Qualification Pack


# Lab Technician-Pharma, Biologics and Medical devices

Scale-up/Kilo Lab

QP Code: LFS/Q0509  Instantiated QP Code: LFS/Q0509-SI002

Version: 4.0

NSQF Level: 3.5

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# Contents

Qualification Pack

# LFS/Q0509-SI002: Lab Technician-Pharma, Biologics and Medical devices

## Brief Job Description

The Lab Technician-Pharma, Biologics and Medical devices performs the processing of glassware for experimentation. The job holder is responsible for storage, handling chemical reagents/solutions and preparation of stock solutions for smooth execution of experiments and tests. They also provide all the required assistance to analysts and researchers in ensuring that laboratory activities are carried out in adherence with procedures laid in current Good Manufacturing/ Laboratory/ Clinical Practices. The individual also assists lab in-charge in complying with WHO, NABL and other environmental, health and safety guidelines.

## Personal Attributes

The individual should be good in communication skills. The job holder should have good analytical skills and possess the ability to take quick decisions. The person should be good in estimation skills and is expected to maintain integrity.

## Applicable National Occupational Standards (NOS)

### Compulsory NOS:

1. LFS/N0581: Discuss about life sciences industry and basic of Research and Development
2. LFS/N0531: Process the laboratory glassware/ plasticware for experimentation
3. LFS/N0533: Store & handle laboratory chemicals and maintain records
4. LFS/N0109: Ensure hygienic, clean and contamination-free work area and hoods in laboratory
5. LFS/N0101: Follow Environment ,health and safety guidelines in cGMP/GLP controlled areas and laboratory
6. LFS/N0561: Coordinate with chemist/researchers and cross-functional teams
7. DGT/VSQ/N0101: Employability Skills (30 Hours)

### Electives*(mandatory to select at least one):*

Elective : Scale-up/Kilo Lab

1. LFS/N0562: Perform Scale-up operations under the supervision of researchers in the Synthesis R&D/Kilo lab

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## Qualification Pack (QP) Parameters

| | |
|---|---|
| **Sector** | Life Sciences |
| **Sub-Sector** | Pharmaceutical, Bio Pharmaceutical, Contract Research, Medical Devices and In Vitro Diagnostic (IVD) |
| **Occupation** | Research and Development |
| **Country** | India |
| **NSQF Level** | 3.5 |
| **Credits** | 12 |
| **Aligned to NCO/ISCO/ISIC Code** | NCO-2015/3141.9900 |
| **Minimum Educational Qualification & Experience** | 11th Class (pass)<br>OR<br>10th Class (pass) with 1.5 years of experience |
| **Minimum Level of Education for Training in School** | 10th Class |
| **Pre-Requisite License or Training** | NA |
| **Minimum Job Entry Age** | 18 Years |
| **Last Reviewed On** | NA |
| **Next Review Date** | 17/12/2027 |
| **NSQC Approval Date** | 17/12/2024 |
| **Version** | 4.0 |
| **Reference code on NQR** | QG-3.5-LS-03405-2024-V2-LSSSDC |
| **NQR Version** | 2.0 |

**Remarks:**

Maximum two Electives can be chosen by a candidate for Qualification Certification and for Pharmacy students

Qualification Pack

# LFS/N0581: Discuss about life sciences industry and basic of Research and Development

## Description

This NOS is about Introduction to life sciences industry and basic concept of Research & Development

## Scope

The scope covers the following :

- Basic of life sciences industry and research and development
- Environment Sustainability

## Elements and Performance Criteria

*Basic of life sciences industry and Research and Development*

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

**PC1.** Elaborate the structure and key sectors (e.g., biotechnology, pharmaceuticals, medical devices) of the Life Sciences industry in both India and globally.

**PC2.** identify and explain the roles of Indian regulatory authorities (e.g., CDSCO, ICMR) and global authorities (e.g., FDA, EMA) relevant to R&D and scale-up labs.

**PC3.** explain the impact of non-compliance, using real or hypothetical examples to show the consequences of regulatory breaches.

