



Qualification Pack



Research Associate- Pharma and Biological Products

Biological Product Development

QP Code: LFS/Q0514 Instantiated QP Code: LFS/Q0514-SI003

Version: 1.0

NSQF Level: 5.5

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LFS/Q0514-SI003: Research Associate- Pharma and Biological Products

Brief Job Description

Research Associate- Pharma and Biological Products is responsible for assisting in biological product development, API synthesis, medicinal chemistry-based research, carrying out research related activities along with also assists in technology transfer and process development activities to large scale manufacturing. The jobholder is also responsible for reporting and documentation, problem solving and decision-making, Co-ordinate with manager and team members and maintaining healthy and safe working environment.

Personal Attributes

The individual should have good communication and interpersonal skills. The person should possess investigational abilities, analytical and reasoning skills. The role holder should have critical thinking skills along with excellent organizational skills.

Applicable National Occupational Standards (NOS)

Compulsory NOS:

1. [LFS/N0111: Ensure adherence to Environment, health and safety guidelines in production facility and GMP controlled areas by self and subordinates](#)
2. [LFS/N0129: Coordinate and communicate with supervisor/production chemist, research teams and auditors](#)
3. [LFS/N0572: Maintain experiment records ensuring data integrity and intellectual property rights](#)
4. [DGT/VSQ/N0103: Employability Skills \(90 Hours\)](#)

Electives (mandatory to select at least one):

Elective : Biological Product Development

1. [LFS/N0576: Assist in new biological product development](#)

Qualification Pack (QP) Parameters

Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical



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Occupation	Research and Development
Country	India
NSQF Level	5.5
Credits	18
Aligned to NCO/ISCO/ISIC Code	NCO-2015/2131.1300
Minimum Educational Qualification & Experience	Pursuing 2nd year of PG (after 3 year UG Degree) (M.Sc in relevant field) OR Pursuing 2nd year of PG (after 3 year UG Degree) (M.Pharm) OR Pursuing 2nd year of PG (after 3 year UG Degree) (M.Tech in relevant Engineering domain)
Minimum Level of Education for Training in School	
Pre-Requisite License or Training	NA
Minimum Job Entry Age	21 Years
Last Reviewed On	NA
Next Review Date	29/09/2026
NSQF Approval Date	29/09/2023
Version	1.0
Reference code on NQR	QG-5.5-LS-00997-2023-V1-LSSSDC
NQR Version	1.0



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LFS/N0111: Ensure adherence to Environment, health and safety guidelines in production facility and GMP controlled areas by self and subordinates

Description

This job function is about the job role holder ensuring adherence to the health, hygiene, safety and environment guidelines while working in the production facility and GMP controlled areas by self and subordinates

Scope

The scope covers the following :

- Follow health and hygiene protocols
- Adherence to safety and security procedures
- Adherence to emergency procedures

Elements and Performance Criteria

Follow health and hygiene protocols

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

- PC1.** comply with health and personal hygiene-related protocols as per WHO standards and ICH GMP guidelines
- PC2.** wash hands before entering in the production area with soap/alcohol based sanitisers
- PC3.** report any allergy, sickness or any other environment-related breach before or after entering the work premises to the designated person
- PC4.** take preventive actions on the report of any allergy, sickness or any other environment-related breach reported by subordinates
- PC5.** follow gowning procedures while entering an environment controlled work area and ensure adherence to the same by others

Adherence to safety and security procedures

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

- PC6.** comply with safety and security policies and procedures
- PC7.** ensure the use of appropriate safety gears like headgear, masks, gloves and other accessories as mentioned in the guidelines, by self and subordinates while carrying out work
- PC8.** take preventive and corrective actions based on the report of any identified breaches in safety and security policies and procedures by subordinates
- PC9.** ensure that discipline for material segregation and 5S system is followed at the storage area
- PC10.** comply with material handling, segregation, and storage guidelines for hazardous material
- PC11.** take corrective actions for reported hazards in consultation with EHS personnel
- PC12.** complete the records of safety drills and trainings undertaken by self and subordinates

