

Qualification Pack



Biologist / Biotechnologist

In-Vitro Micro-propagation of Plants

Regulated Entrepreneurship

QP Code: LFS/Q4101 Instantiated QP Code: LFS/Q4101-SI007

Version: 1.0

NSQF Level: 5

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LFS/Q4101-SI007: Biologist / Biotechnologist

Brief Job Description

Biologist/Biotechnologist is a critical role and performs the critical activities in various specialized areas like Manufacturing of Bio-products / Biologics Formulation Products or In-Vitro Micro propagation of Plants or Quality Control of Biological Products / Plant based products. Sometimes the role holder is also involved in research work for computational Biology. He/ she is responsible to ensure documentation, quality assurance and compliance with applicable regulation at workplace. The individual also guides junior staff for manufacturing/ quality control of biological products. He/she is involved in relevant processes as per standard operating procedures (SOP) and is responsible for implementation of quality standards like good manufacturing practices, good documentation practices, good storage practices, 5S system etc.

Personal Attributes

The individual should have good communication and analytical skills. The person should possess good technical knowledge, investigational abilities and reasoning skills. The role holder should pay attention to details. The individual should have the critical thinking approach 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/N0117: Coordinate with Manager, team-members, cross-functional teams and auditors](#)
3. [DGT/VSQ/N0102: Employability Skills \(60 Hours\)](#)

Electives(mandatory to select at least one):

Elective : In-Vitro Micro-propagation of Plants

1. [LFS/N4105: Monitor the In-Vitro micro-propagation process and its compliance with regulatory and quality norms](#)

Options(Not mandatory):

Option : Regulated Entrepreneurship

1. [LFS/N0123: Establish licensed biotechnology led and perform various entrepreneurial activities to run the regulated business operations](#)



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2. [LFS/N0124: Maintain the Critical Business documents as Biotechnology led entrepreneur](#)

Qualification Pack (QP) Parameters

Sector	Life Sciences
Sub-Sector	Biotechnology
Occupation	Biotechnology Production and Quality
Country	India
NSQF Level	5
Credits	27
Aligned to NCO/ISCO/ISIC Code	NCO-2015/2131.1300
Minimum Educational Qualification & Experience	B.Tech ((Biotechnology) Final Year Student) OR M.Sc ((biology and biotechnology related subject) Final Year Student) OR B.Pharma (final year student (with Pharmacognosy Subject)) OR Certificate-NSQF (Level 4 Certificate of Production Machine Operator Sterile Formulations) with 3 Years of experience OR B.Sc ((biology and biotechnology related subject) Pass)
Minimum Level of Education for Training in School	
Pre-Requisite License or Training	NA
Minimum Job Entry Age	20 Years
Last Reviewed On	NA
Next Review Date	03/05/2026
NSQC Approval Date	03/05/2023
Version	1.0



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Reference code on NQR	QG-05-LS-00372-2023-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/N0117: Coordinate with Manager, team-members, cross-functional teams and auditors

Description

This NOS unit is about a person coordinating with cross-functional teams, Supervisor, team members and responding to auditors

Scope

The scope covers the following :

- Coordination with Manager
- Coordination within team and cross-functional teams
- Respond to audit queries
- Sensitivity towards all genders and people with disability

Elements and Performance Criteria

Coordination with Manager

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

- PC1.** coordinate with the reporting manager to obtain work instructions and develop the production plan
- PC2.** communicate to reporting manager about process-flow improvements and production defects received from previous process
- PC3.** inform concern authority for any potential hazards or expected process disruptions
- PC4.** provide maintenance, engineering related or process related change control request and its impact reports proactively to the manager
- PC5.** report periodically the status of planned batch/ continuous manufacturing schedule to manager within the timeline

Coordination within the team and cross-functional teams

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

- PC6.** work as a team with colleagues and share work as per their own workload
- PC7.** train junior chemists on procedures and provide assistance to them when needed
- PC8.** communicate and discuss workflow related difficulties to find solutions with mutual agreement
- PC9.** coordinate with maintenance team for any breakdowns and preventive and corrective maintenance of production equipments
- PC10.** coordinate with Engineering department at the time of equipment qualification activities
- PC11.** coordinate with Stores manager to receive chemicals and materials in time
- PC12.** coordinate with quality control team for raw material availability / release of raw materials and, semi-finished and finished goods
- PC13.** coordinate with QA team for line clearance, change control approvals , calibration and validation activities



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Respond to audit queries

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

- PC14.** provide clear answers to the auditor's queries
- PC15.** produce the documented records of performed activities and operations to auditors
- PC16.** 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:

- PC17.** respect all genders, religions, and caste
- PC18.** empathize with people with disability
- PC19.** offer support or help to a person with disability only when asked
- PC20.** ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act
- PC21.** report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** the reporting structure of the organization
- KU2.** types of audits in the life sciences sector for the manufacturing plant
- KU3.** the required regulatory and statutory compliance related documentation
- KU4.** the guidelines for data integrity, ethics, and compliance in the life sciences industry
- KU5.** the guidelines laid on Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act
- KU6.** the methods of workplace communication
- KU7.** the methods of team coordination
- KU8.** the types of possible disabilities among people with disability (PWD)
- KU9.** the importance of awareness for gender sensitization and prevention of sexual harassment (POSH) act
- KU10.** the importance of respect for all the religions, caste, and cultures

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/typed report or computer-based record/electronic mail
- GS3.** use written communication skills to maintain proper and concise records as per given format



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- GS4.** use verbal communication skills to communicate confidential and sensitive information discretely to the authorized person while interacting with teammates
- GS5.** use team-building skills during the interaction with teammates while managing the difficult/stressful or emotional situations at work
- GS6.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS7.** 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
- GS8.** apply customer-centricity while responding to auditors, customer representatives and QA personnel

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Coordination with Manager</i>	10	15	3	2
PC1. coordinate with the reporting manager to obtain work instructions and develop the production plan	-	-	-	-
PC2. communicate to reporting manager about process-flow improvements and production defects received from previous process	-	-	-	-
PC3. inform concern authority for any potential hazards or expected process disruptions	-	-	-	-
PC4. provide maintenance, engineering related or process related change control request and its impact reports proactively to the manager	-	-	-	-
PC5. report periodically the status of planned batch/ continuous manufacturing schedule to manager within the timeline	-	-	-	-
<i>Coordination within the team and cross-functional teams</i>	10	15	3	2
PC6. work as a team with colleagues and share work as per their own workload	-	-	-	-
PC7. train junior chemists on procedures and provide assistance to them when needed	-	-	-	-
PC8. communicate and discuss workflow related difficulties to find solutions with mutual agreement	-	-	-	-
PC9. coordinate with maintenance team for any breakdowns and preventive and corrective maintenance of production equipments	-	-	-	-
PC10. coordinate with Engineering department at the time of equipment qualification activities	-	-	-	-
PC11. coordinate with Stores manager to receive chemicals and materials in time	-	-	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. coordinate with quality control team for raw material availability / release of raw materials and, semi-finished and finished goods	-	-	-	-
PC13. coordinate with QA team for line clearance, change control approvals , calibration and validation activities	-	-	-	-
<i>Respond to audit queries</i>	5	10	3	2
PC14. provide clear answers to the auditor's queries	-	-	-	-
PC15. produce the documented records of performed activities and operations to auditors	-	-	-	-
PC16. maintain data integrity while responding to auditors and regulatory inspectors	-	-	-	-
<i>Sensitivity towards all genders and people with disability</i>	5	10	3	2
PC17. respect all genders, religions, and caste	-	-	-	-
PC18. empathize with people with disability	-	-	-	-
PC19. offer support or help to a person with disability only when asked	-	-	-	-
PC20. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act	-	-	-	-
PC21. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee	-	-	-	-
NOS Total	30	50	12	8



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0117
NOS Name	Coordinate with Manager, team-members, cross-functional teams and auditors
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Pharma Manufacturing
NSQF Level	5
Credits	2.00
Version	2.0
Last Reviewed Date	NA
Next Review Date	31/03/2025
NSQC Clearance Date	31/03/2022



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DGT/VSQ/N0102: Employability Skills (60 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.** identify employability skills required for jobs in various industries
- PC2.** identify and explore learning and employability portals

Constitutional values – Citizenship

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

- PC3.** 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.
- PC4.** follow environmentally sustainable practices

Becoming a Professional in the 21st Century

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

- PC5.** recognize the significance of 21st Century Skills for employment
- PC6.** 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

Basic English Skills

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



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- PC7.** use basic English for everyday conversation in different contexts, in person and over the telephone
- PC8.** read and understand routine information, notes, instructions, mails, letters etc. written in English
- PC9.** 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:

- PC10.** understand the difference between job and career
- PC11.** prepare a career development plan with short- and long-term goals, based on aptitude

Communication Skills

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

- PC12.** follow verbal and non-verbal communication etiquette and active listening techniques in various settings
- PC13.** work collaboratively with others in a team

Diversity & Inclusion

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

- PC14.** communicate and behave appropriately with all genders and PwD
- PC15.** 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:

- PC16.** select financial institutions, products and services as per requirement
- PC17.** carry out offline and online financial transactions, safely and securely
- PC18.** identify common components of salary and compute income, expenses, taxes, investments etc
- PC19.** 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:

- PC20.** operate digital devices and carry out basic internet operations securely and safely
- PC21.** use e- mail and social media platforms and virtual collaboration tools to work effectively
- PC22.** use basic features of word processor, spreadsheets, and presentations

Entrepreneurship

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

- PC23.** identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research
- PC24.** develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion
- PC25.** 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:

- PC26.** identify different types of customers
- PC27.** identify and respond to customer requests and needs in a professional manner.