**PC4.** Describe and follow the quality management principles behind ISO-9000, ISO-14001, and OHSAS-18000, particularly in the context of laboratories and manufacturing.

**PC5.** follow ICH Q7 and 21 CFR for active pharmaceutical ingredient (API) manufacturing and product safety

**PC6.** follow guidelines and ensure compliance with international standards for quality, safety, and environmental responsibility.

**PC7.** explain the use of common laboratory equipment and technologies and their importance to daily operations.

*Environment Sustainability*

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

**PC8.** ensure energy conservation by switching off the machine and equipment post operation

**PC9.** identify ways to optimize the usage of electricity/energy in various tasks/activities/processes

**PC10.** ensure no leakage of water in the lab premises

**PC11.** segregate waste into different categories to achieve zero pollution of land and water

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

**KU1.** the quality management systems guidelines from ISO-9000, ISO-14001, OHSAS-18000, ICH Q7 and 21 CFR

**KU2.** essential laboratory-related guidelines of Good Laboratory Practices, (GLP), current Good Manufacturing Practices (cGMP), Good Clinical Practices (GCP), National Accreditation Board (NABL) and WHO (World Health Organization) for laboratories

**KU3.** the environment sustainable procedures to dispose of expired and waste laboratory chemicals

**KU4.** the importance of identifying non-conforming products and the methods for storage of the same

**KU5.** the general hazards in lab and ways to deal with them

**KU6.** the methods of general housekeeping, storage and use of equipment, and maintenance.

**KU7.** operating process of equipment for controlling and monitoring storage conditions

**KU8.** the guidelines for waste chemical segregation in laboratory

## Generic Skills (GS)

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

**GS1.** use reading and comprehending skills to interpret manuals, SOPs, health and safety instructions, memos, reports, and notes/comments from the lab in charge

**GS2.** use the handwritten report or computer-based record/electronic mail to record and communicate details of work done to appropriate stakeholders

**GS3.** use organization skills to maintain proper and concise records as per given format and compliant with ALCOA principle

**GS4.** use verbal communication skills to communicate confidential and sensitive information discretely to the authorized person and to interact with teammates

**GS5.** apply problem-solving skills to find solutions for workflow-related difficulties

**GS6.** apply planning and organizing skills for all the activities to ensure their timely completion to achieve resource optimization

**GS7.** apply critical thinking skills to identify when and how to report an issue/concern to the lab in-charge and other colleagues

**GS8.** give attention to detail and apply analytical skills in choosing a well-defined method/instruction to resolve day to day problems

## Assessment Criteria

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| *Basic of life sciences industry and Research and Development* | **20** | **15** | **5** | **5** |
| **PC1.** Elaborate the structure and key sectors (e.g., biotechnology, pharmaceuticals, medical devices) of the Life Sciences industry in both India and globally. | - | - | - | - |
| **PC2.** identify and explain the roles of Indian regulatory authorities (e.g., CDSCO, ICMR) and global authorities (e.g., FDA, EMA) relevant to R&D and scale-up labs. | - | - | - | - |
| **PC3.** explain the impact of non-compliance, using real or hypothetical examples to show the consequences of regulatory breaches. | - | - | - | - |
| **PC4.** Describe and follow the quality management principles behind ISO-9000, ISO-14001, and OHSAS-18000, particularly in the context of laboratories and manufacturing. | - | - | - | - |
| **PC5.** follow ICH Q7 and 21 CFR for active pharmaceutical ingredient (API) manufacturing and product safety | - | - | - | - |
| **PC6.** follow guidelines and ensure compliance with international standards for quality, safety, and environmental responsibility. | - | - | - | - |
| **PC7.** explain the use of common laboratory equipment and technologies and their importance to daily operations. | - | - | - | - |
| *Environment Sustainability* | **20** | **15** | **10** | **10** |
| **PC8.** ensure energy conservation by switching off the machine and equipment post operation | - | - | - | - |
| **PC9.** identify ways to optimize the usage of electricity/energy in various tasks/activities/processes | - | - | - | - |
| **PC10.** ensure no leakage of water in the lab premises | - | - | - | - |

