

## Qualification Pack



# Microbiologist-Quality Control

QP Code: LFS/Q0308

Version: 4.0

NSQF Level: 5.5

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## Qualification Pack

### Contents

LFS/Q0308: Microbiologist-Quality Control .....	3
<i>Brief Job Description</i> .....	3
Applicable National Occupational Standards (NOS) .....	3
<i>Compulsory NOS</i> .....	3
<i>Qualification Pack (QP) Parameters</i> .....	3
LFS/N0362: Discuss about Life Sciences industry and Basics of Quality Control .....	5
LFS/N0344: Perform checks in a microbiology lab before the start of the microbiological test .....	11
LFS/N0342: Perform test for microbial analysis in compliance with regulatory guideline .....	16
LFS/N0110: Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab .....	20
LFS/N0343: Perform reporting and documentation to meet quality and regulatory standards .....	26
LFS/N0302: Coordinate with Manager, colleagues and auditors .....	31
DGT/VSQ/N0103: Employability Skills (90 Hours) .....	36
Assessment Guidelines and Weightage .....	44
<i>Assessment Guidelines</i> .....	44
<i>Assessment Weightage</i> .....	45
Acronyms .....	47
Glossary .....	52



## Qualification Pack

### LFS/Q0308: Microbiologist-Quality Control

#### Brief Job Description

Microbiologist-Quality Control carries out various microbial analysis of raw materials and finished products in the quality control laboratory as per laid down methods and specifications and performs research work to support the development of new testing protocols. The person is responsible for preparing the documents for reporting the test results and ensures cGMP, GLP and workplace safety. The role holder also carries out the validation of testing protocols and sterilization methods used.

#### 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/N0362: Discuss about Life Sciences industry and Basics of Quality Control](#)
2. [LFS/N0344: Perform checks in a microbiology lab before the start of the microbiological test](#)
3. [LFS/N0342: Perform test for microbial analysis in compliance with regulatory guideline](#)
4. [LFS/N0110: Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab](#)
5. [LFS/N0343: Perform reporting and documentation to meet quality and regulatory standards](#)
6. [LFS/N0302: Coordinate with Manager, colleagues and auditors](#)
7. [DGT/VSQ/N0103: Employability Skills \(90 Hours\)](#)

#### Qualification Pack (QP) Parameters

<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceutical, Bio Pharmaceutical, Contract Research
<b>Occupation</b>	Quality
<b>Country</b>	India



## Qualification Pack

<b>NSQF Level</b>	5.5
<b>Credits</b>	18
<b>Aligned to NCO/ISCO/ISIC Code</b>	NCO 2015/ 2131.12, NCO-2015/2131.07
<b>Minimum Educational Qualification &amp; Experience</b>	UG in relevant field (Biochemistry/Biology/Chemistry/ Immunology/ Biomedical Science/ Biotechnology/ Microbiology) OR M.Sc (Biochemistry/Biology/Chemistry/ Immunology/ Biomedical Science/ Microbiology)
<b>Minimum Level of Education for Training in School</b>	
<b>Pre-Requisite License or Training</b>	NA
<b>Minimum Job Entry Age</b>	18 Years
<b>Last Reviewed On</b>	NA
<b>Next Review Date</b>	17/12/2027
<b>NSQC Approval Date</b>	17/12/2024
<b>Version</b>	4.0
<b>Reference code on NQR</b>	QG-5.5-LS-00264-2024-V2-LSSSDC
<b>NQR Version</b>	2.0



## Qualification Pack

# LFS/N0362: Discuss about Life Sciences industry and Basics of Quality Control

## Description

This NOS is about the introducing the Life Sciences industry and Basics of Quality Control

## Scope

The scope covers the following :

- Introduction to life sciences Industry
- Basics of Quality Control

## Elements and Performance Criteria

### *Introduction to life sciences industry*

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

- PC1.** Explain the principles of current Good Manufacturing Practices (cGMP), Good Laboratory Practices (GLP), and Good Documentation Practices (GDP) and their role in quality control in life sciences manufacturing.
- PC2.** Discuss the potential environmental impact of improper disposal of chemicals and non-compliance with environmental safety standards.
- PC3.** Explain the responsibilities of the QC Analyst in maintaining regulatory compliance and preventing non-conformance during product testing.
- PC4.** Use these QC terminologies appropriately to explain testing protocols and procedures in a quality control environment.

### *Basics of Quality Control*

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

- PC5.** Explain key quality principles (e.g., safety, consistency, efficacy) that are essential in life sciences manufacturing.
- PC6.** Describe the Quality by Design (QbD) approach and its significance in product development and manufacturing.
- PC7.** Explain how QbD principles help in identifying critical quality attributes (CQA) and mitigating risks through Quality Risk Management (QRM).
- PC8.** Perform measurements and apply mathematical and statistical concepts (e.g., precision, accuracy, standard deviation) in quality control.
- PC9.** Explain methods of preserving samples to avoid contamination or degradation, ensuring accurate analysis.
- PC10.** Demonstrate awareness of emergency procedures (e.g., spill management, first aid) for hazardous substance exposure.
- PC11.** perform correct labeling and storage practices in alignment with safety regulations.

## Knowledge and Understanding (KU)



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The individual on the job needs to know and understand:

- KU1.** quality principles and concepts applied in life sciences sector
- KU2.** types of tests performed in quality control lab for various formulations, API and packaging material
- KU3.** legal and regulatory frameworks relevant to the quality control and further implications of failing to comply
- KU4.** measurement units and mathematical and statistical concepts
- KU5.** relevant regulatory guidelines along with ICH-GMP, GLP, Schedule M, NABL and WHO guidelines etc.
- KU6.** properties of reagents, solvents and hazardous chemicals, incompatibility of chemicals, hazards and storage procedures, safe storage of chemicals as per hazard classification
- KU7.** sample handling, processing and preservation procedures
- KU8.** handling procedures of hazardous and poisonous substances
- KU9.** pharmacopoeia and application of standards
- KU10.** interaction of environmental factors(Light, Temperature & Humidity) with sample matter
- KU11.** operating procedure of Lab Information Management System
- KU12.** operating procedure of analytical instruments and equipment
- KU13.** guidelines for change control management, Standard Testing Procedures(STP), protocols, equipment qualification documents, method development, and validation protocols
- KU14.** interpretation of graphs from analytical instruments and tests
- KU15.** 5S and design of quality control lab to enhance efficiency and effectiveness
- KU16.** concepts of data integrity and ALCOA PLUS
- KU17.** procedure for instrument calibration, instrument accuracy test and importance of preventive maintenance
- KU18.** procedures for laboratory investigations and validation tests performed in QC lab of life sciences sector

## Generic Skills (GS)

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

- GS1.** use written communication skills to record information accurately in compliance with ALCOA principles as per SOP and GMP guidelines in the English language
- GS2.** use reading and comprehension skills to read the various coding systems, instructions, guidelines, procedures, rules, and signages
- GS3.** use listening skills to understand the instructions, escalation matrix, procedures to be followed and to seek clarifications
- GS4.** use verbal communication skills to interact with teammates, researchers, assistants, lab in charge and cross functional teams
- GS5.** use team-building skills while interacting with teammates
- GS6.** apply problem-solving skills to find solutions for workflow-related difficulties using concepts of basic sciences (chemistry), mathematics, statistics