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PC28. follow appropriate hygiene and grooming standards

Getting ready for apprenticeship & Jobs

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

PC29. create a professional Curriculum vitae (Résumé)

PC30. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively

PC31. apply to identified job openings using offline /online methods as per requirement

PC32. answer questions politely, with clarity and confidence, during recruitment and selection

PC33. 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

KU11. 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 and use applications such as word processors, spreadsheets etc.

KU16. how to identify business opportunities

KU17. types and needs of customers

KU18. how to apply for a job and prepare for an interview

KU19. 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

GS2. communicate effectively using appropriate language in formal and informal settings



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- GS3.** behave politely and appropriately with all
- GS4.** how to work in a virtual mode
- 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. identify employability skills required for jobs in various industries	-	-	-	-
PC2. identify and explore learning and employability portals	-	-	-	-
<i>Constitutional values – Citizenship</i>	1	1	-	-
PC3. 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.	-	-	-	-
PC4. follow environmentally sustainable practices	-	-	-	-
<i>Becoming a Professional in the 21st Century</i>	2	4	-	-
PC5. recognize the significance of 21st Century Skills for employment	-	-	-	-
PC6. 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	-	-	-	-
<i>Basic English Skills</i>	2	3	-	-
PC7. use basic English for everyday conversation in different contexts, in person and over the telephone	-	-	-	-
PC8. read and understand routine information, notes, instructions, mails, letters etc. written in English	-	-	-	-
PC9. write short messages, notes, letters, e-mails etc. in English	-	-	-	-
<i>Career Development & Goal Setting</i>	1	2	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC10. understand the difference between job and career	-	-	-	-
PC11. prepare a career development plan with short- and long-term goals, based on aptitude	-	-	-	-
<i>Communication Skills</i>	2	2	-	-
PC12. follow verbal and non-verbal communication etiquette and active listening techniques in various settings	-	-	-	-
PC13. work collaboratively with others in a team	-	-	-	-
<i>Diversity & Inclusion</i>	1	2	-	-
PC14. communicate and behave appropriately with all genders and PwD	-	-	-	-
PC15. escalate any issues related to sexual harassment at workplace according to POSH Act	-	-	-	-
<i>Financial and Legal Literacy</i>	2	3	-	-
PC16. select financial institutions, products and services as per requirement	-	-	-	-
PC17. carry out offline and online financial transactions, safely and securely	-	-	-	-
PC18. identify common components of salary and compute income, expenses, taxes, investments etc	-	-	-	-
PC19. identify relevant rights and laws and use legal aids to fight against legal exploitation	-	-	-	-
<i>Essential Digital Skills</i>	3	4	-	-
PC20. operate digital devices and carry out basic internet operations securely and safely	-	-	-	-
PC21. use e- mail and social media platforms and virtual collaboration tools to work effectively	-	-	-	-
PC22. use basic features of word processor, spreadsheets, and presentations	-	-	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Entrepreneurship</i>	2	3	-	-
PC23. identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research	-	-	-	-
PC24. develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion	-	-	-	-
PC25. identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity	-	-	-	-
<i>Customer Service</i>	1	2	-	-
PC26. identify different types of customers	-	-	-	-
PC27. identify and respond to customer requests and needs in a professional manner.	-	-	-	-
PC28. follow appropriate hygiene and grooming standards	-	-	-	-
<i>Getting ready for apprenticeship & Jobs</i>	2	3	-	-
PC29. create a professional Curriculum vitae (Résumé)	-	-	-	-
PC30. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively	-	-	-	-
PC31. apply to identified job openings using offline /online methods as per requirement	-	-	-	-
PC32. answer questions politely, with clarity and confidence, during recruitment and selection	-	-	-	-
PC33. identify apprenticeship opportunities and register for it as per guidelines and requirements	-	-	-	-
NOS Total	20	30	-	-



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National Occupational Standards (NOS) Parameters

NOS Code	DGT/VSQ/N0102
NOS Name	Employability Skills (60 Hours)
Sector	Cross Sectoral
Sub-Sector	Professional Skills
Occupation	Employability
NSQF Level	4
Credits	2
Version	1.0
Last Reviewed Date	18/02/2025
Next Review Date	18/02/2028
NSQC Clearance Date	18/02/2025



Qualification Pack

LFS/N4105: Monitor the In-Vitro micro-propagation process and its compliance with regulatory and quality norms

Description

This NOS is about the Biologist monitoring the In-Vitro micro-propagation process and its compliance with regulatory and quality norms

Scope

The scope covers the following :

- Monitor in-vitro micro propagation of plants
- Containerization
- Monitor packaging and transportation

