

## Qualification Pack



# Biologist / Biotechnologist

Quality Control of Biological Products

QP Code: LFS/Q4101 Instantiated QP Code: LFS/Q4101-SI004

Version: 1.0

NSQF Level: 5

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## Qualification Pack

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### LFS/Q4101-SI004: 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 : Quality Control of Biological Products

1. [LFS/N4106: Perform Quality Control analysis of Biological Products](#)

#### Qualification Pack (QP) Parameters

<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Biotechnology



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<b>Occupation</b>	Biotechnology Production and Quality
<b>Country</b>	India
<b>NSQF Level</b>	5
<b>Credits</b>	18
<b>Aligned to NCO/ISCO/ISIC Code</b>	NCO-2015/2131.1300
<b>Minimum Educational Qualification &amp; Experience</b>	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)
<b>Minimum Level of Education for Training in School</b>	
<b>Pre-Requisite License or Training</b>	NA
<b>Minimum Job Entry Age</b>	20 Years
<b>Last Reviewed On</b>	NA
<b>Next Review Date</b>	03/05/2026
<b>NSQF Approval Date</b>	03/05/2023
<b>Version</b>	1.0
<b>Reference code on NQR</b>	QG-05-LS-00372-2023-V1-LSSSDC
<b>NQR Version</b>	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:





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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>	<b>10</b>	<b>15</b>	-	<b>5</b>
<b>PC1.</b> comply with health and personal hygiene-related protocols as per WHO standards and ICH GMP guidelines	-	-	-	-
<b>PC2.</b> wash hands before entering in the production area with soap/alcohol based sanitisers	-	-	-	-
<b>PC3.</b> report any allergy, sickness or any other environment-related breach before or after entering the work premises to the designated person	-	-	-	-
<b>PC4.</b> take preventive actions on the report of any allergy, sickness or any other environment-related breach reported by subordinates	-	-	-	-
<b>PC5.</b> 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>	<b>10</b>	<b>25</b>	-	<b>5</b>
<b>PC6.</b> comply with safety and security policies and procedures	-	-	-	-
<b>PC7.</b> 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	-	-	-	-
<b>PC8.</b> take preventive and corrective actions based on the report of any identified breaches in safety and security policies and procedures by subordinates	-	-	-	-
<b>PC9.</b> ensure that discipline for material segregation and 5S system is followed at the storage area	-	-	-	-
<b>PC10.</b> comply with material handling, segregation, and storage guidelines for hazardous material	-	-	-	-
<b>PC11.</b> 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
<b>PC12.</b> complete the records of safety drills and trainings undertaken by self and subordinates	-	-	-	-
<i>Adherence to emergency procedures</i>	<b>10</b>	<b>15</b>	-	<b>5</b>
<b>PC13.</b> report any hazards that he/she is not competent to deal with the relevant EHS personnel and warn other people who may be affected	-	-	-	-
<b>PC14.</b> raise the alarm and inform the concerned person immediately for action in the cases of spill, fall, injury, toxic inhale, fire or explosion	-	-	-	-
<b>PC15.</b> follow emergency protocols for any alarms and ensure the safety of subordinates in the area under supervision	-	-	-	-
<b>PC16.</b> follow emergency procedures efficiently	-	-	-	-
<b>PC17.</b> ensure injured employees are provided appropriate first aid and medical aid	-	-	-	-
<b>NOS Total</b>	<b>30</b>	<b>55</b>	-	<b>15</b>



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### National Occupational Standards (NOS) Parameters