### Qualification Pack

- GS7.** apply planning and organizing skills to plan and organize tools and material required to fulfil own work requirements in timely manner
- GS8.** apply critical thinking skills to analyze and identify when to report an issue/concern to the lab in charge
- GS9.** apply analytical skills to observe laboratory investigations and identify OOS/ OOT/ deviations/ abnormal incidents
- GS10.** apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations



## Qualification Pack

### Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Introduction to life sciences industry</i>	<b>20</b>	-	<b>5</b>	<b>5</b>
<b>PC1.</b> Explain the principles of current Good Manufacturing Practices (cGMP), Good Laboratory Practices (GLP), and Good Documentation Practices (GDP) and their role in quality control in life sciences manufacturing.	-	-	-	-
<b>PC2.</b> Discuss the potential environmental impact of improper disposal of chemicals and non-compliance with environmental safety standards.	-	-	-	-
<b>PC3.</b> Explain the responsibilities of the QC Analyst in maintaining regulatory compliance and preventing non-conformance during product testing.	-	-	-	-
<b>PC4.</b> Use these QC terminologies appropriately to explain testing protocols and procedures in a quality control environment.	-	-	-	-
<i>Basics of Quality Control</i>	<b>20</b>	<b>30</b>	<b>10</b>	<b>10</b>
<b>PC5.</b> Explain key quality principles (e.g., safety, consistency, efficacy) that are essential in life sciences manufacturing.	-	-	-	-
<b>PC6.</b> Describe the Quality by Design (QbD) approach and its significance in product development and manufacturing.	-	-	-	-
<b>PC7.</b> Explain how QbD principles help in identifying critical quality attributes (CQA) and mitigating risks through Quality Risk Management (QRM).	-	-	-	-
<b>PC8.</b> Perform measurements and apply mathematical and statistical concepts (e.g., precision, accuracy, standard deviation) in quality control.	-	-	-	-
<b>PC9.</b> Explain methods of preserving samples to avoid contamination or degradation, ensuring accurate analysis.	-	-	-	-





## Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<b>PC10.</b> Demonstrate awareness of emergency procedures (e.g., spill management, first aid) for hazardous substance exposure.	-	-	-	-
<b>PC11.</b> perform correct labeling and storage practices in alignment with safety regulations.	-	-	-	-
<b>NOS Total</b>	<b>40</b>	<b>30</b>	<b>15</b>	<b>15</b>



## Qualification Pack

### National Occupational Standards (NOS) Parameters

<b>NOS Code</b>	LFS/N0362
<b>NOS Name</b>	Discuss about Life Sciences industry and Basics of Quality Control
<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceutical, Bio Pharmaceutical, Contract Research
<b>Occupation</b>	Quality
<b>NSQF Level</b>	5
<b>Credits</b>	1.00
<b>Version</b>	1.0
<b>Last Reviewed Date</b>	17/12/2024
<b>Next Review Date</b>	17/12/2027
<b>NSQC Clearance Date</b>	17/12/2024



## Qualification Pack

### LFS/N0344: Perform checks in a microbiology lab before the start of the microbiological test

#### Description

This NOS is about Microbiologist conducting routine checks in the microbiology lab before the start of microbial analysis

#### Scope

The scope covers the following :

- Laboratory-specific routine checks
- Environment Sustainability

#### Elements and Performance Criteria

##### *Laboratory-specific routine checks*

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

- PC1.** ensure the use of PPE before entering the lab and follow cleanroom behaviour
- PC2.** ensure that all reagents (including stock solutions), media, diluents and other suspending fluids are adequately labelled to indicate the identity, concentration, storage conditions, preparation date, validated expiry date and/or recommended storage period
- PC3.** provide clear instructions to wet lab analyst/lab technician for performing different activities in the microbiology laboratory
- PC4.** conduct regular checks for lab equipment and instrument for their calibration and validation state
- PC5.** ensure out of order/ non calibrated/ non validated equipment are labelled and segregated for maintenance
- PC6.** ensure to minimize the risks of cross-contamination, false-positive and false-negative results
- PC7.** maintain positive and negative controls during testing as per defined action limits
- PC8.** ensure aseptic conditions are maintained in the testing area
- PC9.** ensure logbook entries of all the test performed are done as per SOP

##### *Environment Sustainability*

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

- PC10.** ensure energy conservation by switching off the machine and equipment post operations
- PC11.** identify ways to optimize the usage of electricity/energy in various tasks/activities/processes
- PC12.** ensure energy conservation by optimizing the machine/ equipment performance
- PC13.** identify recyclable and non-recyclable, and hazardous waste generated
- PC14.** segregate waste into different categories to achieve minimum pollution of land and water

#### Knowledge and Understanding (KU)

The individual on the job needs to know and understand:



## Qualification Pack

- KU1.** the different PPE and their use in the microbiology lab
- KU2.** the different quality management systems (ISO-9000, OHSAS-18000, etc.), good laboratory and manufacturing practices
- KU3.** the organizational coding system of different material and equipment
- KU4.** the quality specifications and policy of the company
- KU5.** the environment sustainability guidelines
- KU6.** the levels of hygiene required for the workplace and the importance of maintaining the same
- KU7.** the current guidelines of Good Manufacturing Practices (cGMP) and Good Laboratory Practices (GLP)
- KU8.** the escalation procedures for soils or stains that could not be removed
- KU9.** the standard limits of positive and negative control
- KU10.** the requirements for sterility testing
- KU11.** the properties of reagents, solvents and hazardous chemicals and their storage conditions
- KU12.** the procedure for reporting incidents where standard operating procedures are not followed
- KU13.** the importance of decontamination, cleaning and sterilization procedures
- KU14.** the different sterilization protocols
- KU15.** the units of measurement of temperature, humidity and pressure
- KU16.** worksheets, logbooks, date and time formats to be followed in a microbiology laboratory

## 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 problem-solving skills in dealing with any deviation from SOPs and day-to-day problems
- GS3.** apply critical thinking skills to analyze and identify when to report an issue/concern to the lab in charge
- GS4.** 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
- GS5.** 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

