

Qualification Pack



Biologist / Biotechnologist

Biologics Formulation Manufacturing

QP Code: LFS/Q4101 Instantiated QP Code: LFS/Q4101-SI002

Version: 1.0

NSQF Level: 5

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LFS/Q4101-SI002: 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 : Biologics Formulation Manufacturing

1. [LFS/N4104: Supervise the manufacturing process for biologics formulation in compliance with GMP and other regulatory guidelines](#)

Qualification Pack (QP) Parameters

Sector	Life Sciences
Sub-Sector	Biotechnology



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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	<p>B.Tech ((Biotechnology) Final Year Student) OR M.Sc ((biology and biotechnology related subject) Final Year Student) OR B.Pharm (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)</p>
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



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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/N4104: Supervise the manufacturing process for biologics formulation in compliance with GMP and other regulatory guidelines

Description

This NOS is about Supervising the manufacturing process for biologics formulation in compliance with GMP and other regulatory guidelines

Scope

The scope covers the following :

- Monitor and supervise excipient preparation and blending
- Monitor filling and containerization
- GMP Activities post filling and containerization
- Documentation

Elements and Performance Criteria

Monitor and supervise excipient preparation and blending

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 in the biomanufacturing environment
- PC2.** ensure that environmental conditions of the manufacturing area are maintained within the limits specified in the respective BMR
- PC3.** ensure that all the pre analysis checks are performed as per Standard Operating Procedure (SOP) and GMP guidelines
- PC4.** ensure that work is carried out in accordance with standard operating procedures for preparation of excipients and their sterilization
- PC5.** confirm that the blending equipment is set up and ready for operation as per SOP
- PC6.** follow the defined procedures for starting and running the blending equipment as per SOP
- PC7.** perform the blending operations for biologics in accordance with standard operating procedures for blending process/operations
- PC8.** draw sample of final blend and send for quality control analysis and ensure that the final blend is aseptically transferred for filling operation

Monitor filling and containerization

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

- PC9.** 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
- PC10.** ensure that work is carried out in accordance with standard operating procedures for filling and containerization, visual inspection, sterilization, decontamination and disposal
- PC11.** monitor that the defined procedures for starting and running the equipment operating system as per SOP are followed
- PC12.** 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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- PC13.** monitor that for liquid products the filling, containerization and sealing process for vial /syringe or any other container type are performed as per SOP
- PC14.** monitor that for lyophilized products, filling, containerization, lyophilization and sealing process for vial /syringe or any other container type are performed as per SOP
- PC15.** 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

GMP Activities post filling and containerization

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

- PC16.** perform the in-process quality checks for volume, leakage and ensure the visual inspections are done as per SOP
- PC17.** monitor the labelling process to meet the labelling requirement as per relevant regulation
- PC18.** ensure that the production output is as per the required specification with respect to batch yield, percentage of rejection and quality parameters like volume and visual appearance
- PC19.** monitor that waste disposal are being carried out as per SOP and ensure cleanliness in the work area
- PC20.** record details of the work done in BMR and communicate the required information about the work done to authorized people
- PC21.** monitor the line clearance activities performed by junior staff on the shop floors for smooth work- flow
- PC22.** 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

Documentation

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

- PC23.** record details of the work done in BMR and communicate the required information about the work done to authorized people
- PC24.** review the entries done by operator /colleagues for verification and authorization
- PC25.** observe production incidents for any deviations from the standard production process and record and report as per SOP and respond to audit related queries

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** principles and requirements specific to biologics formulation, including knowledge of the biologic's structure, stability, and compatibility with excipients.
- KU2.** GXP guidelines and their application to biologics formulation, including documentation practices, process validation, equipment calibration, hygiene, and quality control.
- KU3.** National and international regulatory guidelines applicable to biologics formulation
- KU4.** formulation development principles and techniques is necessary like excipient selection, solubility considerations, stability assessments, and compatibility studies.
- KU5.** equipment used in biologics formulation, such as mixers, homogenizers, filtration systems, and fill-finish equipment.



