format	For demonstration	1
3.	High Speed Internet Connection	Minimum 16 MBPS	1
4.	High Speed Black and White Printer	As per standard requirement	1
5.	ICH GCP and GLP Guidelines e-subscription	e version to be made available on every computer	30
6.	Stedman' s Medical Dictionary e-subscription	e version to be made available on every computer	30
7.	White Screen	35 Sq Ft Preferred	1
8.	Indian Drug Formulary	Published by IPC	5
9.	Projector	Any make (DLP or LCD) projector	1
10.	US Pharmacopia National Formulary (USP-41-NF-36)	Either online subscription/ Print subscription	5
11.	Flip Charts	For Each Classroom	5

12.	Indian Pharmacopia 2022, 9th Edition/ IP 2018	Either online subscription/ Print subscription	5
13.	Computer Workdesk	As per standard requirement	30
14.	Computer	As per standard requirement	30
15.			

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
5. Pencil

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.	MAJUSHREE TECHNOPACK LIMITED	KISHORE	HR MANAGER	Near fire station, Vadlapudi village, Kurmannapalem, Visakhapatnam, Andhra Pradesh 530046.	9581199200	Kishore.karrimanjushreeindia.com	
2.	CMS Laboratories India Private Limted	Guntuku Jagadeeswara Rao	Managing Director	47-10-50, Dwaraka Nagar, 4th Lane, 3rd Floor, Above Union Bank, Visakhapatnam-530016	8919168131	jdguntuku@gmail.com	
3.	Synaptics Labs Pvt Ltd	M BHARATH	SENIOR MANAGER	Plot No:28-B,APIIC, Lalamkoduru Vill, Rambill(|MD),Visakhapatnam,Andhra Pradesh-531011	7569279497	hr@synapticslabs.com	
4.	VLR FACILITATORS PRIVATE LIMITED	JAYASHREE	HR	Hoty Child School, near dundigal police station, Gandi Maisamma, Hyderabad, Telangana 500043.	8247212205	jayashreem@gmail.com	
5.	National Institute of Pharmaceutical Education and Research	Subham Banerjee	Associate Professor	NIPER-Guwahati, Changsari-781101, Kamrup (Rural), Assam &			
6.	AIIMS, New Delhi, Ansari Nagar East-110029, New Delhi	9599878950	subham@niperguwahati.in				

7.	Trivitron Healthcare Private LTD	Rajeev Kumar Singh	Regulatory affair Manager		9971321391	rk.singh@trivitron.com	
8.	Zydus Lifesciences Limited	Harsh Raj purohit	Deputy Manager	Zydus corporate park , Ahemdabad	7041309081	harsh.rajpurohit@zyduslife.com	
9.	Dr. Reddys Laboratories Ltd.	Y Nagender	Technical Capabilities Expert	8-2-337, Road No. 3, Banjara Hills, Hydrabad, Telangana, India 500034	98449282791	nagendery@srreddys.com	
10.	Emcure Pharmaceuticals Limited	Rajesh Nair	President HR	Plot No. P-1 & P-2, IT-BT Park, Phase-II, MIDC, Hinjawadi, Pune-411057 Maharshtra	9373314937	Prakash.Khandare@emcure.com	
11.	Tirupati Lifescience Limited	Jagdish Chauhan	Manager HRD	Nahan Road, Ponta Sahib,Distt Sirmour (H.P)	9816633372	jagdish.chauhan@tirupatiwellness.in	
12.	Tirupati Medicare Limited	Jagdish Chauhan	Manager HRD	Nahan Road, Ponta Sahib,Distt Sirmour (H.P)	9816633372	jagdish.chauhan@tirupatiwellness.in	
13.	Tirupati Wellness Limited	Jagdish Chauhan	Manager HRD	Nahan Road, Ponta Sahib,Distt Sirmour (H.P)	9816633372	jagdish.chauhan@tirupatiwellness.in	

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
1	500	-	500	-	-	-
2	500	-	500	-	-	-
3	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
Ver 1.0	2023	9	0	0									
Ver 1.0	2024	780	397	343									
Ver 1.0	2025	247	198	194									

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. PMKVY 4.0
2. NAPS

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/N0582 V1.0: Introduction to the Life sciences Sector and Fundamentals of Regulatory Affairs in IVD and Medical Devices Industry	*Basics of IVD and medical devices sector*	26	14	4	6
	PC1. Describe the structure of the IVD and medical devices industry and its relevance in India and globally.				
	PC2. Identify regulatory authorities such as CDSCO, USFDA, and Notified Bodies responsible for IVDs and medical devices.				
	PC3. Interpret the regulatory classification system for IVD and medical devices (e.g., Class A-D).				
	PC4. Outline key national and international regulations like MDR 2017, IVDR (EU), and 21 CFR Part 820.				