## Qualification Pack

### Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Laboratory-specific routine checks</i>	<b>15</b>	<b>30</b>	<b>10</b>	<b>5</b>
<b>PC1.</b> ensure the use of PPE before entering the lab and follow cleanroom behaviour	-	-	-	-
<b>PC2.</b> ensure that all reagents (including stock solutions), media, diluents and other suspending fluids are adequately labelled to indicate the identity, concentration, storage conditions, preparation date, validated expiry date and/or recommended storage period	-	-	-	-
<b>PC3.</b> provide clear instructions to wet lab analyst/lab technician for performing different activities in the microbiology laboratory	-	-	-	-
<b>PC4.</b> conduct regular checks for lab equipment and instrument for their calibration and validation state	-	-	-	-
<b>PC5.</b> ensure out of order/ non calibrated/ non validated equipment are labelled and segregated for maintenance	-	-	-	-
<b>PC6.</b> ensure to minimize the risks of cross-contamination, false-positive and false-negative results	-	-	-	-
<b>PC7.</b> maintain positive and negative controls during testing as per defined action limits	-	-	-	-
<b>PC8.</b> ensure aseptic conditions are maintained in the testing area	-	-	-	-
<b>PC9.</b> ensure logbook entries of all the test performed are done as per SOP	-	-	-	-
<i>Environment Sustainability</i>	<b>10</b>	<b>20</b>	<b>5</b>	<b>5</b>
<b>PC10.</b> ensure energy conservation by switching off the machine and equipment post operations	-	-	-	-
<b>PC11.</b> identify ways to optimize the usage of electricity/energy in various tasks/activities/processes	-	-	-	-



## Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<b>PC12.</b> ensure energy conservation by optimizing the machine/ equipment performance	-	-	-	-
<b>PC13.</b> identify recyclable and non-recyclable, and hazardous waste generated	-	-	-	-
<b>PC14.</b> segregate waste into different categories to achieve minimum pollution of land and water	-	-	-	-
<b>NOS Total</b>	<b>25</b>	<b>50</b>	<b>15</b>	<b>10</b>



## Qualification Pack

### National Occupational Standards (NOS) Parameters

<b>NOS Code</b>	LFS/N0344
<b>NOS Name</b>	Perform checks in a microbiology lab before the start of the microbiological test
<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceutical, Bio Pharmaceutical
<b>Occupation</b>	Quality
<b>NSQF Level</b>	5.5
<b>Credits</b>	4.00
<b>Version</b>	3.0
<b>Last Reviewed Date</b>	17/12/2024
<b>Next Review Date</b>	17/12/2027
<b>NSQC Clearance Date</b>	17/12/2024





## Qualification Pack

### LFS/N0342: Perform test for microbial analysis in compliance with regulatory guideline

#### Description

This NOS is about a Microbiologist performing different microbiological test for analysis and research work to support the development of new testing protocols

#### Scope

The scope covers the following :

- Perform microbiological test's analysis
- Support in R&D activities

#### Elements and Performance Criteria

##### *Perform microbiological analysis test*

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

- PC1.** prepare culture/media for microbiological analysis of the samples and maintain standard cultures
- PC2.** perform microbial isolation, plate pouring, serial dilutions and screening of microbes
- PC3.** perform sample-specific microbial tests for detection of different microorganisms in samples
- PC4.** identify microorganisms and monitor their growth/colonies in the sample
- PC5.** record the observations of performed tests
- PC6.** prepare inspection reports of the microbial tests performed
- PC7.** identify the reason for unwanted growth of microorganisms and check for OOT and OOS samples and take corrective and preventive actions (CAPA)

##### *Support in R&D activities*

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

- PC8.** perform the literature search for culture/media development for different microbial strains
- PC9.** record the observations of microbial growth
- PC10.** present research analysis to the R&D team and support in the development of new testing protocols

#### Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** the different microbial culture media used
- KU2.** the different microorganisms and their standard detection limits
- KU3.** the basic techniques, e.g. counting of colonies, plate pouring, serial dilutions, etc.
- KU4.** the importance of complete and accurate documentation
- KU5.** the use and working principle of BOD incubators, laminar air flows, autoclaves, etc.



## Qualification Pack

- KU6.** the units of measurement of microbial growth
- KU7.** the different chemical and reagents used in microbiology laboratories and their storage conditions
- KU8.** the optimum growth conditions for different microorganisms
- KU9.** the method and importance of containment of microorganisms within the laboratory facility
- KU10.** the different microbial analysis tests like endotoxin test, sterility and non-sterility tests
- KU11.** the different scientific literature search tools
- KU12.** how to develop new testing protocols
- KU13.** the optimum growth conditions for different microorganisms

## Generic Skills (GS)

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

- GS1.** use reading and comprehending skills to read and understand manuals, SOPs, health and safety instructions
- GS2.** use written communication skills to draft reports or electronic mails to communicate the details of work done to appropriate people
- GS3.** use problem-solving skills in dealing with any deviation from SOPs and day-today problems
- GS4.** apply critical thinking skills to analyze and identify when to report an issue/concern to the lab in charge
- GS5.** apply problem-solving skills to find solutions for workflow-related difficulties using concepts of basic sciences (chemistry), mathematics, statistics
- GS6.** use planning and organizing skills in every activity planned and performed in production operations and to achieve resource optimization
- GS7.** apply analytical skill to observe and identify OOS/ OOT/ deviations in the process
- GS8.** apply decision making skills to take balanced judgments within the authority while dealing with daily work-life situations

## Qualification Pack

### Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Perform microbiological analysis test</i>	<b>15</b>	<b>30</b>	<b>10</b>	<b>5</b>
<b>PC1.</b> prepare culture/media for microbiological analysis of the samples and maintain standard cultures	-	-	-	-
<b>PC2.</b> perform microbial isolation, plate pouring, serial dilutions and screening of microbes	-	-	-	-
<b>PC3.</b> perform sample-specific microbial tests for detection of different microorganisms in samples	-	-	-	-
<b>PC4.</b> identify microorganisms and monitor their growth/colonies in the sample	-	-	-	-
<b>PC5.</b> record the observations of performed tests	-	-	-	-
<b>PC6.</b> prepare inspection reports of the microbial tests performed	-	-	-	-
<b>PC7.</b> identify the reason for unwanted growth of microorganisms and check for OOT and OOS samples and take corrective and preventive actions (CAPA)	-	-	-	-
<i>Support in R&amp;D activities</i>	<b>10</b>	<b>20</b>	<b>5</b>	<b>5</b>
<b>PC8.</b> perform the literature search for culture/media development for different microbial strains	-	-	-	-
<b>PC9.</b> record the observations of microbial growth	-	-	-	-
<b>PC10.</b> present research analysis to the R&D team and support in the development of new testing protocols	-	-	-	-
<b>NOS Total</b>	<b>25</b>	<b>50</b>	<b>15</b>	<b>10</b>



## Qualification Pack

### National Occupational Standards (NOS) Parameters

<b>NOS Code</b>	LFS/N0342
<b>NOS Name</b>	Perform test for microbial analysis in compliance with regulatory guideline
<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceutical, Bio Pharmaceutical
<b>Occupation</b>	Quality
<b>NSQF Level</b>	5.5
<b>Credits</b>	6.00
<b>Version</b>	3.0
<b>Last Reviewed Date</b>	17/12/2024
<b>Next Review Date</b>	17/12/2027
<b>NSQC Clearance Date</b>	17/12/2024



## Qualification Pack

### LFS/N0110: Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab

#### Description

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

#### Scope

The scope covers the following :

- Adhere to health and hygiene protocols
- Adhere to safety and security procedures
- Adhere to emergency procedures

