Qualification Pack

Biologist / Biotechnologist

Manufacturing of Bio-Products

QP Code: LFS/Q4101 Instantiated QP Code: LFS/Q4101-SI001

Version: 1.0

NSQF Level: 5

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Contents

Qualification Pack

LFS/Q4101-SI001: 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 : Manufacturing of Bio-Products

1. LFS/N4101: Monitor the bio-product manufacturing process in compliance with Good Manufacturing Practices (GMP) and applicable regulatory guidelines
2. LFS/N4102: Perform critical activities in upstream processing of bio-products
3. LFS/N4103: Perform purification of harvested material by downstream processing

Qualification Pack (QP) Parameters

Qualification Pack

Sector	Life Sciences
Sub-Sector	Biotechnology
Occupation	Biotechnology Production and Quality
Country	India
NSQF Level	5
Credits	18
Aligned to NCO/ISCO/ISIC Code	NCO-2015/2131.1300
Minimum Educational Qualification & Experience	B.Tech ((Biotechology) 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
Reference code on NQR	QG-05-LS-00372-2023-V1-LSSSDC
NQR Version	1.0

Qualification Pack

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:

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

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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Follow health and hygiene protocols	**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	-	-	-	-
Adherence to safety and security procedures	**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	-	-	-	-

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	-	-	-	-
Adherence to emergency procedures	**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**

Qualification Pack

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

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

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

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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Coordination with Manager	**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	-	-	-	-
Coordination within the team and cross-functional teams	**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	-	-	-	-

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	-	-	-	-
Respond to audit queries	**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	-	-	-	-
Sensitivity towards all genders and people with disability	**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**

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

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:

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.

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

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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Introduction to Employability Skills	**1**	**1**	**-**	**-**
PC1. identify employability skills required for jobs in various industries	-	-	-	-
PC2. identify and explore learning and employability portals	-	-	-	-
Constitutional values – Citizenship	**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	-	-	-	-
Becoming a Professional in the 21st Century	**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	-	-	-	-
Basic English Skills	**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	-	-	-	-
Career Development & Goal Setting	**1**	**2**	**-**	**-**

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	-	-	-	-
Communication Skills	**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	-	-	-	-
Diversity & Inclusion	**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	-	-	-	-
Financial and Legal Literacy	**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	-	-	-	-
Essential Digital Skills	**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	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Entrepreneurship	**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	-	-	-	-
Customer Service	**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	-	-	-	-
Getting ready for apprenticeship & Jobs	**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**	**-**	**-**

Qualification Pack

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

LFS/N4101: Monitor the bio-product manufacturing process in compliance with Good Manufacturing Practices (GMP) and applicable regulatory guidelines

Description

This NOS is about a person monitoring the bio-product manufacturing process in compliance with Good Manufacturing Practices (GMP) and applicable regulatory guidelines

Scope

The scope covers the following :

- Pre-production checks
- Production Process
- Post-production process

Elements and Performance Criteria

Pre-production checks

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

PC1. ensure all manufacturing processes meets national legislation and obligations of marketing authorization, product license requirements and operation as per the relevant Standard Operating Procedures (SOPs)

PC2. ensure that environmental conditions of the production area are maintained within the limits specified in the respective manufacturing records

PC3. ensure that all the pre analysis checks are performed as per Standard Operating Procedure (SOP)and GMP guidelines

Production Process

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

PC4. ensure the availability of sufficient stock of raw materials, working seed, cultures, equipment, consumables and documents are available and ready for use in the manufacturing area

PC5. maintain GMP standards at shop floor and conditions suitable for production of quality products as per requirement

PC6. ensure the raw material is processed strictly as per pre-defined and validated manufacturing process guidelines and SOP

PC7. check the production process is carried out as per the respective production schedules

PC8. monitor all the critical operations including in-process checks, production yields and reconciliations at each stage as per the validated manufacturing process flow and SOP

PC9. Observe production incidents for any deviations from the standard production process and record the same as per SOP

PC10. verify various online documentation entries at each production step in a manufacturing process information system and lab management information system

Post-production process

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

PC11. ensure all necessary reconciliation calculations are correct and accurate for the bio-product, packaging and labels

PC12. ensure all product labels and packaging (including any secondary packaging) meet applicable license and quality control requirements

PC13. observe to ensure waste disposal in compliance with WHO guidelines and ICH-cGMP rules

PC14. monitor the line clearance activities performed by junior staff on the shop floors for smooth work- flow

PC15. ensure SOPs are accurately followed when equipment is dismantled, cleaned, decontaminated, stored or disposed of correctly at the end of a manufacturing or packaging process

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. the principles of GXP, including documentation practices

KU2. Concepts and application process validation, equipment calibration and hygiene

KU3. relevant regulatory guidelines and requirements set by national ad international regulatory authorities for bio-product manufacturing, labelling, packaging, storage, and distribution.