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| **PC11.** segregate waste into different categories to achieve zero pollution of land and water | - | - | - | - |
| **NOS Total** | **40** | **30** | **15** | **15** |

Qualification Pack

## National Occupational Standards (NOS) Parameters

| | |
|---|---|
| **NOS Code** | LFS/N0581 |
| **NOS Name** | Discuss about life sciences industry and basic of Research and Development |
| **Sector** | Life Sciences |
| **Sub-Sector** | Pharmaceutical, Bio Pharmaceutical, Contract Research |
| **Occupation** | Research and Development |
| **NSQF Level** | 3.5 |
| **Credits** | 1.00 |
| **Version** | 1.0 |
| **Last Reviewed Date** | 17/12/2024 |
| **Next Review Date** | 17/12/2027 |
| **NSQC Clearance Date** | 17/12/2024 |

# LFS/N0531: Process the laboratory glassware/ plasticware for experimentation

## Description

This NOS is about processing the glassware/plastic ware for experimentation

## Scope

The scope covers the following :

- Processing the glassware/plastic ware
- Environment sustainability

## Elements and Performance Criteria

*Processing the glassware/plasticware*

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

**PC1.** check the working condition of water nozzles and supply of the distilled and de-ionized water

**PC2.** select detergent which is compatible with area water and leaves behind no undesirable residue on the cleansed laboratory ware and equipment

**PC3.** wash and clean the glassware with appropriate solution and type of water

**PC4.** rinse the cleaned laboratory ware and equipment by de-ionized distilled water at the end of the cleaning process

**PC5.** inspect washed laboratory-ware and equipment for acid/reagent residues

**PC6.** dry and sterilize glassware in an Autoclave/Hot air oven/Dryer before further use

**PC7.** label the laboratory ware and equipment for specific laboratory studies

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

**KU1.** the proper procedure for selecting the material/product for cleaning

**KU2.** the characteristics of the product/material/detergents used for processing glassware/plasticware

**KU3.** use of monitoring and measuring devices in laboratory

**KU4.** the working principle and applications of autoclave, dryer, and water wash

**KU5.** the laboratory safety manual.

**KU6.** the standard operating procedures (SOPs) for the Cleaning process, handling laboratory chemicals and detergents, and maintenance of records for each instrument/equipment

**KU7.** the relevant guidelines for Good Laboratory Practices, (GLP), current Good Manufacturing Practices (GMP) Good Clinical Practices (GCP) along with National Accreditation Board (NABL) and WHO for laboratories

**KU8.** the process of preparation and testing of reagent water in the laboratory

**KU9.** purpose of tests during the cleaning process, methods, and the equipment used

**KU10.** the quality requirements of materials and the effect of variation on process performance

**KU11.** the possible instrument faults, related causes, and the required corrective action

**KU12.** the safety measures adopted during handling, managing, any accidental exposure

## Generic Skills (GS)

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

**GS1.** use reading and comprehending skills to interpret manuals, SOPs, health and safety instructions, memos, reports, and notes/comments from the lab in charge

**GS2.** use the handwritten report or computer-based record/electronic mail to record and communicate details of work done to appropriate stakeholders

**GS3.** use organization skills to maintain proper and concise records as per given format and in compliance with ALCOA principle

**GS4.** use verbal communication skills to communicate confidential and sensitive information discretely to the authorized person and to interact with teammates

**GS5.** apply problem-solving skills to find solutions for workflow-related difficulties

**GS6.** apply planning and organizing skills for the activities to ensure their timely completion to achieve resource optimization

**GS7.** apply critical thinking skills to identify when and how to report an issue/concern to the lab in charge and other colleagues