Elements and Performance Criteria

Monitor in-vitro micro propagation of plants

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

- PC1.** follow the gowning procedure and wear the appropriate personal protection equipment (PPE) while working
- PC2.** ensure that environmental conditions of the lab area are maintained within the limits specified
- PC3.** ensure that the work is carried out in accordance with standard operating procedures for preparation of plant tissue culture media
- PC4.** carryout sterilization of supplies to be used
- PC5.** follow the defined procedures for micropropagation and aseptically transfer the culture to the fresh media
- PC6.** incubate the culture in the suitable environment as per SOP
- PC7.** observe the growth at regular intervals as per protocol

Containerization

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

- PC8.** confirm that the equipment (filling, packaging line, lyophilize (in case of freeze-dried product etc) are set up and ready for operation as per checklist
- PC9.** ensure that work is carried out in accordance with standard operating procedures for filling and containerization, visual inspection, sterilization, decontamination and disposal
- PC10.** monitor that the defined procedures for starting and running the equipment operating system as per SOP are followed
- PC11.** deal promptly and effectively with error messages or equipment faults that are within your control and report those that cannot be solved
- PC12.** monitor that for liquid products the filling, containerization and sealing process for vial /syringe or any other container type are performed as per SOP
- PC13.** monitor that for lyophilized products, filling, containerization, lyophilization and sealing process for vial /syringe or any other container type are performed as per SOP



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PC14. ensure the aseptic/sterile conditions are maintained during the entire process of filling, containerization and sealing and process is carried out as per the SOP for both liquid and lyophilized products

Monitor packaging and transportation

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

PC15. Monitor packaging is done with a nutritive medium for survival of the tissues in a sealed sterile container

PC16. Monitor transport of the plant tissue is done in secure and sealed container

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** the principles and techniques involved in in-vitro micro-propagation, including tissue culture, aseptic techniques, media preparation, and plant regeneration methods.
- KU2.** regulatory guidelines applicable to in-vitro micro-propagation, such as those set by government bodies or plant regulatory authorities. Understand the specific requirements for compliance with regulations related to plant material, labelling, documentation, and distribution.
- KU3.** quality norms specific to in-vitro micro-propagation, including quality procedures, quality assurance practices
- KU4.** adherence to standards for tissue culture processes and products.
- KU5.** Formulation of culture media used in in-vitro micro-propagation, including knowledge of nutrient requirements, growth regulators, pH adjustment, and media sterilization techniques.
- KU6.** methods to maintain sterile conditions during the in-vitro micro-propagation process.
- KU7.** techniques for disinfection, sterile handling of plant material, and prevention of contamination.
- KU8.** growth and development of plants during the micro-propagation process including stages of plant development, morphogenesis, rooting, acclimatization, and environmental requirements for optimal growth.
- KU9.** critical parameters to monitor during in-vitro micro-propagation, such as temperature, humidity, light intensity, and photoperiod.
- KU10.** methods to maintain and control these parameters to ensure successful plant propagation.
- KU11.** creating and maintaining essential documents, including standard operating procedures (SOPs), batch records, culture management records, and quality-related documents
- KU12.** importance of accurate record-keeping and compliance with Good Documentation Practices, Data Integrity and ALCOA Plus
- KU13.** safety protocols, including handling of hazardous chemicals, waste management, and compliance with environmental regulations.
- KU14.** importance of maintaining a safe working environment for personnel.
- KU15.** Concepts of Qbd
- KU16.** Cleanroom Classification and Compliance

Generic Skills (GS)



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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
- GS2.** use written communication skills to maintain proper and concise records as per given format and compliant with ALCOA principle
- GS3.** use problem-solving skills in dealing with any deviation from SOPs and day-today problems
- GS4.** use critical thinking skills in analysing any situation which needs an immediate escalation or emergency alarm
- GS5.** apply problem-solving skills to find solutions for workflow-related difficulties and people management
- GS6.** use planning and organizing skills in production management and operations to achieve resource optimization and production timelines.
- GS7.** apply analytical skill to observe and identify OOS/ OOT/ deviations in the production process
- GS8.** apply decision making skills to make balanced judgments within the authority while dealing with daily work-life situations
- GS9.** use written communication skills to maintain proper and concise records as per given format and compliant with ALCOA principle