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



## Qualification Pack

### 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

## Qualification Pack

### Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Coordination with Manager</i>	<b>10</b>	<b>15</b>	<b>3</b>	<b>2</b>
<b>PC1.</b> coordinate with the reporting manager to obtain work instructions and develop the production plan	-	-	-	-
<b>PC2.</b> communicate to reporting manager about process-flow improvements and production defects received from previous process	-	-	-	-
<b>PC3.</b> inform concern authority for any potential hazards or expected process disruptions	-	-	-	-
<b>PC4.</b> provide maintenance, engineering related or process related change control request and its impact reports proactively to the manager	-	-	-	-
<b>PC5.</b> 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>	<b>10</b>	<b>15</b>	<b>3</b>	<b>2</b>
<b>PC6.</b> work as a team with colleagues and share work as per their own workload	-	-	-	-
<b>PC7.</b> train junior chemists on procedures and provide assistance to them when needed	-	-	-	-
<b>PC8.</b> communicate and discuss workflow related difficulties to find solutions with mutual agreement	-	-	-	-
<b>PC9.</b> coordinate with maintenance team for any breakdowns and preventive and corrective maintenance of production equipments	-	-	-	-
<b>PC10.</b> coordinate with Engineering department at the time of equipment qualification activities	-	-	-	-
<b>PC11.</b> 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
<b>PC12.</b> coordinate with quality control team for raw material availability / release of raw materials and, semi-finished and finished goods	-	-	-	-
<b>PC13.</b> coordinate with QA team for line clearance, change control approvals , calibration and validation activities	-	-	-	-
<i>Respond to audit queries</i>	<b>5</b>	<b>10</b>	<b>3</b>	<b>2</b>
<b>PC14.</b> provide clear answers to the auditor's queries	-	-	-	-
<b>PC15.</b> produce the documented records of performed activities and operations to auditors	-	-	-	-
<b>PC16.</b> maintain data integrity while responding to auditors and regulatory inspectors	-	-	-	-
<i>Sensitivity towards all genders and people with disability</i>	<b>5</b>	<b>10</b>	<b>3</b>	<b>2</b>
<b>PC17.</b> respect all genders, religions, and caste	-	-	-	-
<b>PC18.</b> empathize with people with disability	-	-	-	-
<b>PC19.</b> offer support or help to a person with disability only when asked	-	-	-	-
<b>PC20.</b> ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act	-	-	-	-
<b>PC21.</b> report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee	-	-	-	-
<b>NOS Total</b>	<b>30</b>	<b>50</b>	<b>12</b>	<b>8</b>



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### National Occupational Standards (NOS) Parameters

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



## Qualification Pack

### 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>	<b>1</b>	<b>1</b>	-	-
<b>PC1.</b> identify employability skills required for jobs in various industries	-	-	-	-
<b>PC2.</b> identify and explore learning and employability portals	-	-	-	-
<i>Constitutional values – Citizenship</i>	<b>1</b>	<b>1</b>	-	-
<b>PC3.</b> 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.	-	-	-	-
<b>PC4.</b> follow environmentally sustainable practices	-	-	-	-
<i>Becoming a Professional in the 21st Century</i>	<b>2</b>	<b>4</b>	-	-
<b>PC5.</b> recognize the significance of 21st Century Skills for employment	-	-	-	-
<b>PC6.</b> 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>	<b>2</b>	<b>3</b>	-	-
<b>PC7.</b> use basic English for everyday conversation in different contexts, in person and over the telephone	-	-	-	-
<b>PC8.</b> read and understand routine information, notes, instructions, mails, letters etc. written in English	-	-	-	-
<b>PC9.</b> write short messages, notes, letters, e-mails etc. in English	-	-	-	-
<i>Career Development &amp; Goal Setting</i>	<b>1</b>	<b>2</b>	-	-

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

### Qualification Pack

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



## Qualification Pack

### National Occupational Standards (NOS) Parameters

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



## Qualification Pack

### LFS/N4106: Perform Quality Control analysis of Biological Products

#### Description

This NOS is about Biologist Performing Quality Control analysis of Biological Products

#### Scope

The scope covers the following :

- Perform quality analysis
- Documentation

#### Elements and Performance Criteria

##### *Perform quality analysis*

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

- PC1.** secure the isolated samples for biological analysis
- PC2.** prepare the buffer, solvent solutions, and reagents for running quality tests
- PC3.** follow the instrument cleaning procedure and sequence available for the analysis before using the instrument
- PC4.** ensure raw materials, chemicals and reagents used in sterile quality analysis process are properly capped and stored according to specified conditions to avoid cross contamination
- PC5.** perform biopharmaceutical sample analysis using specified techniques as per written work instructions
- PC6.** create test plans, scripts, and cases necessary for testing projects
- PC7.** record, analyze, and document all the test observations and results
- PC8.** prepare quality reports for the analyzed samples
- PC9.** identify causes for out-of-specific biopharmaceutical products and then recommend changes by following CAPA to improve the quality
- PC10.** Keep all necessary documents and quality SOP's and Ultimately ensure final product quality

##### *Documentation*

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

- PC11.** perform documentation of the activities as per ALCOA principles
- PC12.** record the required information of all significant activities, incidents, and deviations as per recording formats in compliance with SOP and ICH-GMP guidelines
- PC13.** identify corrective and preventive action (CAPA) for every incident and deviations in compliance with GMP and other regulatory guidelines
- PC14.** review and approve the change control request in case of deviations in consultation with QA and regulatory team
- PC15.** review and approve the logbook entries and trial run records
- PC16.** maintain online documentation related to production activities like BMRs, BPRs, log books, daily records and production SOP's as per GMP and GDP guidelines