#### Elements and Performance Criteria

##### *Adhere to 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.** sanitize your hands before entering in laboratory and production area and ensure the adherence of same by subordinates as per SOP
- 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 by subordinates
- PC5.** wear lab coat all the time while working in a laboratory and ensure adherence of the same by every person visiting/ working in the lab area
- PC6.** follow gowning procedures while entering an environment controlled work area and ensure the adherence of the same by subordinates

##### *Adhere to safety and security procedures*

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

- PC7.** observe compliance by self and subordinates with safety and security policies and procedures
- PC8.** 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
- PC9.** use helmets, ropes, harness, and ladders while working at heights
- PC10.** use pulleys/ forklift (if available) to transport the material/ spares/ heavy assembly and tools
- PC11.** take preventive and corrective actions on the report of any identified breaches in safety and security policies and procedures by subordinates
- PC12.** segregate material and follow the 5S system at the storage area as per cGMP
- PC13.** adhere to storage and handling guidelines for hazardous material



## Qualification Pack

- PC14.** supervise the disposal of waste/unused and expired reagents/ chemicals / biological waste using environmentally sustainable methods in the presence of EHS personnel
- PC15.** identify and correct any hazards that one can deal with safely, competently and within the limits of authority in consultation with EHS personnel
- PC16.** complete record the details of completed safety drills and training undertaken by self and subordinates

### *Adhere to emergency procedures*

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

- PC17.** raise the alarm and report any hazards that one is not competent to deal with, to the relevant person in line with organizational procedures and warn other people who may be affected
- PC18.** follow emergency protocol for any alarms and ensure the safety of subordinates in the area under supervision
- PC19.** follow emergency procedures efficiently
- PC20.** 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.** relevant legislative requirements and company's procedures for the environment, health and safety and individual's role and responsibilities in relation to this
- KU2.** implications that any non-compliance with health, safety and security may have on individuals and the organization
- KU3.** how and when to report workplace hazards in the manufacturing facility in the life sciences sector
- KU4.** limits of individual responsibility for dealing with hazards
- KU5.** chemical substances, their characteristics, and required precautions and safety measures
- KU6.** gowning procedure in life sciences facility
- KU7.** the organization's procedures for different emergency situations 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.** types of safety gears and procedure to use them
- KU14.** 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:



## Qualification Pack

- GS1.** use written communication skills to record information accurately in compliance with ALCOA principles as per SOP and GMP guidelines in the English language
- GS2.** use reading and comprehension skills to read the various coding systems, instructions, guidelines, procedures, rules, and signages
- GS3.** use listening skills to understand the instructions, procedures and alarms
- GS4.** use verbal communication skills to interact with teammates, lab in charge and cross functional teams to communicate hazards, safety instructions and accidents
- GS5.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS6.** apply planning and organizing skills to plan and organize tools and material required for work to fulfil environment, health, safety and security requirements
- GS7.** apply critical thinking skills to analyze and identify when to report an issue/concern to the lab in charge and when to deal with a colleague individually, depending on the type of concern
- GS8.** use critical thinking skills to ascertain the breach/ compliance of EHS protocols
- GS9.** apply customer-centricity to remain compliant with data integrity rules, cGMP guidelines and to evaluate the impact of errors
- GS10.** apply decision making skills to make balanced judgments within the authority to different situations while dealing with hazards and breaches



## Qualification Pack

### Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Adhere to 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> sanitize your hands before entering in laboratory and production area and ensure the adherence of same by subordinates as per SOP	-	-	-	-
<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 by subordinates	-	-	-	-
<b>PC5.</b> wear lab coat all the time while working in a laboratory and ensure adherence of the same by every person visiting/ working in the lab area	-	-	-	-
<b>PC6.</b> follow gowning procedures while entering an environment controlled work area and ensure the adherence of the same by subordinates	-	-	-	-
<i>Adhere to safety and security procedures</i>	<b>10</b>	<b>25</b>	-	<b>5</b>
<b>PC7.</b> observe compliance by self and subordinates with safety and security policies and procedures	-	-	-	-
<b>PC8.</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>PC9.</b> use helmets, ropes, harness, and ladders while working at heights	-	-	-	-
<b>PC10.</b> use pulleys/ forklift (if available) to transport the material/ spares/ heavy assembly and tools	-	-	-	-
<b>PC11.</b> take preventive and corrective actions on the report of any identified breaches in safety and security policies and procedures by subordinates	-	-	-	-

### Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<b>PC12.</b> segregate material and follow the 5S system at the storage area as per cGMP	-	-	-	-
<b>PC13.</b> adhere to storage and handling guidelines for hazardous material	-	-	-	-
<b>PC14.</b> supervise the disposal of waste/unused and expired reagents/ chemicals / biological waste using environmentally sustainable methods in the presence of EHS personnel	-	-	-	-
<b>PC15.</b> identify and correct any hazards that one can deal with safely, competently and within the limits of authority in consultation with EHS personnel	-	-	-	-
<b>PC16.</b> complete record the details of completed safety drills and training undertaken by self and subordinates	-	-	-	-
<i>Adhere to emergency procedures</i>	<b>10</b>	<b>15</b>	-	<b>5</b>
<b>PC17.</b> raise the alarm and report any hazards that one is not competent to deal with, to the relevant person in line with organizational procedures and warn other people who may be affected	-	-	-	-
<b>PC18.</b> follow emergency protocol for any alarms and ensure the safety of subordinates in the area under supervision	-	-	-	-
<b>PC19.</b> follow emergency procedures efficiently	-	-	-	-
<b>PC20.</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>



## Qualification Pack

### National Occupational Standards (NOS) Parameters

<b>NOS Code</b>	LFS/N0110
<b>NOS Name</b>	Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab
<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>	1.00
<b>Version</b>	3.0
<b>Last Reviewed Date</b>	17/12/2024
<b>Next Review Date</b>	17/12/2027
<b>NSQC Clearance Date</b>	17/12/2024



## Qualification Pack

### LFS/N0343: Perform reporting and documentation to meet quality and regulatory standards

#### Description

This NOS unit is about Microbiologist carrying out reporting and documentation to meet quality standards and ensure that the final documents comply with regulatory requirements

#### Scope

The scope covers the following :

- Reporting
- Recording and documentation
- Information Security

#### Elements and Performance Criteria

##### Reporting

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

- PC1.** report defects/problem/incidents/quality issues/test results as applicable in a timely manner to the appropriate authority as per SOP
- PC2.** prepare analytical reports for detailed findings and recommendations as per SOPs
- PC3.** work with production management and quality assurance to provide feedback regarding quality standards and issues
- PC4.** help other R&D lab staff with any other testing required during the developmental work

##### Recording and documentation

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

- PC5.** identify documentation to be completed relating to one's role
- PC6.** record details accurately in an appropriate format
- PC7.** maintain all controlled document files and test records in a timely and accurate manner as per cGMP/ global MDR Guidelines
- PC8.** ensure that the final document meets regulatory and compliance requirements
- PC9.** make sure documents are available to all appropriate authorities to inspect
- PC10.** evaluate problems in the test reports and make initial recommendations for possible corrective action to supervise
- PC11.** perform a review of records and other documentation for compliance to established procedures and good documentation practices
- PC12.** write and update the inspection procedures, protocols, and checklists
- PC13.** prepare inspection reports as per the inspection activity performed