## Assessment Criteria

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| *Processing the glassware/plasticware* | **25** | **40** | **20** | **15** |
| **PC1.** check the working condition of water nozzles and supply of the distilled and de-ionized water | - | - | - | - |
| **PC2.** select detergent which is compatible with area water and leaves behind no undesirable residue on the cleansed laboratory ware and equipment | - | - | - | - |
| **PC3.** wash and clean the glassware with appropriate solution and type of water | - | - | - | - |
| **PC4.** rinse the cleaned laboratory ware and equipment by de-ionized distilled water at the end of the cleaning process | - | - | - | - |
| **PC5.** inspect washed laboratory-ware and equipment for acid/reagent residues | - | - | - | - |
| **PC6.** dry and sterilize glassware in an Autoclave/Hot air oven/Dryer before further use | - | - | - | - |
| **PC7.** label the laboratory ware and equipment for specific laboratory studies | - | - | - | - |
| **NOS Total** | **25** | **40** | **20** | **15** |

Qualification Pack

## National Occupational Standards (NOS) Parameters

| | |
|---|---|
| **NOS Code** | LFS/N0531 |
| **NOS Name** | Process the laboratory glassware/ plasticware for experimentation |
| **Sector** | Life Sciences |
| **Sub-Sector** | Pharmaceutical, Bio Pharmaceutical, Contract Research |
| **Occupation** | Research and Development |
| **NSQF Level** | 3.5 |
| **Credits** | 2.00 |
| **Version** | 4.0 |
| **Last Reviewed Date** | 17/12/2024 |
| **Next Review Date** | 17/12/2027 |
| **NSQC Clearance Date** | 17/12/2024 |

# LFS/N0533: Store & handle laboratory chemicals and maintain records

## Description

This NOS is about storing and handling of chemicals/reagents/solutions and maintaining their records in a laboratory

## Scope

The scope covers the following :

- Storage and handling of chemicals
- Maintain laboratory records

## Elements and Performance Criteria

*Storage and handling of chemicals*

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

**PC1.** collect chemicals/reagents/solutions from the storage area by following the SOP

**PC2.** label the chemical containers with other information including date

**PC3.** store large bottles of acids and other hazardous substances on a shelf that is not more than three feet above floor level by following proper safety guidelines

**PC4.** place the acid-resistant trays under bottles of mineral acids

**PC5.** wear appropriate safety eyewear and other personal protective equipment while handling chemicals/reagents/solutions

**PC6.** ensure that incompatible chemicals are kept away from each other

**PC7.** take Corrective Action and Preventive Actions (CAPA) in case of a spill or release of chemicals while transferring from one place to another

**PC8.** segregate and dispose of expired and waste laboratory chemicals as per the guidelines

*Maintain laboratory records*

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

**PC9.** maintain catalog recordings and ensure to avail them when requested (if the department houses audio-visual resources)

**PC10.** ensure that SOPs and manuals for each of the experiments is available

**PC11.** maintain the master logs for laboratory records and archive them

**PC12.** maintain test-specific reports and other records like sample logbook, registers, quality control data, incident reports, audit reports and printouts of instrument handling manuals

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

**KU1.** the quality management systems guidelines from ISO-9000, ISO-14001, OHSAS-18000, ICH Q7 and 21 CFR

**KU2.** essential laboratory-related guidelines of Good Laboratory Practices, (GLP), Current Good Manufacturing Practices (cGMP), Good Clinical Practices (GCP), National Accreditation Board (NABL) and WHO (World Health Organization) for laboratories

**KU3.** the environment sustainable procedures to dispose of expired and waste laboratory chemicals

**KU4.** the importance of identifying non-conforming products and the methods for storage of the same

**KU5.** the properties of all chemicals/reagents/solutions used in laboratory and procedure to use Material Safety Datasheets (MSDS) for each chemical

**KU6.** the general hazards in lab and ways to deal with them

**KU7.** the procedures of carrying out routine maintenance of laboratory instruments and equipment as well as environmental monitoring in the lab.