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Monitor in-vitro micro propagation of plants</i>	10	10	5	3
PC1. follow the gowning procedure and wear the appropriate personal protection equipment (PPE) while working	-	-	-	-
PC2. ensure that environmental conditions of the lab area are maintained within the limits specified	-	-	-	-
PC3. ensure that the work is carried out in accordance with standard operating procedures for preparation of plant tissue culture media	-	-	-	-
PC4. carryout sterilization of supplies to be used	-	-	-	-
PC5. follow the defined procedures for micropropagation and aseptically transfer the culture to the fresh media	-	-	-	-
PC6. incubate the culture in the suitable environment as per SOP	-	-	-	-
PC7. observe the growth at regular intervals as per protocol	-	-	-	-
<i>Containerization</i>	10	20	5	3
PC8. confirm that the equipment (filling, packaging line, lyophilize (in case of freeze-dried product etc) are set up and ready for operation as per checklist	-	-	-	-
PC9. ensure that work is carried out in accordance with standard operating procedures for filling and containerization, visual inspection, sterilization, decontamination and disposal	-	-	-	-
PC10. monitor that the defined procedures for starting and running the equipment operating system as per SOP are followed	-	-	-	-
PC11. deal promptly and effectively with error messages or equipment faults that are within your control and report those that cannot be solved	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. monitor that for liquid products the filling, containerization and sealing process for vial /syringe or any other container type are performed as per SOP	-	-	-	-
PC13. monitor that for lyophilized products, filling, containerization, lyophilization and sealing process for vial /syringe or any other container type are performed as per SOP	-	-	-	-
PC14. ensure the aseptic/sterile conditions are maintained during the entire process of filling, containerization and sealing and process is carried out as per the SOP for both liquid and lyophilized products	-	-	-	-
<i>Monitor packaging and transportation</i>	10	20	2	2
PC15. Monitor packaging is done with a nutritive medium for survival of the tissues in a sealed sterile container	-	-	-	-
PC16. Monitor transport of the plant tissue is done in secure and sealed container	-	-	-	-
NOS Total	30	50	12	8



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N4105
NOS Name	Monitor the In-Vitro micro-propagation process and its compliance with regulatory and quality norms
Sector	Life Sciences
Sub-Sector	Biotechnology, Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Biotechnology Production and Quality, Bio-Pharma Manufacturing
NSQF Level	5
Credits	9
Version	1.0
Last Reviewed Date	NA
Next Review Date	03/05/2026
NSQC Clearance Date	03/05/2023



Qualification Pack

LFS/N0123: Establish licensed biotechnology led and perform various entrepreneurial activities to run the regulated business operations

Description

This NOS is about Biotechnologist entrepreneur setting up his/her own licensed Biotechnology led enterprise and performing various entrepreneurial activities to run the regulated business operations

Scope

The scope covers the following :

- Set up biotechnology led enterprises and perform entrepreneurial activities
- Maintenance of accounts and ledgers
- Comply with legal, regulatory, and statutory standards

Elements and Performance Criteria

Set up enterprise and perform entrepreneurial activities

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

- PC1.** identify the Biotechnology domain for business activities and identify prospective customers and business opportunity
- PC2.** identify biotechnology led products and/ or services and their sources, that match the business opportunity
- PC3.** develop a business proposal with an objective and identified business area for registering the proposed business as an independent entity with competent authorities & incubation center
- PC4.** submit business proposals and scientific feasibility plans for securing the required funding from govt. schemes for MSMEs like MUDRA etc. as and when needed
- PC5.** present the business proposal to investors and stakeholders to gain their confidence and trust for possible funding
- PC6.** ensure setting up the technological infrastructure and resources for business as per the approved plan and investors/ shareholders agreement
- PC7.** enrol into various government schemes and programs for MSME and avail the benefits
- PC8.** promote the product/ services through various means including digital promotions in line to regulations for promotion and sale as per land of law
- PC9.** develop the supply chain and distribution network in compliance to regulations
- PC10.** maintain updated information regarding new market trends to provide service to customers and constantly upskill self and employees for futuristic advanced technologies, innovations and methodologies in biotechnology

Maintenance of accounts and ledgers

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

- PC11.** ensure to generate a final invoice for the services rendered/ or products sold
- PC12.** collect payment either in cash (as per RBI guidelines)/ cheque/ demand draft or through online transactions via RTGS/NEFT/UPI etc.

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- PC13.** ensure accounts and ledgers are maintained for the material supplied, payables and receivables, loan ledgers, taxes collected and paid into government treasury as well for wages paid and statutory benefits like PF, ESI contribution deposited with authorities
- PC14.** ensure maintenance and reconciliation of a monthly account as well as movable and immovable assets and stock to keep track of profit/ loss as well as periodic audit as per legal requirements

Comply with legal, regulatory and statutory standards

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

- PC15.** comply with workplace health and safety rules stipulated by local authorities
- PC16.** comply with rules related to taxes and licensing regulations
- PC17.** comply with prevalent labour laws and keep records for employee's qualifications, employment as well as trainings
- PC18.** comply with regulations and protocols related to maintenance of product/ service license including the pre conditions (if any)
- PC19.** comply with quality systems like ISO/GMP/GLP/NCS-TCP etc and any other rule mandated by appropriate regulatory authorities
- PC20.** comply with pollution norms as per land of law and ensure near zero pollution for a sustainable environment and to earn carbon credits
- PC21.** ensure that business facility and employees are always prepared and ready for any surprise inspection/ audit from clients/ regulatory/ statutory authorities