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- KU6.** methods to monitor critical parameters during the formulation process, such as temperature, pH, pressure, and mixing speed.
- KU7.** Implementation of appropriate control strategies to maintain process integrity
- KU8.** quality assurance and its principles specific to biologics formulation
- KU9.** sampling techniques, testing methodologies, data analysis, and interpretation of results to ensure product quality and consistency.
- KU10.** Concept of creating and maintaining essential documents, including batch records, standard operating procedures (SOPs), equipment logbooks, and quality-related documents
- KU11.** importance of accurate record-keeping and adherence to data integrity, good documentation practices and ALCOA Plus.
- KU12.** safety protocols, including handling of hazardous materials, waste management, and compliance with environmental regulations.
- KU13.** importance of maintaining a safe working environment for personnel.
- KU14.** Concepts of continuous improvement, seeking opportunities for process optimization, efficiency enhancements, and cost reductions while maintaining compliance with regulatory requirements for biologics Formulations.
- KU15.** Concepts of QBD
- KU16.** 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-to-day problems in manufacturing process
- 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

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Monitor and supervise excipient preparation and blending</i>	5	10	3	2
PC1. follow the gowning procedure and wear the appropriate personal protection equipment (PPE) while working in the biomanufacturing environment	-	-	-	-
PC2. ensure that environmental conditions of the manufacturing area are maintained within the limits specified in the respective BMR	-	-	-	-
PC3. ensure that all the pre analysis checks are performed as per Standard Operating Procedure (SOP) and GMP guidelines	-	-	-	-
PC4. ensure that work is carried out in accordance with standard operating procedures for preparation of excipients and their sterilization	-	-	-	-
PC5. confirm that the blending equipment is set up and ready for operation as per SOP	-	-	-	-
PC6. follow the defined procedures for starting and running the blending equipment as per SOP	-	-	-	-
PC7. perform the blending operations for biologics in accordance with standard operating procedures for blending process/operations	-	-	-	-
PC8. draw sample of final blend and send for quality control analysis and ensure that the final blend is aseptically transferred for filling operation	-	-	-	-
<i>Monitor filling and containerization</i>	10	25	3	2
PC9. 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	-	-	-	-
PC10. ensure that work is carried out in accordance with standard operating procedures for filling and containerization, visual inspection, sterilization, decontamination and disposal	-	-	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC11. monitor that the defined procedures for starting and running the equipment operating system as per SOP are followed	-	-	-	-
PC12. deal promptly and effectively with error messages or equipment faults that are within your control and report those that cannot be solved	-	-	-	-
PC13. monitor that for liquid products the filling, containerization and sealing process for vial /syringe or any other container type are performed as per SOP	-	-	-	-
PC14. monitor that for lyophilized products, filling, containerization, lyophilization and sealing process for vial /syringe or any other container type are performed as per SOP	-	-	-	-
PC15. 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>GMP Activities post filling and containerization</i>	5	10	3	2
PC16. perform the in-process quality checks for volume, leakage and ensure the visual inspections are done as per SOP	-	-	-	-
PC17. monitor the labelling process to meet the labelling requirement as per relevant regulation	-	-	-	-
PC18. ensure that the production output is as per the required specification with respect to batch yield, percentage of rejection and quality parameters like volume and visual appearance	-	-	-	-
PC19. monitor that waste disposal are being carried out as per SOP and ensure cleanliness in the work area	-	-	-	-
PC20. record details of the work done in BMR and communicate the required information about the work done to authorized people	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC21. monitor the line clearance activities performed by junior staff on the shop floors for smooth work- flow	-	-	-	-
PC22. 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	-	-	-	-
<i>Documentation</i>	5	10	3	2
PC23. record details of the work done in BMR and communicate the required information about the work done to authorized people	-	-	-	-
PC24. review the entries done by operator /colleagues for verification and authorization	-	-	-	-
PC25. observe production incidents for any deviations from the standard production process and record and report as per SOP and respond to audit related queries	-	-	-	-
NOS Total	25	55	12	8



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N4104
NOS Name	Supervise the manufacturing process for biologics formulation in compliance with GMP and other regulatory guidelines
Sector	Life Sciences
Sub-Sector	Biotechnology, Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Biotechnology Production and Quality, Manufacturing, Quality
NSQF Level	5
Credits	9.00
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	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 Biologics Formulation Manufacturing



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National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N4104. Supervise the manufacturing process for biologics formulation in compliance with GMP and other regulatory guidelines	25	55	12	8	100	60
Total	25	55	12	8	100	60