**KU8.** the methods of general housekeeping, storage and use of equipment, and maintenance.

**KU9.** operating process of equipment for controlling and monitoring storage conditions

**KU10.** the guidelines for waste chemical segregation in laboratory

## Generic Skills (GS)

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

**GS1.** use reading and comprehending skills to interpret manuals, SOPs, health and safety instructions, memos, reports, and notes/comments from the lab in charge

**GS2.** use the handwritten report or computer-based record/electronic mail to record and communicate details of work done to appropriate stakeholders

**GS3.** use organization skills to maintain proper and concise records as per given format and compliant with ALCOA principle

**GS4.** use verbal communication skills to communicate confidential and sensitive information discretely to the authorized person and to interact with teammates

**GS5.** apply problem-solving skills to find solutions for workflow-related difficulties

**GS6.** apply planning and organizing skills for all the activities to ensure their timely completion to achieve resource optimization

**GS7.** apply critical thinking skills to identify when and how to report an issue/concern to the lab in-charge and other colleagues

**GS8.** give attention to detail and apply analytical skills in choosing a well-defined method/instruction to resolve day to day problems

## Assessment Criteria

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| *Storage and handling of chemicals* | **25** | **35** | **-** | **5** |
| **PC1.** collect chemicals/reagents/solutions from the storage area by following the SOP | - | - | - | - |
| **PC2.** label the chemical containers with other information including date | - | - | - | - |
| **PC3.** store large bottles of acids and other hazardous substances on a shelf that is not more than three feet above floor level by following proper safety guidelines | - | - | - | - |
| **PC4.** place the acid-resistant trays under bottles of mineral acids | - | - | - | - |
| **PC5.** wear appropriate safety eyewear and other personal protective equipment while handling chemicals/reagents/solutions | - | - | - | - |
| **PC6.** ensure that incompatible chemicals are kept away from each other | - | - | - | - |
| **PC7.** take Corrective Action and Preventive Actions (CAPA) in case of a spill or release of chemicals while transferring from one place to another | - | - | - | - |
| **PC8.** segregate and dispose of expired and waste laboratory chemicals as per the guidelines | - | - | - | - |
| *Maintain laboratory records* | **10** | **20** | **-** | **5** |
| **PC9.** maintain catalog recordings and ensure to avail them when requested (if the department houses audio-visual resources) | - | - | - | - |
| **PC10.** ensure that SOPs and manuals for each of the experiments is available | - | - | - | - |
| **PC11.** maintain the master logs for laboratory records and archive them | - | - | - | - |

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| **PC12.** maintain test-specific reports and other records like sample logbook, registers, quality control data, incident reports, audit reports and printouts of instrument handling manuals | - | - | - | - |
| **NOS Total** | **35** | **55** | **-** | **10** |

Qualification Pack

## National Occupational Standards (NOS) Parameters

| | |
|---|---|
| **NOS Code** | LFS/N0533 |
| **NOS Name** | Store & handle laboratory chemicals and maintain records |
| **Sector** | Life Sciences |
| **Sub-Sector** | Pharmaceutical, Bio Pharmaceutical, Contract Research |
| **Occupation** | Research and Development |
| **NSQF Level** | 3.5 |
| **Credits** | 2.00 |
| **Version** | 4.0 |
| **Last Reviewed Date** | 17/12/2024 |
| **Next Review Date** | 17/12/2027 |
| **NSQC Clearance Date** | 17/12/2024 |

# LFS/N0109: Ensure hygienic, clean and contamination-free work area and hoods in laboratory

## Description

This job function is about ensuring the maintenance of hygienic, clean and contamination-free work area and hoods in a laboratory by following the Good Laboratory Practices and regulatory guidelines

## Scope

The scope covers the following :

- Cleaning and sanitation activities before work
- Cleaning and sanitation activities during work
- Cleaning and sanitation activities after completion of work

## Elements and Performance Criteria

*Cleaning and sanitation activities before work*

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

**PC1.** ensure not to enter the lab without wearing a lab coat and PPE

**PC2.** inspect the lab, hood and machine area for proper ventilation, temperature and the availability of supplies for experiments