KU4. In-depth knowledge of the various stages of bio-product manufacturing, such as sourcing, cultivation/extraction, purification, formulation, and packaging.

KU5. quality assurance and its principles, including sampling, testing methodologies, data analysis, and use of quality check tools.

KU6. Ability to create and maintain important documents like SOPs, batch records, and equipment logbooks, and understand the significance of accurate record-keeping.

KU7. Familiarity with the operation, maintenance, and troubleshooting of manufacturing equipment and instruments used in bio product manufacturing like bioreactor, incubator, fermenter ,down-flow booth etc.

KU8. safety protocols, PPE, hazardous material handling, waste management, and environmental regulations relevant to bio-product manufacturing.

KU9. Concepts of continuous improvement, process optimization, efficiency improvements.

Generic Skills (GS)

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

GS1. use reading and comprehension skills to read and understand manuals, SOPs, health and safety instructions

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 in manufacturing process

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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Pre-production checks	**10**	**10**	**5**	**3**
PC1. ensure all manufacturing processes meets national legislation and obligations of marketing authorization, product license requirements and operation as per the relevant Standard Operating Procedures (SOPs)	-	-	-	-
PC2. ensure that environmental conditions of the production area are maintained within the limits specified in the respective manufacturing records	-	-	-	-
PC3. ensure that all the pre analysis checks are performed as per Standard Operating Procedure (SOP)and GMP guidelines	-	-	-	-
Production Process	**10**	**20**	**5**	**3**
PC4. ensure the availability of sufficient stock of raw materials, working seed, cultures, equipment, consumables and documents are available and ready for use in the manufacturing area	-	-	-	-
PC5. maintain GMP standards at shop floor and conditions suitable for production of quality products as per requirement	-	-	-	-
PC6. ensure the raw material is processed strictly as per pre-defined and validated manufacturing process guidelines and SOP	-	-	-	-
PC7. check the production process is carried out as per the respective production schedules	-	-	-	-
PC8. monitor all the critical operations including in-process checks, production yields and reconciliations at each stage as per the validated manufacturing process flow and SOP	-	-	-	-
PC9. Observe production incidents for any deviations from the standard production process and record the same as per SOP	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC10. verify various online documentation entries at each production step in a manufacturing process information system and lab management information system	-	-	-	-
Post-production process	**10**	**20**	**2**	**2**
PC11. ensure all necessary reconciliation calculations are correct and accurate for the bio-product, packaging and labels	-	-	-	-
PC12. ensure all product labels and packaging (including any secondary packaging) meet applicable license and quality control requirements	-	-	-	-
PC13. observe to ensure waste disposal in compliance with WHO guidelines and ICH-cGMP rules	-	-	-	-
PC14. monitor the line clearance activities performed by junior staff on the shop floors for smooth work- flow	-	-	-	-
PC15. ensure SOPs are accurately followed when equipment is dismantled, cleaned, decontaminated, stored or disposed of correctly at the end of a manufacturing or packaging process	-	-	-	-
NOS Total	**30**	**50**	**12**	**8**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N4101
NOS Name	Monitor the bio-product manufacturing process in compliance with Good Manufacturing Practices (GMP) and applicable regulatory guidelines
Sector	Life Sciences
Sub-Sector	Biotechnology, Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Biotechnology Production and Quality
NSQF Level	5
Credits	3.00
Version	1.0
Last Reviewed Date	NA
Next Review Date	03/05/2026
NSQC Clearance Date	03/05/2023

LFS/N4102: Perform critical activities in upstream processing of bio-products

Description

This NOS is about Biologist performing critical activities in upstream processing of bio-products

Scope

The scope covers the following :

- Follow Pre-production checks
- monitor fermentation process
- harvesting of biomaterial
- Documentation

Elements and Performance Criteria

Follow Pre-production checks

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

PC1. ensure that work is carried out in accordance with standard operating procedures and cleanroom guidelines

PC2. remove the culture from cryo-storage to the work area, in accordance with SOP

PC3. revive the culture for scale-up by inoculating in the appropriate media as per SOP

PC4. incubate and grow the culture in growth solution and scale-up as per SOP

PC5. perform tests to show that the culture has reached the required specification

PC6. add culture and growth media in the correct quantities at required levels in the bioreactor

Monitor fermentation process

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

PC7. ensure sterilization of equipment, in accordance with established practices and procedures