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** business administration, financial and planning activities
- KU2.** data analysis techniques for continuous improvement and identifying new business opportunities
- KU3.** maintaining confidentiality for information about finances, business secrets and information shared by clients/ stakeholders
- KU4.** procedures for funding approvals, and presenting new business idea/ opportunity for license or stakeholder approvals
- KU5.** prevailing and possible environmental issues and expected quality standards
- KU6.** license, patent and copyright laws
- KU7.** applicable tax, duties and labour laws
- KU8.** fundamentals of costing, pricing and profit
- KU9.** accounting principles and use of accounting software and government software/ portals for taxes and returns
- KU10.** Good Practices (GxP), ISO and other quality systems
- KU11.** talent management and resource planning
- KU12.** Awareness of applicable engineering concepts
- KU13.** audits and regulations in Life Sciences sector applicable for chosen business area
- KU14.** market promotion, globally trending strategies and distribution network
- KU15.** concept of innovation and jugaad principle



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Generic Skills (GS)

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

- GS1.** note the information to be communicated
- GS2.** fill relevant applications where required
- GS3.** write clear communications to government officials, funding partners, team members, etc
- GS4.** discuss task lists, schedules and activities with customers, peers, partners, vendors etc.
- GS5.** effectively communicate with teams
- GS6.** interact with successful local entrepreneurs, and enterprises in a similar field for best practices and expertise
- GS7.** ask questions in order to understand problems and clarify queries
- GS8.** multi-task and adapt to meet work timelines
- GS9.** apply emotional intelligence while dealing with other genders and people with disability



Qualification Pack

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Set up enterprise and perform entrepreneurial activities</i>	20	30	6	3
PC1. identify the Biotechnology domain for business activities and identify prospective customers and business opportunity	-	-	-	-
PC2. identify biotechnology led products and/ or services and their sources, that match the business opportunity	-	-	-	-
PC3. develop a business proposal with an objective and identified business area for registering the proposed business as an independent entity with competent authorities & incubation center	-	-	-	-
PC4. submit business proposals and scientific feasibility plans for securing the required funding from govt. schemes for MSMEs like MUDRA etc. as and when needed	-	-	-	-
PC5. present the business proposal to investors and stakeholders to gain their confidence and trust for possible funding	-	-	-	-
PC6. ensure setting up the technological infrastructure and resources for business as per the approved plan and investors/ shareholders agreement	-	-	-	-
PC7. enrol into various government schemes and programs for MSME and avail the benefits	-	-	-	-
PC8. promote the product/ services through various means including digital promotions in line to regulations for promotion and sale as per land of law	-	-	-	-
PC9. develop the supply chain and distribution network in compliance to regulations	-	-	-	-
PC10. maintain updated information regarding new market trends to provide service to customers and constantly upskill self and employees for futuristic advanced technologies, innovations and methodologies in biotechnology	-	-	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Maintenance of accounts and ledgers</i>	10	20	6	5
PC11. ensure to generate a final invoice for the services rendered/ or products sold	-	-	-	-
PC12. collect payment either in cash (as per RBI guidelines)/ cheque/ demand draft or through online transactions via RTGS/NEFT/UPI etc.	-	-	-	-
PC13. ensure accounts and ledgers are maintained for the material supplied, payables and receivables, loan ledgers, taxes collected and paid into government treasury as well for wages paid and statutory benefits like PF, ESI contribution deposited with authorities	-	-	-	-
PC14. ensure maintenance and reconciliation of a monthly account as well as movable and immovable assets and stock to keep track of profit/ loss as well as periodic audit as per legal requirements	-	-	-	-
<i>Comply with legal, regulatory and statutory standards</i>	-	-	-	-
PC15. comply with workplace health and safety rules stipulated by local authorities	-	-	-	-
PC16. comply with rules related to taxes and licensing regulations	-	-	-	-
PC17. comply with prevalent labour laws and keep records for employee's qualifications, employment as well as trainings	-	-	-	-
PC18. comply with regulations and protocols related to maintenance of product/ service license including the pre conditions (if any)	-	-	-	-
PC19. comply with quality systems like ISO/GMP/GLP/NCS-TCP etc and any other rule mandated by appropriate regulatory authorities	-	-	-	-
PC20. comply with pollution norms as per land of law and ensure near zero pollution for a sustainable environment and to earn carbon credits	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC21. ensure that business facility and employees are always prepared and ready for any surprise inspection/ audit from clients/ regulatory/ statutory authorities	-	-	-	-
NOS Total	30	50	12	8



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0123
NOS Name	Establish licensed biotechnology led and perform various entrepreneurial activities to run the regulated business operations
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research, Biotechnology
Occupation	Generic
NSQF Level	6
Credits	5.00
Version	1.0
Last Reviewed Date	NA
Next Review Date	03/05/2026
NSQC Clearance Date	03/05/2023