**PC3.** check for cleaning validation tag on machines, accessories, and glassware before starting the work

**PC4.** sterilize the hands before the start of work

*Cleaning and sanitation activities during work*

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

**PC5.** follow appropriate process and precautions while working with different chemicals/reagents/solutions according to their chemical properties in adherence with MSDS and GLP guidelines

**PC6.** deal with accidental spillage, caused while carrying out the work

**PC7.** identify and report to the appropriate person for any required additional cleaning

**PC8.** segregate, store and dispose of the rejected products or generated waste, under the supervision of the supervisor and EHS personnel

*Cleaning and sanitation activities after completion of work*

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

**PC9.** ensure that, on completion of the work the area is left clean and dry and meets WHO and cGMP/GLP requirements of sanitized premises

**PC10.** perform the cleaning of the hood, equipment, and machine after every experiment

**PC11.** ensure that there is no chemical residue/substance left on the work area/equipment/machine/floor to avoid contamination in a new experiment

**PC12.** ensure that no waste/scrap material/ broken glassware is lying around

**PC13.** segregate and dispose of the waste garnered from the activity following the SOP

**PC14.** dispose of used and un-used solutions under supervision of the supervisor and EHS personnel following manufacturer's instructions, and clean the equipment thoroughly

**PC15.** place the trolley, equipment, and unused materials at their designated storage area, after use

**PC16.** ensure that personal protective equipment in the lab is clean, safe and securely stored

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

**KU1.** the hygiene standards required in lab area and the importance of maintaining the same

**KU2.** the method to check the treated surface and equipment on completion of cleaning

**KU3.** the list of various equipment, machines, and instruments used in a lab

**KU4.** the role of different materials, chemicals, and equipment in cleaning and sanitation of lab area

**KU5.** the essential guidelines from WHO, Good Laboratory Practices (GLP), and current Good Manufacturing Practices (cGMP) for cleaning and sanitation activity

**KU6.** the process of cleaning validation

**KU7.** types of hazards and their handling procedures

## Generic Skills (GS)

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

**GS1.** use written communication skills to record and communicate details of work done to appropriate people using written report or computer-based record/electronic mail

**GS2.** use reading and comprehension skills to understand the various coding systems as per company norms

**GS3.** use verbal communication skills to interact with teammates, lab in charge, and cross functional teams

**GS4.** apply problem-solving skills to find solutions for workflow-related difficulties

**GS5.** apply planning and organizing skills for all the activities to ensure their timely completion to achieve resource optimization

**GS6.** 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

## Assessment Criteria

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| *Cleaning and sanitation activities before work* | **10** | **20** | **-** | **5** |
| **PC1.** ensure not to enter the lab without wearing a lab coat and PPE | - | - | - | - |
| **PC2.** inspect the lab, hood and machine area for proper ventilation, temperature and the availability of supplies for experiments | - | - | - | - |
| **PC3.** check for cleaning validation tag on machines, accessories, and glassware before starting the work | - | - | - | - |
| **PC4.** sterilize the hands before the start of work | - | - | - | - |
| *Cleaning and sanitation activities during work* | **10** | **15** | **-** | **5** |
| **PC5.** follow appropriate process and precautions while working with different chemicals/reagents/solutions according to their chemical properties in adherence with MSDS and GLP guidelines | - | - | - | - |
| **PC6.** deal with accidental spillage, caused while carrying out the work | - | - | - | - |
| **PC7.** identify and report to the appropriate person for any required additional cleaning | - | - | - | - |
| **PC8.** segregate, store and dispose of the rejected products or generated waste, under the supervision of the supervisor and EHS personnel | - | - | - | - |
| *Cleaning and sanitation activities after completion of work* | **10** | **20** | **-** | **5** |
| **PC9.** ensure that, on completion of the work the area is left clean and dry and meets WHO and cGMP/GLP requirements of sanitized premises | - | - | - | - |
| **PC10.** perform the cleaning of the hood, equipment, and machine after every experiment | - | - | - | - |
| **PC11.** ensure that there is no chemical residue/substance left on the work area/equipment/machine/floor to avoid contamination in a new experiment | - | - | - | - |

