

Qualification Pack



Associate-Clinical Research Management (Pharma, Biologics and Medical devices)

Electives: Data management

QP Code: LFS/Q3501 Instantiated QP Code: LFS/Q3501-SI003

Version: 3.0

NSQF Level: 5.5



Qualification Pack

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LFS/Q3501-SI003: Associate-Clinical Research Management (Pharma, Biologics and Medical devices)

Brief Job Description

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.

Personal Attributes

The individual should have excellent communication skills and analytical skills. The person should possess good critical thinking, attention to detail, and decision-making skills. The role holder should be proactive in planning and organizing skills.

Applicable National Occupational Standards (NOS)

Compulsory NOS:

1. [LFS/N3507: Introduction to life sciences industry and basics of Clinical trial occupation](#)
2. [LFS/N0119: Ensure environment sustainability and sensitivity towards all genders and people with disability](#)
3. [LFS/N3506: Carry out management activities related for clinical trial](#)
4. [DGT/VSQ/N0103: Employability Skills \(90 Hours\)](#)

Electives(mandatory to select at least one):

Elective : Data management

This elective is about Associate-Clinical Research Management providing support for clinical data management activities.

1. [LFS/N3505: Provide support for clinical data management activities](#)

Qualification Pack (QP) Parameters

Sector	Life Sciences
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Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Medical Devices and In Vitro Diagnostic (IVD), Biotechnology, Contract Research
Occupation	Clinical Trials, Bio Availability-Bio Equivalence
Country	India
NSQF Level	5.5
Credits	19
Aligned to NCO/ISCO/ISIC Code	NCO 2015/3512.0601
Minimum Educational Qualification & Experience	Completed 3 year UG degree (Biology, Nursing, Medical Lab Technician, Life Sciences, Biotechnology) OR Completed 3 year UG degree program after 12th (B.E/ B. tech. Biotech) OR Completed 3 year UG degree program after 12th (B. Pharma) OR Medical Graduate (BAMS/ BDS/ BUMS/ BHMS/ MBBS)
Minimum Level of Education for Training in School	
Pre-Requisite License or Training	NA
Minimum Job Entry Age	18 Years
Last Reviewed On	NA
Next Review Date	08/04/2028
NSQC Approval Date	08/04/2025
Version	3.0
Reference code on NQR	QG-5.5-LS-00251-2025-V2-LSSSDC
NQR Version	2.0



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LFS/N3507: Introduction to life sciences industry and basics of Clinical trial occupation

Description

This NOS is about an Associate-Clinical Research Management Individual Introduction to life sciences industry and basics of Clinical trial occupation

Scope

The scope covers the following :

- Life sciences industry and clinical trial occupation

Elements and Performance Criteria

Life sciences industry and clinical trial occupation

To be competent, the user/individual on the job must be able to:

- 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., Schedule Y, 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

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** principles of ICH-GCP, Indian GCP and ICMR guidelines, Good Documentation Practices and Good Laboratory Practices
- KU2.** SOPs and organizational policies about communication, code of conduct
- KU3.** clinical research team reporting structure
- KU4.** correct method for carrying out corrective actions outlined for trial-related problems
- KU5.** sponsors and CRO roles and responsibilities
- KU6.** site roles and responsibilities
- KU7.** working in cross functional, cross geographical and cross -cultural teams
- KU8.** information security and confidentiality policy
- KU9.** clinical trial-related regulations and compliances
- KU10.** sample handling procedures
- KU11.** principles of trial protocol



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Generic Skills (GS)

User/individual on the job needs to know how to:

- GS1.** use written communication skills to accurately record the required details in a given format as per SOP and guidelines in the English language
- GS2.** use reading and comprehension skills of various coding systems to read instructions, guidelines, procedures, rules, and signage
- GS3.** use listening skills to interpret the instructions and procedures to be followed
- GS4.** use verbal communication skills to interact with supervisor, teammates, and cross-functional teams for coordination and to communicate confidential and sensitive information discretely to the authorized person
- GS5.** use team-building skills while dealing with teammates and while managing the difficult/stressful or emotional situations at work
- GS6.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS7.** apply planning and organizing skills to plan and organize tools and material required to fulfil documentation related requirements
- GS8.** apply critical thinking skills to analyze and identify what and when to report an issue/concern to the supervisor/ QA team / any other stakeholder
- GS9.** apply customer-centricity while generating and securing documents
- GS10.** apply customer-centricity to remain compliant with data integrity rules, GMP guidelines and to evaluate the impact of wrongdoings
- GS11.** apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations



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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Life sciences industry and clinical trial occupation</i>	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., Schedule Y, 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	-	-	-	-
NOS Total	60	-	20	20



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N3507
NOS Name	Introduction to life sciences industry and basics of Clinical trial occupation
Sector	Life Sciences
Sub-Sector	Contract Research
Occupation	Clinical Trials
NSQF Level	5.5
Credits	1.00
Version	1.0
Last Reviewed Date	08/04/2025
Next Review Date	08/04/2028
NSQC Clearance Date	08/04/2025



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LFS/N0119: Ensure environment sustainability and sensitivity towards all genders and people with disability

Description

This NOS unit is about role holder ensuring environment sustainability and sensitivity towards gender, and people with disabilities at the workplace

Scope

The scope covers the following :

- Environment sustainability
- Sensitivity towards all genders and people with disability

Elements and Performance Criteria

Environment sustainability

To be competent, the user/individual on the job must be able to:

- PC1.** ensure energy conservation by switching off the machine and equipment post operations
- PC2.** identify ways to optimize the usage of electricity/energy in various tasks/activities/processes
- PC3.** ensure energy conservation by optimizing the machine/ equipment performance
- PC4.** identify recyclable and non-recyclable, and hazardous waste generated
- PC5.** segregate waste into different categories to achieve minimum pollution of land and water
- PC6.** check for water leakage in plant/ work area and take corrective actions

Sensitivity towards all genders and people with disability

To be competent, the user/individual on the job must be able to:

- PC7.** respect all genders, religions, and caste
- PC8.** empathize with the people with disability
- PC9.** offer support or help to a person with a disability only when asked
- PC10.** ensure to adhere to the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act
- PC11.** report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** the guidelines laid on Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act
- KU2.** methods of workplace communication
- KU3.** methods of team coordination
- KU4.** the types of possible disabilities among people with disability (PWD)



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- KU5.** the challenges faced by PWD
- KU6.** importance of displaying empathy towards PWD
- KU7.** the right way to use the laws, acts, and provisions defined for PwD by the statutory bodies
- KU8.** the importance of awareness for gender sensitization and prevention of sexual harassment (POSH) act
- KU9.** the guidelines related to environmental sustainability
- KU10.** the WHO guidelines and ICH-cGMP rules for waste disposal and waste management

Generic Skills (GS)

User/individual on the job needs to know how to:

- GS1.** use reading and comprehension skills to gauge the relevant information manuals, SOPs, health and safety instructions, memos, reports, job cards, and notes/comments
- GS2.** use written communication skills to record and communicate details of work done to appropriate stakeholders by using written or computer-based record/electronic mail
- GS3.** use verbal communication skills to communicate confidential and sensitive information discretely to the authorized person while interacting with teammates
- GS4.** use team-building skills while dealing with teammates to manage the difficult/stressful or emotional situations at work
- GS5.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS6.** apply critical thinking skills to analyze and identify when to report an issue/concern to the supervisor and to deal with a colleague individually, depending on the type of concern

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Environment sustainability</i>	15	25	5	5
PC1. ensure energy conservation by switching off the machine and equipment post operations	-	-	-	-
PC2. identify ways to optimize the usage of electricity/energy in various tasks/activities/processes	-	-	-	-
PC3. ensure energy conservation by optimizing the machine/ equipment performance	-	-	-	-
PC4. identify recyclable and non-recyclable, and hazardous waste generated	-	-	-	-
PC5. segregate waste into different categories to achieve minimum pollution of land and water	-	-	-	-
PC6. check for water leakage in plant/ work area and take corrective actions	-	-	-	-
<i>Sensitivity towards all genders and people with disability</i>	15	25	5	5
PC7. respect all genders, religions, and caste	-	-	-	-
PC8. empathize with the people with disability	-	-	-	-
PC9. offer support or help to a person with a disability only when asked	-	-	-	-
PC10. ensure to adhere to the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act	-	-	-	-
PC11. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee	-	-	-	-
NOS Total	30	50	10	10