Qualification Pack

LFS/N0124: Maintain the Critical Business documents as Biotechnology led entrepreneur

Description

This NOS is about an entrepreneur maintaining the critical business documents for its biotechnology led business

Scope

The scope covers the following :

- Infrastructure documents
- Supply Chain documents
- Documentation for sales & marketing
- Quality audit and client/regulatory inspections related documentation
- IPR related Documents

Elements and Performance Criteria

Infrastructure documents

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

- PC1.** ensure documentation and maintenance of records for architectural building layout like blueprint of plant/lab, electric circuit and plumbing layouts and safety equipment layout, infrastructure and asset insurance and lease/rent contracts/ sale deed (if owned facility)
- PC2.** ensure documentation and maintenance of records for all machineries, equipment and tools installed/used in the plant/ lab unit, with supplier/manufacturer details, manuals of all machineries / equipment, installation, qualification calibration and validation records and annual maintenance details etc
- PC3.** ensure documentation and maintenance of records for engineering and maintenance of each machinery/equipment, machine utilization, machine performance, breakdown details, corrective actions, spares changed, machine/equipment condition etc

Supply Chain documents

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

- PC4.** ensure documentation and maintenance of records for all raw materials, ingredients and packaging materials handled, like name of the supplier, batch details, quantity supplied and quality of the materials supplies etc as well as per NCS-TCP
- PC5.** ensure documentation and maintenance of records for each supplier quality report on raw materials, ingredients, packaging materials, internal and external quality report on finished products, consumer and customer complaints , corrective actions, legal documents (if any) as per NCS-TCP
- PC6.** ensure documentation and maintenance of records for storage facility, like condition of storage facility, storage parameters if any like temperature, humidity, pressure (as applicable), space utilised, stacking procedure etc

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- PC7.** ensure documentation and maintenance of records for distribution details & cold chain Management like transport details, quality, hygiene and cleanliness of vehicle, quantity loaded in the vehicle, Storage condition in distribution routes , outlet details, customer/ consumer details, distribution quantity, quantity returned etc.

Documentation for sales & marketing

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

- PC8.** ensure documentation and maintenance of records for long term and short term business plans, feasibility reports, investor/shareholder agreements and disbursement and payment records for loan/grant/equity etc.
- PC9.** ensure documentation and maintenance of records for sale like customer details, customer type, location, quantity purchased by each stockist/consumer, frequency of purchase, sale details like quantity of products/brand sold in each territory

Quality audit and client/regulatory inspections related documentation

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

- PC10.** ensure documentation and maintenance of records for internal/ external audits with its observations, notices/ feedback, action reports and final submission of audit action reports
- PC11.** ensure documentation and maintenance of records for every communication sent to or received from regulatory/ licensing authorities

IPR Related Documents

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

- PC12.** interact with a global clientele and draft high-quality business / IP research documents, making impactful inferences after analyzing available data, and articulating them in a clear and cogent manner
- PC13.** Draft and Review IP related document that are associated with company patent registration are fulfilled accordingly to regulatory requirements
- PC14.** ensure accurate and comprehensive IPR documentation, such as patent applications, trade secret agreements, technology transfer documents, and regulatory filings are prepared and submitted
- PC15.** Ensure submission and response associated with IPR documentation, ensuring that filings, submissions, and responses are submitted within the specified timeframes

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** system of documentation as per ISO/ good documentation practices and method of implementation
- KU2.** scoring, grading and accreditation system of affiliating bodies and clients
- KU3.** guidelines for facing audits and best practices for making organization audit ready
- KU4.** software and latest information technology tools for documentation and record maintenance
- KU5.** statistical tools for analysis and monitoring
- KU6.** various recording and documentation formats applicable in sales, marketing, supply chain etc
- KU7.** basic awareness of engineering drawing and architectural layouts
- KU8.** best practices in engineering and maintenance in sector



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- KU9.** accounting standards and regulations
- KU10.** primary research and secondary research, focused on intellectual property landscape associated biotechnology sector
- KU11.** basics of patent / prior art searching
- KU12.** biological sequence searching (BLAST).
- KU13.** Formulate Search Strings for Identified Invention and Perform Patentability, FTO, Landscape and Invalidity Search

Generic Skills (GS)

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

- GS1.** record and communicate details of work done to appropriate people using written/typed report
- GS2.** interact effectively with team members
- GS3.** communicate with team members for data/ information/support/ advice needed
- GS4.** communicate with people in a form and manner and using language that is open and respectful
- GS5.** apply balanced judgement to different situations
- GS6.** plan and organize assigned work in order to drive collaboration with team members
- GS7.** effectively interact with the various stakeholders to complete assigned tasks
- GS8.** resolve any difficulties in relationships with colleagues , or get help from an appropriate person, in a way that preserves goodwill and trust
- GS9.** use team-building skills during the interaction with teammates while managing the difficult/stressful or emotional situations at work
- GS10.** apply emotional intelligence while dealing with other genders and people with disability