	PC5. Recognize entrepreneurship opportunities in regulatory affairs for IVDs and devices.				
	PC6. various IVD and device types to relevant licensing and regulatory bodies.				
	PC7. Simulate creation of a regulatory compliance checklist for IVD and device submissions.				
	fundamentals in product development	24	16	6	4
	PC8. Explain key principles of biological and biomedical engineering related to IVD and device development.				
	PC9. Describe functional components of typical IVD products (e.g., reagents, cartridges, analyzers).				
	PC10. Describe basic principles of device design, risk classification, usability, and safety.				
	PC11. Identify R&D lifecycle stages from concept to market for IVD and medical devices.				
	PC12. Demonstrate understanding of risk management practices (ISO 14971) in development.				
	PC13. prepare a sample product summary including intended use, classification, and key components.				
	Total Marks	***50***	***30***	***10***	***10***
2. LFS/N0570 v2.0: Development of Technical Dossier as per the regulatory guidelines of intended market (India and Global) for medical devices and In-vitro Diagnostic Devices (IVD)	*Regulatory Dossier Preparation*	***16***	***30***	***15***	***7***
	PC 1. collaborate with internal stakeholders (manufacturing, R&D, stability) to compile quality dossiers timely, as per country specific requirements				
	PC 2. prepare a Technical Dossier that provides detailed information on your medical device/ in-vitro diagnostic device (IVD) ensuring compliance with regulatory and quality framework as per country specific regulatory authority				
	PC 3. ensure availability of clinical data or clinical studies / Trials data (as applicable basis the classification) in technical dossier referring to the subject device.				
	PC 4. collaborate with research team for Preparing a Design Dossier, ensuring compliance with regulatory and quality framework as per country specific regulatory authority, for CE Marking application or other market authorization applications				
	PC 5. prepare a Clinical Evaluation Report (CER) and performance evaluation report according to regulatory and quality framework as per country specific regulatory authority				

	PC 6. prepare a Declaration of Conformity (DoC), which states that your device complies with the regulatory and quality framework as per country specific regulatory authority				
	PC 7. ensure implementation of quality management system (preferably ISO 13485), in collaboration with design and quality team in compliance with the regulatory and quality framework as per country specific regulatory authority				
	PC 8. maintain a procedure for design transfer as well as maintain an approved device master file with all the approved design specifications (i.e., design outputs) for medical device/ in-vitro diagnostic device (IVD) as per regulatory guidelines				
	PC 9. facilitate in preparation of certificate of analysis (COA), technical data sheet (TDS), method of analysis (MOA), and any other mandatory document for product registration as per regulatory guidelines				
	PC 10. maintain locally the database of product registration				
	Regulatory Compliance for labelling and inserts	***9***	***15***	***5***	***3***
	PC 11. outline requirements for labelling, storage and packaging as per regulatory requirements				
	PC 12. keeping a check on label content and leaflets as per regulatory norms (Label proofing & Artwork)				
	PC 13. create and edit Structured Product Labels using software like pharmaready, Xforms or any other.				
	PC 14. perform label proofing and artwork review with the help of text verification software like TVT or any other.				
	PC 15. review and facilitate development of Patient information leaflet (PIL), and package Insert for regulatory dossier of an intended application				
	Total Marks	**25**	**45**	**20**	**10**
3. LFS/N0502 v3.0: Submission of Technical Dossier as per the regulatory guidelines	*Operating the Regulatory Systems*	***17***	***30***	***7***	***5.5***
	PC 1. register the organization on SUGAM portal of Indian national regulator.				
	PC 2. perform various operations on SUGAM portal related to applications and related Common Technical Document (CTD), query escalation and meeting request with Indian regulatory officers				