PC8. ensure that growth parameters are regularly checked such as pH, stirrer speed, pressure, dissolved oxygen (DO2), temperature etc at regular intervals and set controls correctly for the required production run as per protocol

PC9. monitor the bioreactor, in accordance with SOP, until the required biomaterial specifications are reached

PC10. perform regular sampling to check in-process samples

PC11. ensure waste disposal as per SOP and ensure cleanliness in the work area

PC12. record details of the work done in manufacturing record files/system

Harvesting of biomaterial

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

PC13. prepare the bioreactor for harvesting operations

PC14. harvest biomaterials in sealed sterile containers for downstream processing (DSP), in accordance with established practices and procedures

PC15. store harvested biomaterial in the correct location for further processing

Documentation

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

PC16. record details of the work done in manufacturing record files/system and communicate the required information about the work done to authorized people

PC17. review the entries done by operator /colleagues for verification and authorization

PC18. observe production incidents for any deviations from the standard production process and record and report as per SOP

PC19. respond to audit related queries

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. Basic of sampling techniques, sample collection, sample handling and storage.

KU2. Concepts and process of aseptic techniques, cell line selection, media formulation, and cell propagation for successful cell culture.

KU3. Basic of operations and monitoring of bioreactors, including different types, components, and operational modes.

KU4. nutritional requirements of cells and optimize media formulations to promote cell growth and productivity.

KU5. methods to assess cell viability, perform cell counting, and effectively sample cells for analysis during the upstream process.

KU6. Concepts of experimental design, statistical analysis, and data interpretation to optimize critical parameters for improved productivity and yield.

KU7. contamination prevention measures, including cleanroom practices, sterilization techniques, and environmental monitoring

KU8. challenges and considerations when transitioning from laboratory-scale to larger production scales in cell culture processes.

KU9. Adherence to safety protocols, handle hazardous materials appropriately, manage waste, and comply with regulatory guidelines.

Generic Skills (GS)

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

GS1. use reading and comprehension skills to read and understand manuals, SOPs, health and safety instructions

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 in upstream processing

GS4. use critical thinking skills in analyzing 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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Follow Pre-production checks	**10**	**10**	**3**	**2**
PC1. ensure that work is carried out in accordance with standard operating procedures and cleanroom guidelines	-	-	-	-
PC2. remove the culture from cryo-storage to the work area, in accordance with SOP	-	-	-	-
PC3. revive the culture for scale-up by inoculating in the appropriate media as per SOP	-	-	-	-
PC4. incubate and grow the culture in growth solution and scale-up as per SOP	-	-	-	-
PC5. perform tests to show that the culture has reached the required specification	-	-	-	-
PC6. add culture and growth media in the correct quantities at required levels in the bioreactor	-	-	-	-
Monitor fermentation process	**10**	**20**	**3**	**2**
PC7. ensure sterilization of equipment, in accordance with established practices and procedures	-	-	-	-
PC8. ensure that growth parameters are regularly checked such as pH, stirrer speed, pressure, dissolved oxygen (DO2), temperature etc at regular intervals and set controls correctly for the required production run as per protocol	-	-	-	-
PC9. monitor the bioreactor, in accordance with SOP, until the required biomaterial specifications are reached	-	-	-	-
PC10. perform regular sampling to check in-process samples	-	-	-	-
PC11. ensure waste disposal as per SOP and ensure cleanliness in the work area	-	-	-	-
PC12. record details of the work done in manufacturing record files/system	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Harvesting of biomaterial	**5**	**10**	**3**	**2**
PC13. prepare the bioreactor for harvesting operations	-	-	-	-
PC14. harvest biomaterials in sealed sterile containers for downstream processing (DSP), in accordance with established practices and procedures	-	-	-	-
PC15. store harvested biomaterial in the correct location for further processing	-	-	-	-
Documentation	**5**	**10**	**3**	**2**
PC16. record details of the work done in manufacturing record files/system and communicate the required information about the work done to authorized people	-	-	-	-
PC17. review the entries done by operator /colleagues for verification and authorization	-	-	-	-
PC18. observe production incidents for any deviations from the standard production process and record and report as per SOP	-	-	-	-
PC19. respond to audit related queries	-	-	-	-
NOS Total	**30**	**50**	**12**	**8**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N4102
NOS Name	Perform critical activities in upstream processing of bio-products
Sector	Life Sciences
Sub-Sector	Biotechnology, Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Biotechnology Production and Quality
NSQF Level	5
Credits	3.00
Version	1.0
Last Reviewed Date	NA
Next Review Date	03/05/2026
NSQC Clearance Date	03/05/2023