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Infrastructure documents</i>	5	20	5	2
PC1. ensure documentation and maintenance of records for architectural building layout like blueprint of plant/lab, electric circuit and plumbing layouts and safety equipment layout, infrastructure and asset insurance and lease/rent contracts/ sale deed (if owned facility)	-	-	-	-
PC2. ensure documentation and maintenance of records for all machineries, equipment and tools installed/used in the plant/ lab unit, with supplier/manufacturer details, manuals of all machineries / equipment, installation, qualification calibration and validation records and annual maintenance details etc	-	-	-	-
PC3. ensure documentation and maintenance of records for engineering and maintenance of each machinery/equipment, machine utilization, machine performance, breakdown details, corrective actions, spares changed, machine/equipment condition etc	-	-	-	-
<i>Supply Chain documents</i>	5	10	5	3
PC4. ensure documentation and maintenance of records for all raw materials, ingredients and packaging materials handled, like name of the supplier, batch details, quantity supplied and quality of the materials supplies etc as well as per NCS-TCP	-	-	-	-
PC5. ensure documentation and maintenance of records for each supplier quality report on raw materials, ingredients, packaging materials, internal and external quality report on finished products, consumer and customer complaints , corrective actions, legal documents (if any) as per NCS-TCP	-	-	-	-
PC6. ensure documentation and maintenance of records for storage facility, like condition of storage facility, storage parameters if any like temperature, humidity, pressure (as applicable), space utilised, stacking procedure etc	-	-	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC7. ensure documentation and maintenance of records for distribution details & cold chain Management like transport details, quality, hygiene and cleanliness of vehicle, quantity loaded in the vehicle, Storage condition in distribution routes , outlet details, customer/ consumer details, distribution quantity, quantity returned etc.	-	-	-	-
<i>Documentation for sales & marketing</i>	5	10	3	3
PC8. ensure documentation and maintenance of records for long term and short term business plans, feasibility reports, investor/shareholder agreements and disbursement and payment records for loan/grant/equity etc.	-	-	-	-
PC9. ensure documentation and maintenance of records for sale like customer details, customer type, location, quantity purchased by each stockist/consumer, frequency of purchase, sale details like quantity of products/brand sold in each territory	-	-	-	-
<i>Quality audit and client/regulatory inspections related documentation</i>	5	5	2	2
PC10. ensure documentation and maintenance of records for internal/ external audits with its observations, notices/ feedback, action reports and final submission of audit action reports	-	-	-	-
PC11. ensure documentation and maintenance of records for every communication sent to or received from regulatory/ licensing authorities	-	-	-	-
<i>IPR Related Documents</i>	3	3	2	2
PC12. interact with a global clientele and draft high-quality business / IP research documents, making impactful inferences after analyzing available data, and articulating them in a clear and cogent manner	-	-	-	-
PC13. Draft and Review IP related document that are associated with company patent registration are fulfilled accordingly to regulatory requirements	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC14. ensure accurate and comprehensive IPR documentation, such as patent applications, trade secret agreements, technology transfer documents, and regulatory filings are prepared and submitted	-	-	-	-
PC15. Ensure submission and response associated with IPR documentation, ensuring that filings, submissions, and responses are submitted within the specified timeframes	-	-	-	-
NOS Total	23	48	17	12



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0124
NOS Name	Maintain the Critical Business documents as Biotechnology led entrepreneur
Sector	Life Sciences
Sub-Sector	Biotechnology, Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Generic
NSQF Level	6
Credits	4.00
Version	1.0
Last Reviewed Date	NA
Next Review Date	03/05/2026
NSQC Clearance Date	03/05/2023

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.)

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/N0111.Ensure adherence to Environment, health and safety guidelines in production facility and GMP controlled areas by self and subordinates	30	55	0	15	100	9.37
LFS/N0117.Coordinate with Manager, team-members, cross-functional teams and auditors	30	50	12	8	100	9.37
DGT/VSQ/N0102.Employability Skills (60 Hours)	20	30	-	-	50	6.25
Total	80	135	12	23	250	24.99

Elective: 1 In-Vitro Micro-propagation of Plants



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National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N4105.Monitor the In-Vitro micro-propagation process and its compliance with regulatory and quality norms	30	50	12	8	100	37.5
Total	30	50	12	8	100	37.5

Optional: 1 Regulated Entrepreneurship

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0123.Establish licensed biotechnology led and perform various entrepreneurial activities to run the regulated business operations	30	50	12	8	100	18.75
LFS/N0124.Maintain the Critical Business documents as Biotechnology led entrepreneur	23	48	17	12	100	18.75
Total	53	98	29	20	200	37.5