	PC 3. register the organization on portal of regulator of intended market/ country				
	PC 4. perform various operations on international regulator portal/ software (like electronic submission gateway (ESG), Common European Submission Portal (CESP), eSubmission gateway etc.) related to applications, query escalation and supplement/ amendment submissions as well as for tracking the application status				
	PC 5. ensure efficient operations of international regulator portal/ software for Submission Management, DLP, SLP and Submission Dispatch, Archival and Troubleshooting during the electronic Common Technical Document (eCTD) filing.				
	PC 6. ensure eCTD Validation Criteria, ICH Study Tagging Files (ICH STF) specifications and Submission Transmission Specifications ae met while submitting the eCTD.				
	PC 7. ensure mitigation of risk in eCTD publishing.				
	Regulatory Dossier Submission	***13***	***20***	***5***	***2.5***
	PC 8. prepare and submit dossier for ASEAN countries as per ACTD format of respective country				
	PC 9. prepare and submit dossier for US, EU, Canada, GCC, Australia, Switzerland, South Africa, Thailand as per eCTD format of respective country				
	PC 10. prepare and submit dossier for Australia, New Zealand, EU, Canada, GCC, Bosnia and Herzegovina as per NeeS format of respective country				
	PC 11. prepare and submit dossier for Emerging market like LATAM, MENA, APAC, ASEAN, and CIS region as per pCTD format of respective country				
	PC 12. prepare and submit dossier for European region as per vNeeS format				
	Total Marks	**30**	**50**	**12**	**8**
4. LFS/N0569 v2.0: Assist in managing the regulatory affairs for medical devices and In-vitro Diagnostic Devices (IVD)	*Regulatory facilitation for US Market*	***10***	***15***	***5***	***2***
	PC 1. facilitate for submission of investigational device exemption (IDE) for regulatory approval.				
	PC 2. facilitate for submission of clinical trial applications (CTA) for regulatory approval.				

	PC 3. facilitate for submission of Premarket notification (PMN) application or 510(k) application for Class 2 devices for regulatory approval.				
	PC 4. facilitate for submission of Premarket approval (PMA) application for class 3 devices for regulatory approval.				
	PC 5. facilitate for submission of De Novo application for novel medical devices without a predicate for regulatory approval.				
	PC 6. facilitate for submission of Humanitarian Device Exemption (HDE) application for regulatory approval				
	Regulatory facilitation for Indian and Other Market	***5***	***10***	***5***	***3***
	PC 7. facilitate for submission of investigational device (medical device/ IVD) application / clinical study approval for regulatory approval for EU market.				
	PC 8. facilitate for submission of Premarket approval (PMA) application for medical device/ IVD for regulatory approval for EU market				
	PC 9. facilitate for regulatory approval of medical device/ IVD for market authorization application (MAA) via Gulf Cooperation Council procedure (GCC) for GCC Countries				
	PC 10. facilitate for submission of the application for manufacturing licence for medical device/ In Vitro Diagnostic Device (IVD) from state or national regulatory authority in India as per applicable classification				
	Regulatory facilitation for Miscellaneous Approvals	***5***	***10***	***5***	***2***
	PC 11. classify the medical device/ In Vitro Diagnostic Device (IVD) as per available classification given by regulatory authorities				
	PC 12. register the medical device/ In Vitro Diagnostic Device (IVD) with regulator and get Unique Identification number (UID) either country specific or global as per requirement				
	PC 13. facilitate in obtaining Institutional review board (IRB) / ethics committee approval for clinical trials				
	PC 14. facilitate in obtaining European CE Marking Certificate for medical device/ In Vitro Diagnostic Device (IVD)				
	PC 15. facilitate transition from MDR to MDD for medical device/ In Vitro Diagnostic Device (IVD) approved for EU market				
	PC 16. facilitate in getting the manufacturing plant and laboratory audited by a notified body for compliance with CE marking and ISO 13485 QMS.				