##### Information Security

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

- PC14.** document the results of the testing and analysis accurately



## Qualification Pack

- PC15.** maintain all original and controlled document files and quality records in a timely and accurate manner following ALCOA PLUS principles
- PC16.** respond to requests for information in an appropriate manner whilst following organizational procedures
- PC17.** make sure documents are available to all appropriate authorities to inspect/ audit

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** the types of documentation in an organization and the importance of maintaining the same and different methods of recording information
- KU2.** the reporting and recording formats
- KU3.** the importance of reporting incidents where standard operating procedures are not followed
- KU4.** the importance of complete and accurate documentation
- KU5.** the escalation matrix for reporting identified issues, hazards and breakage
- KU6.** the ALCOA PLUS Principles
- KU7.** the Good Documentation Practices
- KU8.** how to use lab information management system and software applications like MS Office
- KU9.** the guidelines for Electronic Records & Electronic Signatures, Audit Trails, Date and Time Stamps, Data Integrity in life sciences sector

## Generic Skills (GS)

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

- GS1.** use written communication skills to record accurately, legibly and clearly every information required to be reported as per SOP and GMP guidelines in English language
- GS2.** use written communication skills to maintain proper and concise records as per given format and compliant with ALCOA principle
- GS3.** use reading and comprehension skills to understand the various coding systems and to read instructions, guidelines, procedures, rules, and signage to understand the procedure to be followed
- GS4.** use listening skills to understand the instructions and procedures to be followed
- GS5.** use verbal communication skills to interact with supervisor, teammates, cross-functional teams for coordination and to communicate confidential and sensitive information discretely to the authorized person
- GS6.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS7.** apply planning and organizing skills to plan and organize tools and material required to fulfil documentation related requirements
- GS8.** apply customer-centricity while interacting with different stakeholders

## Qualification Pack

### Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Reporting</i>	<b>10</b>	<b>15</b>	<b>5</b>	<b>5</b>
<b>PC1.</b> report defects/problem/incidents/quality issues/test results as applicable in a timely manner to the appropriate authority as per SOP	-	-	-	-
<b>PC2.</b> prepare analytical reports for detailed findings and recommendations as per SOPs	-	-	-	-
<b>PC3.</b> work with production management and quality assurance to provide feedback regarding quality standards and issues	-	-	-	-
<b>PC4.</b> help other R&D lab staff with any other testing required during the developmental work	-	-	-	-
<i>Recording and documentation</i>	<b>10</b>	<b>15</b>	<b>5</b>	<b>5</b>
<b>PC5.</b> identify documentation to be completed relating to one's role	-	-	-	-
<b>PC6.</b> record details accurately in an appropriate format	-	-	-	-
<b>PC7.</b> maintain all controlled document files and test records in a timely and accurate manner as per cGMP/ global MDR Guidelines	-	-	-	-
<b>PC8.</b> ensure that the final document meets regulatory and compliance requirements	-	-	-	-
<b>PC9.</b> make sure documents are available to all appropriate authorities to inspect	-	-	-	-
<b>PC10.</b> evaluate problems in the test reports and make initial recommendations for possible corrective action to supervise	-	-	-	-
<b>PC11.</b> perform a review of records and other documentation for compliance to established procedures and good documentation practices	-	-	-	-
<b>PC12.</b> write and update the inspection procedures, protocols, and checklists	-	-	-	-



## Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<b>PC13.</b> prepare inspection reports as per the inspection activity performed	-	-	-	-
<i>Information Security</i>	<b>10</b>	<b>15</b>	<b>3</b>	<b>2</b>
<b>PC14.</b> document the results of the testing and analysis accurately	-	-	-	-
<b>PC15.</b> maintain all original and controlled document files and quality records in a timely and accurate manner following ALCOA PLUS principles	-	-	-	-
<b>PC16.</b> respond to requests for information in an appropriate manner whilst following organizational procedures	-	-	-	-
<b>PC17.</b> make sure documents are available to all appropriate authorities to inspect/ audit	-	-	-	-
<b>NOS Total</b>	<b>30</b>	<b>45</b>	<b>13</b>	<b>12</b>





## Qualification Pack

### National Occupational Standards (NOS) Parameters

<b>NOS Code</b>	LFS/N0343
<b>NOS Name</b>	Perform reporting and documentation to meet quality and regulatory standards
<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceutical, Bio Pharmaceutical
<b>Occupation</b>	Quality
<b>NSQF Level</b>	5.5
<b>Credits</b>	1.00
<b>Version</b>	3.0
<b>Last Reviewed Date</b>	17/12/2024
<b>Next Review Date</b>	17/12/2027
<b>NSQC Clearance Date</b>	17/12/2024



## Qualification Pack

### LFS/N0302: Coordinate with Manager, colleagues and auditors

#### Description

This NOS unit is about the job holder coordinating with the manager, colleagues, and auditors

#### Scope

The scope covers the following :

- Coordination with manager
- Coordination with colleagues and auditors
- 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
- PC2.** communicate to reporting supervisor about process-flow improvements, production defects received from the previous process, repairs and maintenance of equipment as required
- PC3.** communicate deviations / abnormal incidents to the reporting manager
- PC4.** communicate any potential hazards or expected process disruptions to the manager

##### *Coordination with colleagues and auditors*

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

- PC5.** support team members and colleagues of other departments in work
- PC6.** train lab assistants and trainees
- PC7.** find solutions to workflow related difficulties with mutual agreement
- PC8.** coordinate with QA for audit related documentation for QC analysis
- PC9.** maintain sense of calm/equilibrium in self as well as team members
- PC10.** provide appropriate answers to the auditor's queries
- PC11.** produce the documented records of performed activities and operations to auditors
- PC12.** 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:

- PC13.** respect all genders, religions, and caste
- PC14.** empathize with the people with disability
- PC15.** offer support or help to a person with disability only when asked
- PC16.** ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act
- PC17.** report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee



## Qualification Pack

### Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** company's policies on preferred language of communication, reporting and escalation policy, quality delivery standards, and personnel management
- KU2.** importance of team building skills
- KU3.** stress management strategies to be applied within teams
- KU4.** the types of possible disabilities among people with disability (PwD)
- KU5.** the challenges faced by PwD
- KU6.** the importance of displaying empathy towards PwD
- KU7.** the right way to use the laws acts, and provisions defined for PwD by the statutory bodies
- KU8.** the guidelines laid on Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act
- KU9.** importance of respecting all gender identities, religion, caste, and culture
- KU10.** how to develop a collaborative culture for cross-culture and gender-inclusive team