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0119
NOS Name	Ensure environment sustainability and sensitivity towards all genders and people with disability
Sector	Life Sciences
Sub-Sector	Bio Pharmaceutical, Pharmaceutical, Contract Research
Occupation	Clinical Trials
NSQF Level	5.5
Credits	1.00
Version	3.0
Last Reviewed Date	08/04/2025
Next Review Date	08/04/2028
NSQC Clearance Date	08/04/2025



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LFS/N3506: Carry out management activities related for clinical trial

Description

This NOS is about an Associate-Clinical Research Management Individual Carrying out management activities related for clinical trial

Scope

The scope covers the following :

- Planning, Development, and Compliance
- Financial Management, Data Integrity, and Quality Assurance

Elements and Performance Criteria

Planning, Development, and Compliance

To be competent, the user/individual on the job must be able to:

- 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

To be competent, the user/individual on the job must be able to:

- 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.

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:



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- KU1.** SOPs and organizational policies about communication, code of conduct
- KU2.** clinical research team reporting structure
- KU3.** correct method for carrying out corrective actions outlined for trial-related problems
- KU4.** sponsors and CRO roles and responsibilities
- KU5.** site roles and responsibilities
- KU6.** working in cross functional, cross geographical and cross -cultural teams
- KU7.** information security and confidentiality policy
- KU8.** clinical trial-related regulations and compliances
- KU9.** sample handling procedures
- KU10.** principles of trial protocol

Generic Skills (GS)

User/individual on the job needs to know how to:

- GS1.** use written communication skills to accurately record the required details in a given format as per SOP and guidelines in the English language
- GS2.** use reading and comprehension skills of various coding systems to read instructions, guidelines, procedures, rules, and signage
- GS3.** use listening skills to interpret the instructions and procedures to be followed
- GS4.** use verbal communication skills to interact with supervisor, teammates, and cross-functional teams for coordination and to communicate confidential and sensitive information discretely to the authorized person
- GS5.** use team-building skills while dealing with teammates and while managing the difficult/stressful or emotional situations at work
- GS6.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS7.** apply planning and organizing skills to plan and organize tools and material required to fulfil documentation related requirements
- GS8.** apply critical thinking skills to analyze and identify what and when to report an issue/concern to the supervisor/ QA team / any other stakeholder
- GS9.** apply customer-centricity while generating and securing documents
- GS10.** apply customer-centricity to remain compliant with data integrity rules, GMP guidelines and to evaluate the impact of wrongdoings
- GS11.** apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Planning, Development, and Compliance</i>	15	30	5	10
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.	-	-	-	-
<i>Financial Management, Data Integrity, and Quality Assurance</i>	10	20	5	5
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.	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
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.	-	-	-	-
NOS Total	25	50	10	15



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N3506
NOS Name	Carry out management activities related for clinical trial
Sector	Life Sciences
Sub-Sector	Contract Research
Occupation	Clinical Trials
NSQF Level	5.5
Credits	1.00
Version	1.0
Last Reviewed Date	08/04/2025
Next Review Date	08/04/2028
NSQC Clearance Date	08/04/2025



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DGT/VSQ/N0103: Employability Skills (90 Hours)

Description

This unit is about employability skills, Constitutional values, becoming a professional in the 21st Century, digital, financial, and legal literacy, diversity and Inclusion, English and communication skills, customer service, entrepreneurship, and apprenticeship, getting ready for jobs and career development.

Scope

The scope covers the following :

- Introduction to Employability Skills
- Constitutional values - Citizenship
- Becoming a Professional in the 21st Century
- Basic English Skills
- Career Development & Goal Setting
- Communication Skills
- Diversity & Inclusion
- Financial and Legal Literacy
- Essential Digital Skills
- Entrepreneurship
- Customer Service
- Getting ready for Apprenticeship & Jobs

Elements and Performance Criteria

Introduction to Employability Skills

To be competent, the user/individual on the job must be able to:

- PC1.** understand the significance of employability skills in meeting the current job market requirement and future of work
- PC2.** identify and explore learning and employability relevant portals
- PC3.** research about the different industries, job market trends, latest skills required and the available opportunities