	PC 17. facilitate in obtaining test license and certificate of good manufacturing practices from Indian drug regulatory authority (CDSCO).				
	PC 18. facilitate in obtaining the free sale and commerce certificate (FSC)/ certificate for export from Indian Drug Regulatory authority (CDSCO).				
	PC 19. facilitate in liasoning and filing submission with national pharmaceutical pricing authority (NPPA)				
	Regulatory facilitation for Post Approval Changes	***5***	***10***	***5***	***3***
	PC 20. perform gap assessments for post approval compliance				
	PC 21. facilitate the post approval periodic reports submission like Medical device reporting (MDR) and medical product safety network (MedSun, clinical evaluation reports (CER), post market surveillance (PMS)				
	PC 22. perform compliance checks of current registered information versus manufacturing documentation for licensed medical device/ In Vitro Diagnostic Device (IVD)				
	PC 23. perform change control review and management while implementation of vendor changes, lubricant changes in machines, and change in plant machineries, design specification updates or any process changes etc.				
	PC 24. prepare and facilitate submission of variations to the regulators to close the identified 'compliance gaps'				
	PC 25. provide strategic support to internal management / clients (in case providing services) in advising on the appropriate processes and procedures to ensure sustainable compliance				
	Total Marks	**25**	**45**	**20**	**10**
5. LFS/N0571 v2.0: Assist in intellectual property rights management for life sciences products and assets	*IPR Management*	***30***	***50***	***10***	***10***
	PC 1. develop initial understanding of the invention, creating search strategies, executing search strategies.				
	PC 2. collect the relevant information on products, probable customers and competitors from API Marketing team, IP or secondary sources (IMS, Scifinder, Newport, IPD Analytics).				
	PC 3. conduct comprehensive patent searches of technical and patent information using online database and other information resources.				

	PC 4. perform prior Art Search / Patentability Search by using various paid and freely available databases				
	PC 5. perform extracting and evaluating search results, culling, report formation, mapping and result evaluation, rejection summary and visualization through charts				
	PC 6. create, update & maintain the required reports with the correct information & naming convention.				
	PC 7. perform patent infringement analysis for various jurisdiction.				
	PC 8. assist in preliminary evaluation based on sales projection, possible competitors, expert comments for the success of molecule, IP Analysis etc.				
	PC 9. assist in preparation of patent landscape report for API/ Formulation/ Biological products/ Medical Devices/ In-vitro diagnostic devices (IVD) as per organizational need.				
	PC 10. assist in drafting In-house opinion reports for the Invalidation of patents.				
	PC 11. facilitate in providing clearance reports for various markets.				
	PC 12. draft patent application for provisional/ non provisional & complete filing.				
	PC 13. assist in prosecution of patent application in collaboration with legal department for national and global markets				
	PC 14. liaise with multiple organizational functions like legal, regulatory affairs, research& development, medical affairs, marketing team to gather and validate cross-functional inputs required for decision making				
	Total Marks	**30**	**50**	**10**	**10**
6. LFS/N0567 v2.0: Coordinate with Manager, R&D team, other cross-functional teams, external stakeholders and regulatory agencies to manage regulatory affairs operations	*Coordination with Manager*	***5***	***10***	***3***	***2***
	PC1. effectively communicate and collaborate with manager in order to develop regulatory strategies				
	PC2. provide local regulation intelligence to manager for efficient regulatory affairs management				
	PC3. maintain protocol-related documents and get them reviewed and approved by manager				
	PC4. identify problems arising within the process, resulting from change management or due to change in vendors, or human error, and escalate the same by following the proper escalation matrix				

	Coordination with R&D Team	***5***	***10***	***3***	***2***
	PC5. coordinate with various technical professionals to gather, organize and compile information on new products or processes and maintain confidentiality				
	PC6. work effectively with other staff in clinical operations (e.g., biostatistics, data management, clinical monitoring), regulatory affairs and others in team.				
	PC7. maintain protocol-related documents by obtaining approval from required departments and review staff				
	Coordination with cross-functional teams	***5***	***10***	***3***	***2***
	PC8. coordinate with the quality and production team for required facilitation in various activities for regulatory compliance				
	PC9. coordinate with BA/BE and Clinical Trail Team for seeking the status of project and for filing the IND supplements and other reports				
	PC10. coordinate with pharmacovigilance team for periodic product safety reporting				
	PC11. coordinate with the product development team for development of CMC related documents				
	PC12. support the Regulatory prices related decision making in collaboration with commercial department				
	Coordination with External Stakeholders and Regulatory Agencies	***5***	***10***	***5***	***5***
	PC13. collaborate with the local Regulatory liaison agent for smooth execution & liasoning				
	PC14. participate in Ethics Committee Meetings as and when required				
	PC15. maintain cordial relationship with the national and state level regulatory authorities for keeping self and organization updated and abreast with latest changes in regulations as well as status of applications				
	PC16. obtaining market permissions and approvals for company distributers as per regulatory laws if any				
	Sensitivity towards all genders and people with disability	***5***	***5***	***3***	***2***
	PC17. respect all genders, religions, and caste				
	PC18. empathize with people with disability				