### Generic Skills (GS)

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

- GS1.** use written communication skills to record information accurately in compliance with ALCOA principles as per SOP and cGMP guidelines in the English language
- GS2.** use reading and comprehension skills to read the various coding systems, instructions, guidelines, procedures, rules, and signages
- GS3.** use listening skills to understand the instructions and procedures to be followed
- GS4.** use verbal communication skills to interact with colleagues effectively
- GS5.** use team-building skills while interacting with teammates and while managing the difficult/stressful or emotional situations at work
- GS6.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS7.** apply planning and organizing skills to plan and organize tools and material required to fulfil work requirements
- GS8.** apply critical thinking skills to analyze and identify when to report an issue/concern to the lab in charge and when to deal with a colleague individually, depending on the type of concern
- GS9.** apply customer-centricity to remain compliant with data integrity rules, cGMP/GLP guidelines and to evaluate the impact of wrongdoings
- GS10.** apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations with clear choices and written instructions

## 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>20</b>	-	<b>5</b>
<b>PC1.</b> coordinate with the reporting manager to obtain work instructions	-	-	-	-
<b>PC2.</b> communicate to reporting supervisor about process-flow improvements, production defects received from the previous process, repairs and maintenance of equipment as required	-	-	-	-
<b>PC3.</b> communicate deviations / abnormal incidents to the reporting manager	-	-	-	-
<b>PC4.</b> communicate any potential hazards or expected process disruptions to the manager	-	-	-	-
<i>Coordination with colleagues and auditors</i>	<b>15</b>	<b>25</b>	-	<b>5</b>
<b>PC5.</b> support team members and colleagues of other departments in work	-	-	-	-
<b>PC6.</b> train lab assistants and trainees	-	-	-	-
<b>PC7.</b> find solutions to workflow related difficulties with mutual agreement	-	-	-	-
<b>PC8.</b> coordinate with QA for audit related documentation for QC analysis	-	-	-	-
<b>PC9.</b> maintain sense of calm/equilibrium in self as well as team members	-	-	-	-
<b>PC10.</b> provide appropriate answers to the auditor's queries	-	-	-	-
<b>PC11.</b> produce the documented records of performed activities and operations to auditors	-	-	-	-
<b>PC12.</b> maintain data integrity while responding to auditors and regulatory inspectors	-	-	-	-
<i>Sensitivity towards all genders and people with disability</i>	<b>10</b>	<b>10</b>	-	-
<b>PC13.</b> respect all genders, religions, and caste	-	-	-	-



## Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<b>PC14.</b> empathize with the people with disability	-	-	-	-
<b>PC15.</b> offer support or help to a person with disability only when asked	-	-	-	-
<b>PC16.</b> ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act	-	-	-	-
<b>PC17.</b> report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee	-	-	-	-
<b>NOS Total</b>	<b>35</b>	<b>55</b>	<b>-</b>	<b>10</b>



## Qualification Pack

### National Occupational Standards (NOS) Parameters

<b>NOS Code</b>	LFS/N0302
<b>NOS Name</b>	Coordinate with Manager, colleagues and auditors
<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceutical, Bio Pharmaceutical
<b>Occupation</b>	Quality
<b>NSQF Level</b>	5
<b>Credits</b>	2.00
<b>Version</b>	4.0
<b>Last Reviewed Date</b>	17/12/2024
<b>Next Review Date</b>	17/12/2027
<b>NSQC Clearance Date</b>	17/12/2024



## Qualification Pack

### DGT/VSQ/N0103: Employability Skills (90 Hours)

#### Description

This unit is about employability skills, Constitutional values, becoming a professional in the 21st Century, digital, financial, and legal literacy, diversity and Inclusion, English and communication skills, customer service, entrepreneurship, and apprenticeship, getting ready for jobs and career development.

#### Scope

The scope covers the following :

- Introduction to Employability Skills
- Constitutional values - Citizenship
- Becoming a Professional in the 21st Century
- Basic English Skills
- Career Development & Goal Setting
- Communication Skills
- Diversity & Inclusion
- Financial and Legal Literacy
- Essential Digital Skills
- Entrepreneurship
- Customer Service
- Getting ready for Apprenticeship & Jobs

#### Elements and Performance Criteria

##### *Introduction to Employability Skills*

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

- PC1.** understand the significance of employability skills in meeting the current job market requirement and future of work
- PC2.** identify and explore learning and employability relevant portals
- PC3.** research about the different industries, job market trends, latest skills required and the available opportunities

##### *Constitutional values – Citizenship*

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

- PC4.** recognize the significance of constitutional values, including civic rights and duties, citizenship, responsibility towards society etc. and personal values and ethics such as honesty, integrity, caring and respecting others, etc.
- PC5.** follow environmentally sustainable practices

##### *Becoming a Professional in the 21st Century*

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

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



## Qualification Pack

- PC7.** practice the 21st Century Skills such as Self-Awareness, Behaviour Skills, time management, critical and adaptive thinking, problem-solving, creative thinking, social and cultural awareness, emotional awareness, learning to learn for continuous learning etc. in personal and professional life
- PC8.** adopt a continuous learning mindset for personal and professional development

### *Basic English Skills*

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

- PC9.** use basic English for everyday conversation in different contexts, in person and over the telephone
- PC10.** read and understand routine information, notes, instructions, mails, letters etc. written in English
- PC11.** write short messages, notes, letters, e-mails etc. in English

### *Career Development & Goal Setting*

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

- PC12.** identify career goals based on the skills, interests, knowledge, and personal attributes
- PC13.** prepare a career development plan with short- and long-term goals

### *Communication Skills*

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

- PC14.** follow verbal and non-verbal communication etiquette while communicating in professional and public settings
- PC15.** use active listening techniques for effective communication
- PC16.** communicate in writing using appropriate style and format based on formal or informal requirements
- PC17.** work collaboratively with others in a team

### *Diversity & Inclusion*

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

- PC18.** communicate and behave appropriately with all genders and PwD
- PC19.** escalate any issues related to sexual harassment at workplace according to POSH Act

### *Financial and Legal Literacy*

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

- PC20.** identify and select reliable institutions for various financial products and services such as bank account, debit and credit cards, loans, insurance etc.
- PC21.** carry out offline and online financial transactions, safely and securely, using various methods and check the entries in the passbook
- PC22.** identify common components of salary and compute income, expenses, taxes, investments etc
- PC23.** identify relevant rights and laws and use legal aids to fight against legal exploitation

### *Essential Digital Skills*

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

- PC24.** operate digital devices and use their features and applications securely and safely
- PC25.** carry out basic internet operations by connecting to the internet safely and securely, using the mobile data or other available networks through Bluetooth, Wi-Fi, etc.
- PC26.** display responsible online behaviour while using various social media platforms





## Qualification Pack

- PC27.** create a personal email account, send and process received messages as per requirement
- PC28.** carry out basic procedures in documents, spreadsheets and presentations using respective and appropriate applications
- PC29.** utilize virtual collaboration tools to work effectively

### *Entrepreneurship*

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

- PC30.** identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research
- PC31.** develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion
- PC32.** identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity

### *Customer Service*

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

- PC33.** identify different types of customers and ways to communicate with them
- PC34.** identify and respond to customer requests and needs in a professional manner
- PC35.** use appropriate tools to collect customer feedback
- PC36.** follow appropriate hygiene and grooming standards