LFS/N4103: Perform purification of harvested material by downstream processing

Description

This NOS is about the Biologist performing purification of harvested material by downstream processing

Scope

The scope covers the following :

- Purification of harvest
- Sampling and storage of manufactured bio-product

Elements and Performance Criteria

Purification of harvest

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

PC1. ensure that work is carried out in accordance with standard operating procedures

PC2. prepare the filter unit and connect to the biomaterial source for downstream processing, in accordance with established practices and procedures

PC3. pump biomaterial through the filter unit, monitoring and adjusting the flow-rate according to specification

PC4. collect filtered biomaterial in the correct aseptic containers, and in the required quantities

PC5. perform a filter unit integrity test, in accordance with established practices and procedures

PC6. perform waste disposal as per SOP and ensure cleanliness in the work area

PC7. record details of the work done in manufacturing record files/system and communicate the required information about the work done to authorized people

Sampling and storage of manufactured bio-product

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

PC8. prepare aliquots of sample at every stage as per SOP, label it and inform quality control department for sample analysis

PC9. store the manufactured bio-product at the designated area as per SOP and record the details of the storage

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. Basics of sampling techniques, sample collection, handling and storage

KU2. Concepts of filtration, chromatography, precipitation, and centrifugation methods used for separating target bio-molecules from impurities

KU3. Separation process of target Bio-molecules based on properties like size, charge, hydrophobicity, and affinity to achieve purification.

KU4. Methods to design an effective downstream processing strategy by determining the optimal sequence of purification steps.

KU5. chromatography principles, including resin selection, column packing, sample loading, elution, and column regeneration.

KU6. Concepts of different filtration techniques and their parameters, such as membrane selection, pore size, transmembrane pressure, and fouling mitigation.

KU7. methods to prepare buffers, adjust pH, perform buffer exchange, and maintain buffer integrity and stability during purification steps.

KU8. Various Characterization/ analytical method for testing of sample for intermediate / final product

KU9. Interpretation of analytical data

KU10. importance of process validation, including validation protocols, critical process parameters, and acceptance criteria for consistent product quality.

KU11. Adherence to safety protocols, handle hazardous materials appropriately, manage waste, and comply with regulatory guidelines.

KU12. Cleanroom Classification and compliance

Generic Skills (GS)

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

GS1. use reading and comprehension skills to read and understand manuals, SOPs, health and safety instructions

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 in downstream processing

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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Purification of harvest	**10**	**20**	**5**	**5**
PC1. ensure that work is carried out in accordance with standard operating procedures	-	-	-	-
PC2. prepare the filter unit and connect to the biomaterial source for downstream processing, in accordance with established practices and procedures	-	-	-	-
PC3. pump biomaterial through the filter unit, monitoring and adjusting the flow-rate according to specification	-	-	-	-
PC4. collect filtered biomaterial in the correct aseptic containers, and in the required quantities	-	-	-	-
PC5. perform a filter unit integrity test, in accordance with established practices and procedures	-	-	-	-
PC6. perform waste disposal as per SOP and ensure cleanliness in the work area	-	-	-	-
PC7. record details of the work done in manufacturing record files/system and communicate the required information about the work done to authorized people	-	-	-	-
Sampling and storage of manufactured bio-product	**20**	**30**	**5**	**5**
PC8. prepare aliquots of sample at every stage as per SOP, label it and inform quality control department for sample analysis	-	-	-	-
PC9. store the manufactured bio-product at the designated area as per SOP and record the details of the storage	-	-	-	-
NOS Total	**30**	**50**	**10**	**10**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N4103
NOS Name	Perform purification of harvested material by downstream processing
Sector	Life Sciences
Sub-Sector	Biotechnology, Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Biotechnology Production and Quality
NSQF Level	5
Credits	3.00
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 via 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

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	15
LFS/N0117.Coordinate with Manager, team-members, cross-functional teams and auditors	30	50	12	8	100	15
DGT/VSQ/N0102.Employability Skills (60 Hours)	20	30	-	-	50	10
Total	**80**	**135**	**12**	**23**	**250**	**40**

Elective: 1 Manufacturing of Bio-Products

Qualification Pack

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N4101.Monitor the bio-product manufacturing process in compliance with Good Manufacturing Practices (GMP) and applicable regulatory guidelines	30	50	12	8	100	20
LFS/N4102.Perform critical activities in upstream processing of bio-products	30	50	12	8	100	20
LFS/N4103.Perform purification of harvested material by downstream processing	30	50	10	10	100	20
Total	**90**	**150**	**34**	**26**	**300**	**60**