	PC19. offer support or help to a person with disability only when asked				
	PC20. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act				
	PC21. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee				
	Total Marks	**25**	**45**	**17**	**13**
7.LFS/N0122 v2.0: Ensure adherence to Environment, health and safety guidelines at workplace by self and subordinates	*Adhere to health and hygiene protocols*	***10***	***10***	***3***	***2***
	PC 1. comply with health and personal hygiene-related protocols as per WHO standards , ICH GMP and revised GMP guidelines				
	PC 2. sanitize your hands and follow cleanroom protocol, if applicable before entering in laboratory and production area and ensure the adherence of same by subordinates				
	PC 3. report any allergy, sickness or any other environment-related breach before or after entering the work premises to the designated person				
	PC 4. take preventive actions on the report of any allergy, sickness or any other environment-related breach reported by subordinates				
	Adhere to safety and security procedures	***10***	***10***	***2***	***2***
	PC 5. observe compliance by self and subordinates with safety and security policies and procedures				
	PC 6. ensure the use of appropriate safety gears like headgear, masks, gloves and other accessories as mentioned in the guidelines, by self and subordinates while working or visiting the manufacturing or laboratory area				
	PC 7. take preventive and corrective actions on the report of any identified breaches in safety and security policies and procedures by subordinates and team mates				
	PC 8. ensure proper material segregation and labelling at workplace				
	PC 9. comply with material handling, segregation and storage as per 5S system at workplace				
	Adhere to emergency procedures	***10***	***10***	***3***	***3***
	PC 10. report any hazards that he/she is not competent to deal with the relevant EHS personnel and warn other people who may be affected				
	PC 11. raise the alarm and inform the concerned person immediately for action in the cases of spill, fall, injury, toxic inhale, fire or explosion				

	PC 12. follow emergency protocols for any alarms and ensure the safety of subordinates in the area under supervision				
	PC 13. follow emergency procedures efficiently				
	PC 14. ensure injured employees are provided appropriate first aid and medical aid				
	Environment Sustainability	***10***	***10***	***2***	***3***
	PC 15. ensure energy conservation by switching off the machine (including laptops etc.) and equipment post operations				
	PC 16. identify ways to optimize the usage of electricity/energy in various tasks/activities/processes				
	PC 17. ensure energy conservation by optimizing the machine (including laptop etc) / equipment performance				
	PC 18. identify recyclable and non-recyclable, and hazardous waste generated				
	PC 19. segregate waste into different categories to achieve minimum pollution of land and water				
	PC 20. Ensure no water leakage in work area and take corrective actions, if any				
	Total Marks	**40**	**40**	**10**	**10**
8.DGT/VSQ/N0102 V1.0: Employability Skills (60 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**	**-**	**-**
9. LFS/N0120 v3.0: Establish own enterprise and perform various entrepreneurial activities to run the business operations in Life Sciences Sector	*Set up enterprise and perform entrepreneurial activities*	***10***	***15***	***5***	***5***
	PC 1. perform a survey in the identified area for business activities to identify prospective customers and business opportunity				
	PC 2. identify products and/ or services and it's sources, that match the business opportunity				
	PC 3. develop business proposal with objective and identified business area for registering the proposed business as independent entity with competent authorities				
	PC 4. submit business proposals and feasibility plans for securing the required funding from govt. schemes for MSMEs like MUDRA etc. as and when needed				
	PC 5. present the business proposal to investors and stakeholders to gain their confidence and trust for possible funding				
	PC 6. ensure setting up the infrastructure and resources for business as per approved plan and investors/ shareholders agreement				
	PC 7. enroll into various government schemes and programs for MSME and avail the benefits				
	PC 8. promote the product/ services through various means including digital promotions in line to regulations for promotion and sale as per land of law				
	PC 9. develop the supply chain and distribution network				
	PC 10. maintain updated information regarding new market trends to provide service to customers and constantly upskill self and employees for futuristic technologies, innovations and methodologies				
	Maintenance of accounts and ledgers	***10***	***15***	***5***	***5***
	PC 11. ensure to generate a final invoice for the services rendered/ or products sold				
	PC 12. collect payment either in cash (as per RBI guidelines)/ cheque/ demand draft or through online transactions via RTGS/NEFT/UPI etc.				
	PC 13. ensure accounts and ledgers are maintained for the material supplied, payables and receivables, loan ledgers, taxes collected				