Adherence to emergency procedures

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



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- PC13.** report any hazards that he/she is not competent to deal with the relevant EHS personnel and warn other people who may be affected
- PC14.** raise the alarm and inform the concerned person immediately for action in the cases of spill, fall, injury, toxic inhale, fire or explosion
- PC15.** follow emergency protocols for any alarms and ensure the safety of subordinates in the area under supervision
- PC16.** follow emergency procedures efficiently
- PC17.** ensure injured employees are provided appropriate first aid and medical aid

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** company's procedures for the environment, health, and safety
- KU2.** implications that any non-compliance with health, safety and security may have on individuals and the organization
- KU3.** workplace hazards in the manufacturing facility in the life sciences sector, how and when to report hazards
- KU4.** limits of individual responsibility for dealing with hazards
- KU5.** chemical substances, their characteristics, and required precaution and safety measures
- KU6.** gowning procedure
- KU7.** the organization's emergency procedures for different emergencies and the importance of following these
- KU8.** evacuation procedures for employees, contract staff and visitors
- KU9.** how to summon medical assistance and the emergency services, where necessary
- KU10.** health, safety and accident reporting procedures and the importance of reporting in GMP
- KU11.** different types of breaches in the environment, health, safety and security and how and when to report these
- KU12.** WHO guidelines for personal hygiene
- KU13.** type of safety gears and procedure to use them
- KU14.** the importance of material segregation and 5S system
- KU15.** WHO guidelines for handling and storing hazardous material

Generic Skills (GS)

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

- GS1.** use reading and comprehension skills to understand the various coding systems and to read instructions, guidelines, procedures, rules, and signages to understand the procedure to be followed
- GS2.** use listening skills to follow the instructions and procedures during emergency alarms
- GS3.** use written communication skills to accurately record every information required to be reported as per SOP and GMP guidelines in the prescribed language



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- GS4.** apply planning and organizing skills to plan and organize tools and material required for work to fulfil environment, health, safety and security requirements
- GS5.** use critical thinking skills to take relevant actions on the accidents and breach in compliance with EHS protocols
- GS6.** apply decision-making skills to make balanced judgments within the authority while dealing with hazards and breaches
- GS7.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS8.** use verbal communication skills to communicate with supervisor/ manager/ EHS Incharge or any other concerned authority clearly for escalating any emergency or hazard

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Follow health and hygiene protocols</i>	10	15	-	5
PC1. comply with health and personal hygiene-related protocols as per WHO standards and ICH GMP guidelines	-	-	-	-
PC2. wash hands before entering in the production area with soap/alcohol based sanitisers	-	-	-	-
PC3. report any allergy, sickness or any other environment-related breach before or after entering the work premises to the designated person	-	-	-	-
PC4. take preventive actions on the report of any allergy, sickness or any other environment-related breach reported by subordinates	-	-	-	-
PC5. follow gowning procedures while entering an environment controlled work area and ensure adherence to the same by others	-	-	-	-
<i>Adherence to safety and security procedures</i>	10	25	-	5
PC6. comply with safety and security policies and procedures	-	-	-	-
PC7. ensure the use of appropriate safety gears like headgear, masks, gloves and other accessories as mentioned in the guidelines, by self and subordinates while carrying out work	-	-	-	-
PC8. take preventive and corrective actions based on the report of any identified breaches in safety and security policies and procedures by subordinates	-	-	-	-
PC9. ensure that discipline for material segregation and 5S system is followed at the storage area	-	-	-	-
PC10. comply with material handling, segregation, and storage guidelines for hazardous material	-	-	-	-
PC11. take corrective actions for reported hazards in consultation with EHS personnel	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. complete the records of safety drills and trainings undertaken by self and subordinates	-	-	-	-
<i>Adherence to emergency procedures</i>	10	15	-	5
PC13. report any hazards that he/she is not competent to deal with the relevant EHS personnel and warn other people who may be affected	-	-	-	-
PC14. raise the alarm and inform the concerned person immediately for action in the cases of spill, fall, injury, toxic inhale, fire or explosion	-	-	-	-
PC15. follow emergency protocols for any alarms and ensure the safety of subordinates in the area under supervision	-	-	-	-
PC16. follow emergency procedures efficiently	-	-	-	-
PC17. ensure injured employees are provided appropriate first aid and medical aid	-	-	-	-
NOS Total	30	55	-	15



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0111
NOS Name	Ensure adherence to Environment, health and safety guidelines in production facility and GMP controlled areas by self and subordinates
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Generic
NSQF Level	5
Credits	2.00
Version	2.0
Last Reviewed Date	29/09/2023
Next Review Date	29/09/2026
NSQC Clearance Date	29/09/2023



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LFS/N0129: Coordinate and communicate with supervisor/production chemist, research teams and auditors

Description

This NOS unit is about coordinating with supervisor/ production chemist, research teams, and auditors.