Constitutional values – Citizenship

To be competent, the user/individual on the job must be able to:

- PC4.** 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.
- PC5.** follow environmentally sustainable practices

Becoming a Professional in the 21st Century

To be competent, the user/individual on the job must be able to:

- PC6.** recognize the significance of 21st Century Skills for employment



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- PC7.** practice the 21st Century Skills such as Self-Awareness, Behaviour 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
- PC8.** adopt a continuous learning mindset for personal and professional development

Basic English Skills

To be competent, the user/individual on the job must be able to:

- PC9.** use basic English for everyday conversation in different contexts, in person and over the telephone
- PC10.** read and understand routine information, notes, instructions, mails, letters etc. written in English
- PC11.** write short messages, notes, letters, e-mails etc. in English

Career Development & Goal Setting

To be competent, the user/individual on the job must be able to:

- PC12.** identify career goals based on the skills, interests, knowledge, and personal attributes
- PC13.** prepare a career development plan with short- and long-term goals

Communication Skills

To be competent, the user/individual on the job must be able to:

- PC14.** follow verbal and non-verbal communication etiquette while communicating in professional and public settings
- PC15.** use active listening techniques for effective communication
- PC16.** communicate in writing using appropriate style and format based on formal or informal requirements
- PC17.** work collaboratively with others in a team

Diversity & Inclusion

To be competent, the user/individual on the job must be able to:

- PC18.** communicate and behave appropriately with all genders and PwD
- PC19.** escalate any issues related to sexual harassment at workplace according to POSH Act

Financial and Legal Literacy

To be competent, the user/individual on the job must be able to:

- PC20.** identify and select reliable institutions for various financial products and services such as bank account, debit and credit cards, loans, insurance etc.
- PC21.** carry out offline and online financial transactions, safely and securely, using various methods and check the entries in the passbook
- PC22.** identify common components of salary and compute income, expenses, taxes, investments etc
- PC23.** identify relevant rights and laws and use legal aids to fight against legal exploitation

Essential Digital Skills

To be competent, the user/individual on the job must be able to:

- PC24.** operate digital devices and use their features and applications securely and safely
- PC25.** 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.
- PC26.** display responsible online behaviour while using various social media platforms



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- PC27.** create a personal email account, send and process received messages as per requirement
- PC28.** carry out basic procedures in documents, spreadsheets and presentations using respective and appropriate applications
- PC29.** utilize virtual collaboration tools to work effectively

Entrepreneurship

To be competent, the user/individual on the job must be able to:

- PC30.** identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research
- PC31.** develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion
- PC32.** identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity

Customer Service

To be competent, the user/individual on the job must be able to:

- PC33.** identify different types of customers and ways to communicate with them
- PC34.** identify and respond to customer requests and needs in a professional manner
- PC35.** use appropriate tools to collect customer feedback
- PC36.** follow appropriate hygiene and grooming standards

Getting ready for apprenticeship & Jobs

To be competent, the user/individual on the job must be able to:

- PC37.** create a professional Curriculum vitae (Résumé)
- PC38.** search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively
- PC39.** apply to identified job openings using offline /online methods as per requirement
- PC40.** answer questions politely, with clarity and confidence, during recruitment and selection
- PC41.** identify apprenticeship opportunities and register for it as per guidelines and requirements

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** need for employability skills and different learning and employability related portals
- KU2.** various constitutional and personal values
- KU3.** different environmentally sustainable practices and their importance
- KU4.** Twenty first (21st) century skills and their importance
- KU5.** how to use English language for effective verbal (face to face and telephonic) and written communication in formal and informal set up
- KU6.** importance of career development and setting long- and short-term goals
- KU7.** about effective communication
- KU8.** POSH Act
- KU9.** Gender sensitivity and inclusivity
- KU10.** different types of financial institutes, products, and services



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- KU11.** components of salary and how to compute income and expenditure
- KU12.** importance of maintaining safety and security in offline and online financial transactions
- KU13.** different legal rights and laws
- KU14.** different types of digital devices and the procedure to operate them safely and securely
- KU15.** how to create and operate an e- mail account
- KU16.** use applications such as word processors, spreadsheets etc.
- KU17.** how to identify business opportunities
- KU18.** types and needs of customers
- KU19.** how to apply for a job and prepare for an interview
- KU20.** apprenticeship scheme and the process of registering on apprenticeship portal