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| **PC12.** ensure that no waste/scrap material/ broken glassware is lying around | - | - | - | - |
| **PC13.** segregate and dispose of the waste garnered from the activity following the SOP | - | - | - | - |
| **PC14.** dispose of used and un-used solutions under supervision of the supervisor and EHS personnel following manufacturer's instructions, and clean the equipment thoroughly | - | - | - | - |
| **PC15.** place the trolley, equipment, and unused materials at their designated storage area, after use | - | - | - | - |
| **PC16.** ensure that personal protective equipment in the lab is clean, safe and securely stored | - | - | - | - |
| **NOS Total** | **30** | **55** | **-** | **15** |

## National Occupational Standards (NOS) Parameters

| | |
|---|---|
| **NOS Code** | LFS/N0109 |
| **NOS Name** | Ensure hygienic, clean and contamination-free work area and hoods in laboratory |
| **Sector** | Life Sciences |
| **Sub-Sector** | Pharmaceutical, Bio Pharmaceutical, Contract Research |
| **Occupation** | Generic |
| **NSQF Level** | 4 |
| **Credits** | 1.00 |
| **Version** | 3.0 |
| **Last Reviewed Date** | 17/12/2024 |
| **Next Review Date** | 17/12/2027 |
| **NSQC Clearance Date** | 17/12/2024 |

# LFS/N0101: Follow Environment ,health and safety guidelines in cGMP/GLP controlled areas and laboratory

## Description

This job function is about following the guidelines and rules for health, safety, environment, and security in the laboratory.

## Scope

The scope covers the following :

- Follow health and hygiene protocols
- Follow safety and security procedures
- Follow 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 ,revised GMP and ICH GMP/GLP guidelines

**PC2.** sanitize hands with soap/alcohol based sanitizers before entering in laboratory and production area as per SOP

**PC3.** ensure to wear a lab coat while working in the laboratory

**PC4.** follow gowning procedures while entering in an environment-controlled work area like production shop floor, warehouse etc.

**PC5.** report any environment-related breach while working in laboratory to the lab in-charge or EHS personnel

**PC6.** disinfect the instruments and equipment before and after work as per workplace health and sanitization guidelines

*Follow safety and security procedures*

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

**PC7.** comply with safety and security policies and procedures

**PC8.** use appropriate safety gears like headgear, masks, gloves and other accessories as mentioned in the guidelines, while carrying out work

**PC9.** report any identified breaches/ incidents/ accidents to the designated person

**PC10.** segregate and store sample/ chemicals/ waste material as per 5S system and SOP

**PC11.** adhere to storage and handling guidelines for hazardous material as per MSDS

**PC12.** take preventive actions against hazards in laboratory by following the safety instructions/guidelines as per MSDS and inform the concerned authority for the same

**PC13.** perform quenching of waste/unused and expired reagents and chemicals using environment sustainable methods under supervision of lab in charge and EHS personnel

**PC14.** complete training records with accuracy for all the attended safety drills and training

*Follow emergency procedures*

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

**PC15.** inform the concerned designated person immediately about every unsafe act/ incident (spill, fall, injury, toxic inhale, fire or explosion) for suitable action

**PC16.** follow emergency procedures efficiently

**PC17.** raise alarm and warn other people who may be affected by hazard/unsafe incident

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

**KU1.** individual's role and responsibilities in relation to compliance with environment, health, hygiene and safety rules

**KU2.** the relevant laws and procedures related to the environment, health, and safety regulations

**KU3.** the implications that any non-compliance with health, safety and security may have on individuals and the organization