## Qualification Pack

### Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** principles and techniques used in the analysis of biological products, including assays, tests, and characterization methods specific to biological molecules or organisms.
- KU2.** regulatory guidelines applicable to the quality control analysis of biological products
- KU3.** specific requirements for product testing, documentation, and compliance.
- KU4.** analytical techniques used in the quality control analysis of biological products, including methods such as ELISA, PCR, Western blotting, chromatography (HPLC, GC), mass spectrometry, and bioassays.
- KU5.** principles and implementation of quality control procedures, including sample preparation, handling, storage, and analysis protocols.
- KU6.** good laboratory practices (GLP) and adherence to standard operating procedures (SOPs) for accurate and reliable testing.
- KU7.** operation, maintenance, and calibration of analytical instruments and equipment used in biological product analysis, such as spectrophotometers, centrifuges, PCR machines, chromatography systems, and mass spectrometers.
- KU8.** analyze and interpret data obtained from quality control tests including statistical analysis, data visualization, and the ability to draw meaningful conclusions based on the results.
- KU9.** Importance of creating and maintaining essential documents, including test protocols, data sheets, laboratory notebooks, and quality control records
- KU10.** importance of accurate record-keeping and compliance with documentation practices.
- KU11.** quality assurance principles relevant to biological product analysis, including proficiency testing, control charts, validation of analytical methods, and participation in external quality assessment schemes.
- KU12.** Adherence to safety protocols, handle hazardous materials appropriately, and comply with regulatory guidelines and safety standards
- KU13.** importance of maintaining a safe working environment for personnel and minimizing contamination risks
- KU14.** GMP principles and their application to the quality control analysis of biological products. This includes knowledge of documentation practices, traceability, equipment qualification, and adherence to quality standards.
- KU15.** 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





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- 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

## Qualification Pack

### Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Perform quality analysis</i>	<b>10</b>	<b>20</b>	<b>5</b>	<b>5</b>
<b>PC1.</b> secure the isolated samples for biological analysis	-	-	-	-
<b>PC2.</b> prepare the buffer, solvent solutions, and reagents for running quality tests	-	-	-	-
<b>PC3.</b> follow the instrument cleaning procedure and sequence available for the analysis before using the instrument	-	-	-	-
<b>PC4.</b> ensure raw materials, chemicals and reagents used in sterile quality analysis process are properly capped and stored according to specified conditions to avoid cross contamination	-	-	-	-
<b>PC5.</b> perform biopharmaceutical sample analysis using specified techniques as per written work instructions	-	-	-	-
<b>PC6.</b> create test plans, scripts, and cases necessary for testing projects	-	-	-	-
<b>PC7.</b> record, analyze, and document all the test observations and results	-	-	-	-
<b>PC8.</b> prepare quality reports for the analyzed samples	-	-	-	-
<b>PC9.</b> identify causes for out-of-specific biopharmaceutical products and then recommend changes by following CAPA to improve the quality	-	-	-	-
<b>PC10.</b> Keep all necessary documents and quality SOP's and Ultimately ensure final product quality	-	-	-	-
<i>Documentation</i>	<b>20</b>	<b>30</b>	<b>5</b>	<b>5</b>
<b>PC11.</b> perform documentation of the activities as per ALCOA principles	-	-	-	-



## Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<b>PC12.</b> record the required information of all significant activities, incidents, and deviations as per recording formats in compliance with SOP and ICH-GMP guidelines	-	-	-	-
<b>PC13.</b> identify corrective and preventive action (CAPA) for every incident and deviations in compliance with GMP and other regulatory guidelines	-	-	-	-
<b>PC14.</b> review and approve the change control request in case of deviations in consultation with QA and regulatory team	-	-	-	-
<b>PC15.</b> review and approve the logbook entries and trial run records	-	-	-	-
<b>PC16.</b> maintain online documentation related to production activities like BMRs, BPRs, log books, daily records and production SOP's as per GMP and GDP guidelines	-	-	-	-
<b>NOS Total</b>	<b>30</b>	<b>50</b>	<b>10</b>	<b>10</b>



## Qualification Pack

### National Occupational Standards (NOS) Parameters

<b>NOS Code</b>	LFS/N4106
<b>NOS Name</b>	Perform Quality Control analysis of Biological Products
<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Biotechnology, Pharmaceutical, Bio Pharmaceutical, Contract Research
<b>Occupation</b>	Biotechnology Production and Quality
<b>NSQF Level</b>	5
<b>Credits</b>	9
<b>Version</b>	1.0
<b>Last Reviewed Date</b>	NA
<b>Next Review Date</b>	03/05/2026
<b>NSQC Clearance Date</b>	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
<b>Total</b>	<b>80</b>	<b>135</b>	<b>12</b>	<b>23</b>	<b>250</b>	<b>40</b>

Elective: 1 Quality Control of Biological Products



### Qualification Pack

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N4106.Perform Quality Control analysis of Biological Products	30	50	10	10	100	60
<b>Total</b>	<b>30</b>	<b>50</b>	<b>10</b>	<b>10</b>	<b>100</b>	<b>60</b>