### *Getting ready for apprenticeship & Jobs*

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

- PC37.** create a professional Curriculum vitae (Résumé)
- PC38.** search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively
- PC39.** apply to identified job openings using offline /online methods as per requirement
- PC40.** answer questions politely, with clarity and confidence, during recruitment and selection
- PC41.** identify apprenticeship opportunities and register for it as per guidelines and requirements

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** need for employability skills and different learning and employability related portals
- KU2.** various constitutional and personal values
- KU3.** different environmentally sustainable practices and their importance
- KU4.** Twenty first (21st) century skills and their importance
- KU5.** how to use English language for effective verbal (face to face and telephonic) and written communication in formal and informal set up
- KU6.** importance of career development and setting long- and short-term goals
- KU7.** about effective communication
- KU8.** POSH Act
- KU9.** Gender sensitivity and inclusivity
- KU10.** different types of financial institutes, products, and services



## Qualification Pack

- KU11.** components of salary and how to compute income and expenditure
- KU12.** importance of maintaining safety and security in offline and online financial transactions
- KU13.** different legal rights and laws
- KU14.** different types of digital devices and the procedure to operate them safely and securely
- KU15.** how to create and operate an e- mail account
- KU16.** use applications such as word processors, spreadsheets etc.
- KU17.** how to identify business opportunities
- KU18.** types and needs of customers
- KU19.** how to apply for a job and prepare for an interview
- KU20.** apprenticeship scheme and the process of registering on apprenticeship portal

## Generic Skills (GS)

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

- GS1.** read and write different types of documents/instructions/correspondence in English and other languages
- GS2.** communicate effectively using appropriate language in formal and informal settings
- GS3.** behave politely and appropriately with all to maintain effective work relationship
- GS4.** how to work in a virtual mode, using various technological platforms
- GS5.** perform calculations efficiently
- GS6.** solve problems effectively
- GS7.** pay attention to details
- GS8.** manage time efficiently
- GS9.** maintain hygiene and sanitization to avoid infection

## Qualification Pack

### 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> understand the significance of employability skills in meeting the current job market requirement and future of work	-	-	-	-
<b>PC2.</b> identify and explore learning and employability relevant portals	-	-	-	-
<b>PC3.</b> research about the different industries, job market trends, latest skills required and the available opportunities	-	-	-	-
<i>Constitutional values – Citizenship</i>	<b>1</b>	<b>1</b>	-	-
<b>PC4.</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>PC5.</b> follow environmentally sustainable practices	-	-	-	-
<i>Becoming a Professional in the 21st Century</i>	<b>1</b>	<b>3</b>	-	-
<b>PC6.</b> recognize the significance of 21st Century Skills for employment	-	-	-	-
<b>PC7.</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	-	-	-	-
<b>PC8.</b> adopt a continuous learning mindset for personal and professional development	-	-	-	-
<i>Basic English Skills</i>	<b>3</b>	<b>4</b>	-	-
<b>PC9.</b> use basic English for everyday conversation in different contexts, in person and over the telephone	-	-	-	-

## Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<b>PC10.</b> read and understand routine information, notes, instructions, mails, letters etc. written in English	-	-	-	-
<b>PC11.</b> write short messages, notes, letters, e-mails etc. in English	-	-	-	-
<i>Career Development &amp; Goal Setting</i>	<b>1</b>	<b>2</b>	-	-
<b>PC12.</b> identify career goals based on the skills, interests, knowledge, and personal attributes	-	-	-	-
<b>PC13.</b> prepare a career development plan with short- and long-term goals	-	-	-	-
<i>Communication Skills</i>	<b>2</b>	<b>2</b>	-	-
<b>PC14.</b> follow verbal and non-verbal communication etiquette while communicating in professional and public settings	-	-	-	-
<b>PC15.</b> use active listening techniques for effective communication	-	-	-	-
<b>PC16.</b> communicate in writing using appropriate style and format based on formal or informal requirements	-	-	-	-
<b>PC17.</b> work collaboratively with others in a team	-	-	-	-
<i>Diversity &amp; Inclusion</i>	<b>1</b>	<b>1</b>	-	-
<b>PC18.</b> communicate and behave appropriately with all genders and PwD	-	-	-	-
<b>PC19.</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>PC20.</b> identify and select reliable institutions for various financial products and services such as bank account, debit and credit cards, loans, insurance etc.	-	-	-	-
<b>PC21.</b> carry out offline and online financial transactions, safely and securely, using various methods and check the entries in the passbook	-	-	-	-

## Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<b>PC22.</b> identify common components of salary and compute income, expenses, taxes, investments etc	-	-	-	-
<b>PC23.</b> identify relevant rights and laws and use legal aids to fight against legal exploitation	-	-	-	-
<i>Essential Digital Skills</i>	<b>3</b>	<b>5</b>	-	-
<b>PC24.</b> operate digital devices and use their features and applications securely and safely	-	-	-	-
<b>PC25.</b> carry out basic internet operations by connecting to the internet safely and securely, using the mobile data or other available networks through Bluetooth, Wi-Fi, etc.	-	-	-	-
<b>PC26.</b> display responsible online behaviour while using various social media platforms	-	-	-	-
<b>PC27.</b> create a personal email account, send and process received messages as per requirement	-	-	-	-
<b>PC28.</b> carry out basic procedures in documents, spreadsheets and presentations using respective and appropriate applications	-	-	-	-
<b>PC29.</b> utilize virtual collaboration tools to work effectively	-	-	-	-
<i>Entrepreneurship</i>	<b>2</b>	<b>3</b>	-	-
<b>PC30.</b> identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research	-	-	-	-
<b>PC31.</b> develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion	-	-	-	-
<b>PC32.</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>PC33.</b> identify different types of customers and ways to communicate with them	-	-	-	-



## Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<b>PC34.</b> identify and respond to customer requests and needs in a professional manner	-	-	-	-
<b>PC35.</b> use appropriate tools to collect customer feedback	-	-	-	-
<b>PC36.</b> follow appropriate hygiene and grooming standards	-	-	-	-
<i>Getting ready for apprenticeship &amp; Jobs</i>	<b>2</b>	<b>3</b>	-	-
<b>PC37.</b> create a professional Curriculum vitae (Résumé)	-	-	-	-
<b>PC38.</b> search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively	-	-	-	-
<b>PC39.</b> apply to identified job openings using offline /online methods as per requirement	-	-	-	-
<b>PC40.</b> answer questions politely, with clarity and confidence, during recruitment and selection	-	-	-	-
<b>PC41.</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/N0103
<b>NOS Name</b>	Employability Skills (90 Hours)
<b>Sector</b>	Cross Sectoral
<b>Sub-Sector</b>	Professional Skills
<b>Occupation</b>	Employability
<b>NSQF Level</b>	5
<b>Credits</b>	3
<b>Version</b>	1.0
<b>Last Reviewed Date</b>	08/05/2025
<b>Next Review Date</b>	31/10/2025
<b>NSQC Clearance Date</b>	08/05/2025

## 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



## Qualification Pack

assessment component.