Scope

The scope covers the following :

- Coordination with supervisor/ production chemist
- Coordination with cross-functional teams
- Coordination with auditors
- Sensitivity towards all genders and people with disability

Elements and Performance Criteria

Coordination with Supervisor / production chemist

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

- PC1.** work as per instructions given by reporting supervisor
- PC2.** seek guidance/advice from supervisor on production plan for meeting the timelines
- PC3.** communicate process-flow improvements, production defects received from the previous process, repairs and maintenance of equipment to reporting supervisor/ production chemist
- PC4.** ensure timely intimation to supervisor/ production chemist about planned absence/ illness/ dizziness during work/ critical issues requiring his/her intervention
- PC5.** coordinate with supervisor on work-related and behavioral feedback

Coordination with cross-functional teams

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

- PC6.** support team members and colleagues of other departments in work
- PC7.** take handover from previous shift operator and give handover to next shift operator as per SOP
- PC8.** guide manufacturing and packaging assistants during production process
- PC9.** coordinate with warehouse team for material dispensing and issuance
- PC10.** coordinate with maintenance team for preventive and corrective maintenance, break down and calibration errors
- PC11.** coordinate with quality control team for sample collection and batch release
- PC12.** coordinate with QA for machine/ equipment validation at a routine interval as per SOP
- PC13.** provide inputs to the concerned stakeholders in periodic fence line review to detect non-compliance
- PC14.** coordinate with EHS team for any safety incident, accident and emergency

Coordination with auditors

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

- PC15.** provide clear answers to the auditor's queries



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PC16. provide the required documents of performed activities and operations to auditors on time

PC17. maintain data integrity while responding to auditors and regulatory inspectors

Sensitivity towards all genders and people with disability

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

PC18. respect all genders, religions, and caste

PC19. empathize with people with disability

PC20. offer support or help to a person with disability only when asked

PC21. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act

PC22. 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 company's policies on the preferred language of communication, reporting and escalation policy

KU2. the reporting structure of the organization

KU3. types of audits in the life sciences sector for the manufacturing operations

KU4. the required regulatory and statutory compliance-related documentation

KU5. the guidelines for data integrity, ethics, and compliance in the life sciences industry

KU6. the guidelines laid on Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act

KU7. the methods of workplace communication

KU8. importance of team coordination

KU9. the types of possible disabilities among people with disability (PwD)

KU10. the challenges faced by PwD

KU11. the importance of displaying empathy towards PwD

KU12. the right way to use the laws, acts, and provisions defined for PwD by the statutory bodies

KU13. the importance of awareness for gender sensitization and prevention of sexual harassment (POSH) act

KU14. importance of respecting all gender identities, religion, caste, and culture

KU15. method to receive the performance feedback

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



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- 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 in a given format and compliant with ALCOA principle
- 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 during the interaction with teammates while managing 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
- GS7.** apply customer-centricity skills while responding to auditors and QA personnel