	and paid into government treasury as well for wages paid and statutory benefits like PF, ESI contribution deposited with authorities				
	PC 14. ensure maintenance and reconciliation of a monthly account as well as movable and immovable assets and stock to keep track of profit/ loss as well as periodic audit as per legal requirements				
	Comply with legal, regulatory and statutory standards	***10***	***10***	***5***	***5***
	PC 15. comply with workplace health and safety rules stipulated by local authorities				
	PC 16. comply with rules related to taxes and licensing regulations				
	PC 17. comply with prevalent labour laws and keep records for employee's qualifications, employment as well as trainings				
	PC 18. comply with regulations and protocols related to maintenance of product/ service license including the pre conditions (if any)				
	PC 19. comply with quality system like ISO/cGMP/GLP etc and any other rule mandated by appropriate regulatory authorities				
	PC 20. comply with pollution norms as per land of law and ensure near zero pollution for a sustainable environment and to earn carbon credits				
	PC 21. ensure that business facility and employees are always prepared and ready for any surprise inspection/ audit from clients/ regulatory/ statutory authorities				
	Total Marks	**30**	**40**	**15**	**15**
10. LFS/N0121 v3.0: Maintain the critical business documents as Entrepreneur in Life Sciences Sector	*Infrastructure related documentation*	***5***	***20***	***5***	***2***
	PC 1. ensure documentation and maintenance of records for architectural building layout like blueprint of plant/lab, electric circuit and plumbing layouts and safety equipment layout, infrastructure and asset insurance and lease/rent contracts/ sale deed (if owned facility)				
	PC 2. ensure documentation and maintenance of records for all machineries, equipment and tools installed/used in the plant/ lab unit, with supplier/manufacturer details, manuals of all machineries / equipment, installation and qualification records and annual maintenance details etc				
	PC 3. ensure documentation and maintenance of records for engineering and maintenance of each machinery/equipment, machine				

	utilization, machine performance, breakdown details, corrective actions, spares changed, machine/equipment condition etc				
	Supply Chain related documentation	***5***	***20***	***5***	***3***
	PC 4. ensure documentation and maintenance of records for all raw materials, ingredients and packaging materials handled, like name of the supplier, batch details, quantity supplied and quality of the materials supplies etc as well as				
	PC 5. ensure documentation and maintenance of records for each supplier quality report on raw materials, ingredients, packaging materials, internal and external quality report on finished products, consumer and customer complaints , corrective actions, legal documents (if any)				
	PC 6. ensure documentation and maintenance of records for storage facility, like condition of storage facility, storage parameters if any like temperature, humidity, pressure (as applicable), space utilised, stacking procedure etc				
	PC 7. ensure documentation and maintenance of records for distribution details like transport details, quality, hygiene and cleanliness of vehicle, quantity loaded in the vehicle, distribution routes , outlet details, customer/ consumer details, distribution quantity, quantity returned etc.				
	Documentation for sales & marketing	***5***	***10***	***3***	***3***
	PC 8. ensure documentation and maintenance of records for long term and short term business plans, feasibility reports, investor/shareholder agreements and disbursement and payment records for loan/grant/equity etc.				
	PC 9. ensure documentation and maintenance of records for sale like customer details, customer type, location, quantity purchased by each stockist/consumer, frequency of purchase, sale details like quantity of products/brand sold in each territory				
	Quality audit and client/regulatory inspections related documentation	***5***	***5***	***2***	***2***
	PC 10. ensure documentation and maintenance of records for internal/ external audits with its observations, notices/ feedback, action reports and final submission of audit action reports				
	PC 11. ensure documentation and maintenance of records for every communication sent to or received from regulatory/ licensing authorities				

	Total Marks	**20**	**55**	**15**	**10**
Grand Total		**245**	**400**	**119**	**86**

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 Production Machine Operator 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