Generic Skills (GS)

User/individual on the job needs to know how to:

- GS1.** read and write different types of documents/instructions/correspondence in English and other languages
- GS2.** communicate effectively using appropriate language in formal and informal settings
- GS3.** behave politely and appropriately with all to maintain effective work relationship
- GS4.** how to work in a virtual mode, using various technological platforms
- GS5.** perform calculations efficiently
- GS6.** solve problems effectively
- GS7.** pay attention to details
- GS8.** manage time efficiently
- GS9.** maintain hygiene and sanitization to avoid infection

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Introduction to Employability Skills</i>	1	1	-	-
PC1. understand the significance of employability skills in meeting the current job market requirement and future of work	-	-	-	-
PC2. identify and explore learning and employability relevant portals	-	-	-	-
PC3. research about the different industries, job market trends, latest skills required and the available opportunities	-	-	-	-
<i>Constitutional values – Citizenship</i>	1	1	-	-
PC4. 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.	-	-	-	-
PC5. follow environmentally sustainable practices	-	-	-	-
<i>Becoming a Professional in the 21st Century</i>	1	3	-	-
PC6. recognize the significance of 21st Century Skills for employment	-	-	-	-
PC7. practice the 21st Century Skills such as Self-Awareness, Behaviour 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	-	-	-	-
PC8. adopt a continuous learning mindset for personal and professional development	-	-	-	-
<i>Basic English Skills</i>	3	4	-	-
PC9. use basic English for everyday conversation in different contexts, in person and over the telephone	-	-	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC10. read and understand routine information, notes, instructions, mails, letters etc. written in English	-	-	-	-
PC11. write short messages, notes, letters, e-mails etc. in English	-	-	-	-
<i>Career Development & Goal Setting</i>	1	2	-	-
PC12. identify career goals based on the skills, interests, knowledge, and personal attributes	-	-	-	-
PC13. prepare a career development plan with short- and long-term goals	-	-	-	-
<i>Communication Skills</i>	2	2	-	-
PC14. follow verbal and non-verbal communication etiquette while communicating in professional and public settings	-	-	-	-
PC15. use active listening techniques for effective communication	-	-	-	-
PC16. communicate in writing using appropriate style and format based on formal or informal requirements	-	-	-	-
PC17. work collaboratively with others in a team	-	-	-	-
<i>Diversity & Inclusion</i>	1	1	-	-
PC18. communicate and behave appropriately with all genders and PwD	-	-	-	-
PC19. escalate any issues related to sexual harassment at workplace according to POSH Act	-	-	-	-
<i>Financial and Legal Literacy</i>	2	3	-	-
PC20. identify and select reliable institutions for various financial products and services such as bank account, debit and credit cards, loans, insurance etc.	-	-	-	-
PC21. carry out offline and online financial transactions, safely and securely, using various methods and check the entries in the passbook	-	-	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC22. identify common components of salary and compute income, expenses, taxes, investments etc	-	-	-	-
PC23. identify relevant rights and laws and use legal aids to fight against legal exploitation	-	-	-	-
<i>Essential Digital Skills</i>	3	5	-	-
PC24. operate digital devices and use their features and applications securely and safely	-	-	-	-
PC25. 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.	-	-	-	-
PC26. display responsible online behaviour while using various social media platforms	-	-	-	-
PC27. create a personal email account, send and process received messages as per requirement	-	-	-	-
PC28. carry out basic procedures in documents, spreadsheets and presentations using respective and appropriate applications	-	-	-	-
PC29. utilize virtual collaboration tools to work effectively	-	-	-	-
<i>Entrepreneurship</i>	2	3	-	-
PC30. identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research	-	-	-	-
PC31. develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion	-	-	-	-
PC32. identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity	-	-	-	-
<i>Customer Service</i>	1	2	-	-
PC33. identify different types of customers and ways to communicate with them	-	-	-	-



Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC34. identify and respond to customer requests and needs in a professional manner	-	-	-	-
PC35. use appropriate tools to collect customer feedback	-	-	-	-
PC36. follow appropriate hygiene and grooming standards	-	-	-	-
<i>Getting ready for apprenticeship & Jobs</i>	2	3	-	-
PC37. create a professional Curriculum vitae (Résumé)	-	-	-	-
PC38. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively	-	-	-	-
PC39. apply to identified job openings using offline /online methods as per requirement	-	-	-	-
PC40. answer questions politely, with clarity and confidence, during recruitment and selection	-	-	-	-
PC41. identify apprenticeship opportunities and register for it as per guidelines and requirements	-	-	-	-
NOS Total	20	30	-	-



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	DGT/VSQ/N0103
NOS Name	Employability Skills (90 Hours)
Sector	Cross Sectoral
Sub-Sector	Professional Skills
Occupation	Employability
NSQF Level	5
Credits	3
Version	1.0
Last Reviewed Date	30/05/2024
Next Review Date	30/05/2027
NSQC Clearance Date	30/05/2024



Qualification Pack

LFS/N3505: Provide support for clinical data management activities

Description

This NOS is about an Associate-Clinical Research Management providing support for clinical data management activities

Scope

The scope covers the following :

- Designing eCRF
- Validation of clinical data

Elements and Performance Criteria

Designing eCRF

To be competent, the user/individual on the job must be able to:

- PC1.** assess database design requirements relevant to data capture tool, data extraction, processing, and reporting
- PC2.** eCRF design and edit check programming based on protocol requirements
- PC3.** manage the design specification, development, testing, and validation of electronic case report forms, edit checks standards, and dataset extraction
- PC4.** make recommendations to management concerning complex technical issues and provide solutions
- PC5.** manage multiple studies and projects simultaneously and deliver on the timelines
- PC6.** 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
- PC7.** generate and maintain functional specifications for the eCRF edit checks
- PC8.** generate data listings to support data review
- PC9.** import external data in the EDC based on the data transfer agreement developed in collaboration with the clinical data manager
- PC10.** develop the eCRF completion guidelines

Validation of clinical data

To be competent, the user/individual on the job must be able to:

- PC11.** prepare and update annotation list, data validation plan, edit check specifications, and database/ data entry screens as per study requirements
- PC12.** perform query management activities per study requirements including the manual queries raised by the data entry team and medical coder
- PC13.** fill the data in 2 CRF(s) for data base testing
- PC14.** validate the external data after uploading it into the database
- PC15.** update self-evident correction queries in self-evident correction form per study requirements
- PC16.** update reports and trackers on regular basis or as per study requirements



Qualification Pack

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** organization SOPs
- KU2.** impact of various practices on cost, quality, productivity, delivery, and safety
- KU3.** ICH-GCP guidelines, legislation and regulations as applicable and impact of non-conformance/poor practices
- KU4.** country regulations and compliances relevant to clinical trial process
- KU5.** clinical trial protocol
- KU6.** investigator brochure and knowledge of the characteristics of the investigational drug in the study
- KU7.** Good Documentation Practices and Medical Coding Dictionaries
- KU8.** clinical trial methodology
- KU9.** how to create eCRF specifications, managing eCRF timelines, designing and developing eCRFs
- KU10.** medical, clinical research, and data management process and terminology
- KU11.** data requirements and authoring specifications

Generic Skills (GS)

User/individual on the job needs to know how to:

- GS1.** use reading and comprehension skills to read and understand manuals, SOPs, health and safety instructions, memos, reports, and notes/comments
- GS2.** use written communication skills to record and communicate details of work done to appropriate stakeholders by using written/typed report or computer-based record/electronic mail
- GS3.** use written communication skills to maintain proper and concise records as per given format
- GS4.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS5.** apply critical thinking skills to analyze and identify when to report an issue/concern to the in-charge and when to deal with a colleague individually, depending on the type of concern
- GS6.** apply analytical skills in choosing a well-defined written smooth methods/instruction to resolve day to day problems
- GS7.** apply planning and organizing skills to plan and organize tools and material required to fulfil own work requirements on time
- GS8.** apply the analytical skill to observe investigations and identify deviations/ abnormal incidents
- GS9.** apply customer-centricity while generating and securing documents
- GS10.** apply customer-centricity to remain compliant with data integrity rules, GMP guidelines and to evaluate the impact of wrongdoings
- GS11.** apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations

Qualification Pack

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Designing eCRF</i>	15	30	5	10
PC1. assess database design requirements relevant to data capture tool, data extraction, processing, and reporting	-	-	-	-
PC2. eCRF design and edit check programming based on protocol requirements	-	-	-	-
PC3. manage the design specification, development, testing, and validation of electronic case report forms, edit checks standards, and dataset extraction	-	-	-	-
PC4. make recommendations to management concerning complex technical issues and provide solutions	-	-	-	-
PC5. manage multiple studies and projects simultaneously and deliver on the timelines	-	-	-	-
PC6. 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	-	-	-	-
PC7. generate and maintain functional specifications for the eCRF edit checks	-	-	-	-
PC8. generate data listings to support data review	-	-	-	-
PC9. import external data in the EDC based on the data transfer agreement developed in collaboration with the clinical data manager	-	-	-	-
PC10. develop the eCRF completion guidelines	-	-	-	-
<i>Validation of clinical data</i>	10	20	5	5
PC11. prepare and update annotation list, data validation plan, edit check specifications, and database/ data entry screens as per study requirements	-	-	-	-



Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. perform query management activities per study requirements including the manual queries raised by the data entry team and medical coder	-	-	-	-
PC13. fill the data in 2 CRF(s) for data base testing	-	-	-	-
PC14. validate the external data after uploading it into the database	-	-	-	-
PC15. update self-evident correction queries in self-evident correction form per study requirements	-	-	-	-
PC16. update reports and trackers on regular basis or as per study requirements	-	-	-	-
NOS Total	25	50	10	15



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N3505
NOS Name	Provide support for clinical data management activities
Sector	Life Sciences
Sub-Sector	Contract Research
Occupation	Clinical Trials
NSQF Level	5.5
Credits	13.0
Version	3.0
Last Reviewed Date	08/04/2025
Next Review Date	08/04/2028
NSQC Clearance Date	08/04/2025

Assessment Guidelines and Assessment Weightage

Assessment Guidelines

1. Criteria for assessment for each Qualification Pack will be created by Life Sciences Sector Skill Development Council (LSSSDC)
2. Each Element will be assigned marks proportional to its importance in NOS. LSSSDC will also lay down the proportion of marks for Theory, Practical, Project, and Viva for each Element.
3. The assessment for the theory part will be based on the knowledge bank of questions created by the LSSSDC.
4. Assessment will be conducted for all compulsory NOS, and where applicable, on the selected elective/option NOS/set of NOS.
5. LSSSDC as assessment and awarding body will create unique evaluations for each assessment component i.e. theory, practical, project and viva for every student at each examination/training center based on this criterion.
6. Wherever any assessment component is not applicable/ feasible, the balance assessment components will be used to assess the candidate and accordingly the total marks will be calculated only for the applied



Qualification Pack

assessment component.

7. To pass the Qualification Pack, every trainee should score a minimum of 50-70%% of marks in each NOS to successfully clear the assessment. In the case of a Govt funded program, the program guidelines will be overarching on the pass percentage rules.

8. In case of unsuccessful completion, the trainee may seek re-assessment on the Qualification Pack.

Minimum Aggregate Passing % at QP Level : 70

(Please note: Every Trainee should score a minimum aggregate passing percentage as specified above, to successfully clear the Qualification Pack assessment.)

Minimum Passing % at NOS Level: 70

(Please note: A Trainee must score the minimum percentage for each NOS separately as well as on the QP as a whole.)

Assessment Weightage

Compulsory NOS

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N3507.Introduction to life sciences industry and basics of Clinical trial occupation	60	0	20	20	100	10
LFS/N0119.Ensure environment sustainability and sensitivity towards all genders and people with disability	30	50	10	10	100	10
LFS/N3506.Carry out management activities related for clinical trial	25	50	10	15	100	10
DGT/VSQ/N0103.Employability Skills (90 Hours)	20	30	-	-	50	10
Total	135	130	40	45	350	40

Elective: 1 Data management



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National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N3505.Provide support for clinical data management activities	25	50	10	15	100	60
Total	25	50	10	15	100	60