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Coordination with Supervisor / production chemist</i>	10	10	5	5
PC1. work as per instructions given by reporting supervisor	-	-	-	-
PC2. seek guidance/advice from supervisor on production plan for meeting the timelines	-	-	-	-
PC3. communicate process-flow improvements, production defects received from the previous process, repairs and maintenance of equipment to reporting supervisor/ production chemist	-	-	-	-
PC4. ensure timely intimation to supervisor/ production chemist about planned absence/ illness/ dizziness during work/ critical issues requiring his/her intervention	-	-	-	-
PC5. coordinate with supervisor on work-related and behavioral feedback	-	-	-	-
<i>Coordination with cross-functional teams</i>	10	10	5	5
PC6. support team members and colleagues of other departments in work	-	-	-	-
PC7. take handover from previous shift operator and give handover to next shift operator as per SOP	-	-	-	-
PC8. guide manufacturing and packaging assistants during production process	-	-	-	-
PC9. coordinate with warehouse team for material dispensing and issuance	-	-	-	-
PC10. coordinate with maintenance team for preventive and corrective maintenance, break down and calibration errors	-	-	-	-
PC11. coordinate with quality control team for sample collection and batch release	-	-	-	-
PC12. coordinate with QA for machine/ equipment validation at a routine interval as per SOP	-	-	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC13. provide inputs to the concerned stakeholders in periodic fence line review to detect non-compliance	-	-	-	-
PC14. coordinate with EHS team for any safety incident, accident and emergency	-	-	-	-
<i>Coordination with auditors</i>	10	10	5	5
PC15. provide clear answers to the auditor's queries	-	-	-	-
PC16. provide the required documents of performed activities and operations to auditors on time	-	-	-	-
PC17. maintain data integrity while responding to auditors and regulatory inspectors	-	-	-	-
<i>Sensitivity towards all genders and people with disability</i>	2	3	2	3
PC18. respect all genders, religions, and caste	-	-	-	-
PC19. empathize with people with disability	-	-	-	-
PC20. offer support or help to a person with disability only when asked	-	-	-	-
PC21. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace(Prevention, Prohibition and Redressal) Act	-	-	-	-
PC22. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee	-	-	-	-
NOS Total	32	33	17	18



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0129
NOS Name	Coordinate and communicate with supervisor/production chemist, research teams and auditors
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Generic
NSQF Level	4
Credits	3.00
Version	1.0
Last Reviewed Date	29/09/2023
Next Review Date	29/09/2026
NSQC Clearance Date	29/09/2023



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LFS/N0572: Maintain experiment records ensuring data integrity and intellectual property rights

Description

This Job function is about the job holder maintaining the experiment records ensuring data integrity and intellectual property rights

Scope

The scope covers the following :

- The Scope covers the following :
- Reporting and recording
- Data Integrity
- Intellectual Property

Elements and Performance Criteria

Reporting and recording

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

- PC1.** review and update the test methods and procedures as per the schedule or when a regulatory requirement arises according to the written procedures
- PC2.** fill logbooks, worksheet (an analytical record), reference standard entries, calibration records, parameters of column, reagent, volumetric solution and working standards
- PC3.** report defects/problem/incidents/quality issues/test results as applicable in a timely manner to the appropriate authority as laid down by the company
- PC4.** prepare analytical reports for detailed findings and recommendations as per SOPs
- PC5.** maintain lab records in LNB and eLNB

Data Integrity

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

- PC6.** document the results of the testing and analysis accurately
- PC7.** maintain all original and controlled document files and quality records in a timely and accurate manner following ALCOA PLUS principles
- PC8.** respond to requests for information in an appropriate manner whilst following organizational procedures
- PC9.** make sure documents are available to all appropriate authorities to inspect/ audit
- PC10.** maintain the confidentiality of the research projects and processes

Intellectual Property

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

- PC11.** create a comprehensive report at asset level, detailing every item of content used within a product and the rights associated with it
- PC12.** daily monitoring, logging, prioritizing assessment requests entering them onto appropriate regional tracker.



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PC13. ensure that all titles and asset information is reviewed thoroughly and in-depth

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** Understanding of relevant regulatory requirements and quality standards related to test methods and procedures.
- KU2.** how to review and update test methods and procedures according to established schedules and regulatory changes.
- KU3.** Proficiency in filling logbooks, worksheets, reference standard entries, calibration records, and maintaining records of parameters
- KU4.** Ability to prepare analytical reports that detail findings and recommendations in accordance with Standard Operating Procedures (SOPs).
- KU5.** how to accurately document the results of testing and analysis, following data integrity principles.
- KU6.** Understanding the significance of preserving the confidentiality of research projects and processes.
- KU7.** Knowledge of the daily monitoring, logging, and prioritization of assessment requests and their entry into the appropriate tracking system
- KU8.** Understanding the importance of a thorough and in-depth review of all titles and asset information.