7. To pass the

**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/N0362.Discuss about Life Sciences industry and Basics of Quality Control	40	30	15	15	100	10
LFS/N0344.Perform checks in a microbiology lab before the start of the microbiological test	25	50	15	10	100	20
LFS/N0342.Perform test for microbial analysis in compliance with regulatory guideline	25	50	15	10	100	30
LFS/N0110.Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab	30	55	-	15	100	10
LFS/N0343.Perform reporting and documentation to meet quality and regulatory standards	30	45	13	12	100	10
LFS/N0302.Coordinate with Manager, colleagues and auditors	35	55	-	10	100	10





### Qualification Pack

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
DGT/VSQ/N0103.Employability Skills (90 Hours)	20	30	-	-	50	10
<b>Total</b>	<b>205</b>	<b>315</b>	<b>58</b>	<b>72</b>	<b>650</b>	<b>100</b>



## Qualification Pack

### Acronyms

<b>NOS</b>	National Occupational Standard(s)
<b>NSQF</b>	National Skills Qualifications Framework
<b>QP</b>	Qualifications Pack
<b>TVET</b>	Technical and Vocational Education and Training
<b>SOP</b>	Standard Operating Procedures
<b>CAPA</b>	Corrective and Preventive Action
<b>GDP</b>	Good Documentation Practices
<b>GMP</b>	Good Manufacturing Practices
<b>GLP</b>	Good Laboratory Practices
<b>SOP</b>	Standard Operating Procedures
<b>PPE</b>	Personal Protective Equipment
<b>GMP</b>	Good Manufacturing Practice
<b>GLP</b>	Good Laboratory Practice
<b>WHO</b>	World Health Organization
<b>ICH</b>	International Council for Harmonisation
<b>MSDS</b>	Material Safety Data Sheet
<b>EHS</b>	Environment Health and Safety
<b>SOP</b>	Standard Operating Procedure
<b>QA</b>	Quality Assurance
<b>QC</b>	Quality Control
<b>POSH</b>	Prevention Of Sexual Harassment
<b>SOP</b>	Standard Operating Procedure
<b>GMP</b>	Good Manufacturing Practice
<b>ALCOA</b>	Attributable, Legible, Contemporaneous, Original and Accurate
<b>GMP</b>	Good Manufacturing Practices



## Qualification Pack

<b>GLP</b>	Good Laboratory Practices
<b>SOP</b>	Standard Operating Procedures
<b>PPE</b>	Personal Protective Equipment
<b>SOP</b>	Standard Operating Procedures
<b>CAPA</b>	Corrective and Preventive Action
<b>GMP</b>	Good Manufacturing Practice
<b>GLP</b>	Good Laboratory Practice
<b>WHO</b>	World Health Organization
<b>ICH</b>	International Council for Harmonisation
<b>MSDS</b>	Material Safety Data Sheet
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<b>ALCOA</b>	Attributable, Legible, Contemporaneous, Original and Accurate
<b>AA</b>	Assessment Agency
<b>AB</b>	Awarding Body
<b>ISCO</b>	International Standard Classification of Occupations
<b>NCO</b>	National Classification of Occupations
<b>NCrF</b>	National Credit Framework



## Qualification Pack

<b>NOS</b>	National Occupational Standard(s)
<b>NQR</b>	National Qualification Register
<b>NSQF</b>	National Skills Qualification Framework
<b>OJT</b>	On the Job Training
<b>AA</b>	Assessment Agency
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## Qualification Pack

<b>NCO</b>	National Classification of Occupations
<b>NCrF</b>	National Credit Framework
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<b>NSQF</b>	National Skills Qualification Framework
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## Qualification Pack

### Glossary

<b>Sector</b>	Sector is a conglomeration of different business operations having similar business and interests. It may also be defined as a distinct subset of the economy whose components share similar characteristics and interests.
<b>Sub-sector</b>	Sub-sector is derived from a further breakdown based on the characteristics and interests of its components.
<b>Occupation</b>	Occupation is a set of job roles, which perform similar/ related set of functions in an industry.
<b>Job role</b>	Job role defines a unique set of functions that together form a unique employment opportunity in an organisation.
<b>Occupational Standards (OS)</b>	OS specify the standards of performance an individual must achieve when carrying out a function in the workplace, together with the Knowledge and Understanding (KU) they need to meet that standard consistently. Occupational Standards are applicable both in the Indian and global contexts.
<b>Performance Criteria (PC)</b>	Performance Criteria (PC) are statements that together specify the standard of performance required when carrying out a task.
<b>National Occupational Standards (NOS)</b>	NOS are occupational standards which apply uniquely in the Indian context.
<b>Qualifications Pack (QP)</b>	QP comprises the set of OS, together with the educational, training and other criteria required to perform a job role. A QP is assigned a unique qualifications pack code.
<b>Unit Code</b>	Unit code is a unique identifier for an Occupational Standard, which is denoted by an 'N'
<b>Unit Title</b>	Unit title gives a clear overall statement about what the incumbent should be able to do.
<b>Description</b>	Description gives a short summary of the unit content. This would be helpful to anyone searching on a database to verify that this is the appropriate OS they are looking for.
<b>Scope</b>	Scope is a set of statements specifying the range of variables that an individual may have to deal with in carrying out the function which have a critical impact on quality of performance required.

## Qualification Pack

<b>Knowledge and Understanding (KU)</b>	Knowledge and Understanding (KU) are statements which together specify the technical, generic, professional and organisational specific knowledge that an individual needs in order to perform to the required standard.
<b>Organisational Context</b>	Organisational context includes the way the organisation is structured and how it operates, including the extent of operative knowledge managers have of their relevant areas of responsibility.
<b>Technical Knowledge</b>	Technical knowledge is the specific knowledge needed to accomplish specific designated responsibilities.
<b>Core Skills/ Generic Skills (GS)</b>	Core skills or Generic Skills (GS) are a group of skills that are the key to learning and working in today's world. These skills are typically needed in any work environment in today's world. These skills are typically needed in any work environment. In the context of the OS, these include communication related skills that are applicable to most job roles.
<b>Electives</b>	Electives are NOS/set of NOS that are identified by the sector as contributive to specialization in a job role. There may be multiple electives within a QP for each specialized job role. Trainees must select at least one elective for the successful completion of a QP with Electives.
<b>Options</b>	Options are NOS/set of NOS that are identified by the sector as additional skills. There may be multiple options within a QP. It is not mandatory to select any of the options to complete a QP with Options.
<b>National Occupational Standard</b>	NOS defines the measurable performance outcomes required from an individual engaged in a particular task. They list down what an individual performing that task should know and also do.
<b>Qualification</b>	A formal outcome of an assessment and validation process is obtained when a the competent body determines that an individual has achieved learning outcomes to given standards
<b>Qualification File</b>	A Qualification File is a template designed to capture necessary information about a Qualification from the perspective of NSQF compliance. The Qualification File will be normally submitted by the awarding body for the qualification.
<b>Sector</b>	A grouping of professional activities on the basis of their main economic function, product, service, or technology.
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