Generic Skills (GS)

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

- GS1.** use reading and comprehension skills to understand the various coding systems and to read instructions, guidelines, procedures, rules, and signages to understand the procedure to be followed
- GS2.** use listening skills to follow the instructions and procedures during emergency alarms
- GS3.** use written communication skills to accurately record every information required to be reported as per SOP
- GS4.** apply planning and organizing skills to plan and organize tools and material required for work to fulfil environment, health, safety and security requirements
- GS5.** use critical thinking skills to take relevant actions on the accidents and breach in compliance with EHS protocols
- GS6.** apply decision-making skills to make balanced judgments within the authority while dealing with hazards and breaches
- GS7.** apply problem-solving skills to find solutions for workflow-related difficulties



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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Reporting and recording</i>	10	10	10	10
PC1. review and update the test methods and procedures as per the schedule or when a regulatory requirement arises according to the written procedures	-	-	-	-
PC2. fill logbooks, worksheet (an analytical record), reference standard entries, calibration records, parameters of column, reagent, volumetric solution and working standards	-	-	-	-
PC3. report defects/problem/incidents/quality issues/test results as applicable in a timely manner to the appropriate authority as laid down by the company	-	-	-	-
PC4. prepare analytical reports for detailed findings and recommendations as per SOPs	-	-	-	-
PC5. maintain lab records in LNB and eLNB	-	-	-	-
<i>Data Integrity</i>	10	10	10	10
PC6. document the results of the testing and analysis accurately	-	-	-	-
PC7. maintain all original and controlled document files and quality records in a timely and accurate manner following ALCOA PLUS principles	-	-	-	-
PC8. respond to requests for information in an appropriate manner whilst following organizational procedures	-	-	-	-
PC9. make sure documents are available to all appropriate authorities to inspect/ audit	-	-	-	-
PC10. maintain the confidentiality of the research projects and processes	-	-	-	-
<i>Intellectual Property</i>	5	5	5	5



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC11. create a comprehensive report at asset level, detailing every item of content used within a product and the rights associated with it	-	-	-	-
PC12. daily monitoring, logging, prioritizing assessment requests entering them onto appropriate regional tracker.	-	-	-	-
PC13. ensure that all titles and asset information is reviewed thoroughly and in-depth	-	-	-	-
NOS Total	25	25	25	25



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0572
NOS Name	Maintain experiment records ensuring data integrity and intellectual property rights
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Research and Development
NSQF Level	5.5
Credits	3.0
Version	1.0
Last Reviewed Date	29/09/2023
Next Review Date	29/09/2026
NSQC Clearance Date	29/09/2023



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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	-	-	-	-



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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	18/02/2025
Next Review Date	18/02/2028
NSQC Clearance Date	18/02/2025



Qualification Pack

LFS/N0576: Assist in new biological product development

Description

This job function is about the job holder assisting in new biological product development

Scope

The scope covers the following :

- The Scope Covers the following:
- Pre product development activities
- New biological product development activities

Elements and Performance Criteria

Pre product development activities

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

- PC1.** support in developing exploratory development proposals for new innovation products
- PC2.** perform a literature search for the new product development
- PC3.** support in carrying out technical feasibility analysis on the NPD ideas
- PC4.** collect and analyze current development plans, new scientific developments and competitive activities
- PC5.** carryout research on assigned research problems contributing to the attainment of a defined research objective

New biological product development activities

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

- PC6.** support in execution of product (innovation) development related activities
- PC7.** conduct stability studies, generate stability data & prepare stability reports for innovation products
- PC8.** support execution of allocated product development responsibilities
- PC9.** perform standardization ,optimization and scale-up of biological product synthesis reaction
- PC10.** monitor reaction work-up and extraction process for new biological product synthesis
- PC11.** monitor and conduct regular checks on equipment and instrument conditions, document calibrations
- PC12.** use appropriate measuring instruments, equipment, tools, accessories, MSDS and relevant personal protective equipment (PPE) as required
- PC13.** perform all the experimentation in adherence to safety ,GRP and GLP guidelines
- PC14.** identify issues on projects and report to higher authorities
- PC15.** assist in resolution of issues supported by good data analysis

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:



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- KU1.** Understanding of the product development lifecycle and innovation processes.
- KU2.** Research and information retrieval skills using scientific databases and resources.
- KU3.** Familiarity with biological product development terminology and relevant literature.
- KU4.** Skills to assess technical, regulatory, and market feasibility.
- KU5.** Research methodology, experiment design, and data collection skills.
- KU6.** Knowledge of laboratory and pilot-scale equipment and procedures as per SOPs
- KU7.** Knowledge of stability testing protocols, including ICH guidelines.
- KU8.** Ability to work collaboratively in a research and development environment.
- KU9.** Knowledge of chemical engineering processes.
- KU10.** Knowledge of equipment maintenance and calibration procedures.
- KU11.** Knowledge of safety regulations, including Good Laboratory Practices (GLP) and Good Research Practices (GRP).
- KU12.** Understanding of root cause analysis and data-driven decision-making.

Generic Skills (GS)

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

- GS1.** use reading and comprehension skills to understand the various coding systems and to read instructions, guidelines, procedures, rules, and signages to understand the procedure to be followed
- GS2.** use listening skills to follow the instructions and procedures during emergency alarms
- GS3.** use written communication skills to accurately record every information required to be reported as per SOP and GMP guidelines in the prescribed language
- GS4.** apply planning and organizing skills to plan and organize tools and material required for work to fulfil environment, health, safety and security requirements
- GS5.** apply decision-making skills to make balanced judgments within the authority while dealing with hazards and breaches
- GS6.** use critical thinking skills to take relevant actions on the accidents and breach in compliance with EHS protocols
- GS7.** use problem-solving skills to determine the root cause and devise a corrective action plan to address it effectively.



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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Pre product development activities</i>	20	20	5	5
PC1. support in developing exploratory development proposals for new innovation products	-	-	-	-
PC2. perform a literature search for the new product development	-	-	-	-
PC3. support in carrying out technical feasibility analysis on the NPD ideas	-	-	-	-
PC4. collect and analyze current development plans, new scientific developments and competitive activities	-	-	-	-
PC5. carryout research on assigned research problems contributing to the attainment of a defined research objective	-	-	-	-
<i>New biological product development activities</i>	20	20	5	5
PC6. support in execution of product (innovation) development related activities	-	-	-	-
PC7. conduct stability studies, generate stability data & prepare stability reports for innovation products	-	-	-	-
PC8. support execution of allocated product development responsibilities	-	-	-	-
PC9. perform standardization ,optimization and scale-up of biological product synthesis reaction	-	-	-	-
PC10. monitor reaction work-up and extraction process for new biological product synthesis	-	-	-	-
PC11. monitor and conduct regular checks on equipment and instrument conditions, document calibrations	-	-	-	-
PC12. use appropriate measuring instruments, equipment, tools, accessories, MSDS and relevant personal protective equipment (PPE) as required	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC13. perform all the experimentation in adherence to safety ,GRP and GLP guidelines	-	-	-	-
PC14. identify issues on projects and report to higher authorities	-	-	-	-
PC15. assist in resolution of issues supported by good data analysis	-	-	-	-
NOS Total	40	40	10	10



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0576
NOS Name	Assist in new biological product development
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Biotechnology
Occupation	Research and Development
NSQF Level	5.5
Credits	5.0
Version	1.0
Last Reviewed Date	29/09/2023
Next Review Date	29/09/2026
NSQC Clearance Date	29/09/2023

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



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assessment component.

7. To pass the Qualification Pack, every trainee should score a minimum of 50%-70% of marks in each NOS (depending on NSQF Level) 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.)

Assessment Weightage

Compulsory NOS

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0111.Ensure adherence to Environment, health and safety guidelines in production facility and GMP controlled areas by self and subordinates	30	55	-	15	100	15
LFS/N0129.Coordinate and communicate with supervisor/production chemist, research teams and auditors	32	33	17	18	100	15
LFS/N0572.Maintain experiment records ensuring data integrity and intellectual property rights	25	25	25	25	100	20
DGT/VSQ/N0103.Employability Skills (90 Hours)	20	30	-	-	50	10
Total	107	143	42	58	350	60

Elective: 1 Biological Product Development



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National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0576.Assist in new biological product development	40	40	10	10	100	40
Total	40	40	10	10	100	40