**KU4.** the limits of individual responsibility for dealing with hazards

**KU5.** workplace hazards in life sciences facility and reporting procedure for accident/ hazard as per cGMP guidelines

**KU6.** the characteristics of chemical substances, precaution and safety measures required while handling them

**KU7.** the gowning procedure for controlled areas

**KU8.** the organization's emergency procedures for different situations and the importance of following these

**KU9.** the evacuation procedures for employees, contract staff and visitors

**KU10.** the procedure to summon medical assistance and the emergency services in case of necessity

**KU11.** the types of breaches in the environment, health, safety, and security and their reporting procedures

**KU12.** the type of safety gears and procedure to use them

**KU13.** the importance of material segregation and 5S system

**KU14.** the WHO guidelines for personal hygiene, handling and storing hazardous material

**KU15.** the ALCOA principles for documentation and data integrity

## Generic Skills (GS)

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

**GS1.** use written communication skills to accurately record the required information to be reported as per SOP

**GS2.** use reading and comprehension skills for interpreting the various coding systems and to read instructions, guidelines, procedures, rules, and signage to understand the procedure to be followed

**GS3.** use listening skills to act appropriately on the emergency alarms

**GS4.** use verbal communication skills to interact with teammates, lab in charge and cross-functional teams to communicate about 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

**GS10.** apply decision-making skills to make balanced judgments within the authority in different situations while dealing with the hazards and breaches

## Assessment Criteria

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| *Follow health and hygiene protocols* | **10** | **20** | **-** | **5** |
| **PC1.** comply with health and personal hygiene-related protocols as per WHO standards ,revised GMP and ICH GMP/GLP guidelines | - | - | - | - |
| **PC2.** sanitize hands with soap/alcohol based sanitizers before entering in laboratory and production area as per SOP | - | - | - | - |
| **PC3.** ensure to wear a lab coat while working in the laboratory | - | - | - | - |
| **PC4.** follow gowning procedures while entering in an environment-controlled work area like production shop floor, warehouse etc. | - | - | - | - |
| **PC5.** report any environment-related breach while working in laboratory to the lab in-charge or EHS personnel | - | - | - | - |
| **PC6.** disinfect the instruments and equipment before and after work as per workplace health and sanitization guidelines | - | - | - | - |
| *Follow safety and security procedures* | **10** | **20** | **-** | **5** |
| **PC7.** comply with safety and security policies and procedures | - | - | - | - |
| **PC8.** use appropriate safety gears like headgear, masks, gloves and other accessories as mentioned in the guidelines, while carrying out work | - | - | - | - |
| **PC9.** report any identified breaches/ incidents/ accidents to the designated person | - | - | - | - |
| **PC10.** segregate and store sample/ chemicals/ waste material as per 5S system and SOP | - | - | - | - |
| **PC11.** adhere to storage and handling guidelines for hazardous material as per MSDS | - | - | - | - |

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| **PC12.** take preventive actions against hazards in laboratory by following the safety instructions/guidelines as per MSDS and inform the concerned authority for the same | - | - | - | - |
| **PC13.** perform quenching of waste/unused and expired reagents and chemicals using environment sustainable methods under supervision of lab in charge and EHS personnel | - | - | - | - |
| **PC14.** complete training records with accuracy for all the attended safety drills and training | - | - | - | - |
| *Follow emergency procedures* | **10** | **15** | **-** | **5** |
| **PC15.** inform the concerned designated person immediately about every unsafe act/ incident (spill, fall, injury, toxic inhale, fire or explosion) for suitable action | - | - | - | - |
| **PC16.** follow emergency procedures efficiently | - | - | - | - |
| **PC17.** raise alarm and warn other people who may be affected by hazard/unsafe incident | - | - | - | - |
| **NOS Total** | **30** | **55** | **-** | **15** |

## National Occupational Standards (NOS) Parameters

| | |
|---|---|
| **NOS Code** | LFS/N0101 |
| **NOS Name** | Follow Environment ,health and safety guidelines in cGMP/GLP controlled areas and laboratory |
| **Sector** | Life Sciences |
| **Sub-Sector** | Pharmaceutical, Bio Pharmaceutical, Contract Research |
| **Occupation** | Generic |
| **NSQF Level** | 4 |
| **Credits** | 1.00 |
| **Version** | 4.0 |
| **Last Reviewed Date** | 17/12/2024 |
| **Next Review Date** | 17/12/2027 |
| **NSQC Clearance Date** | 17/12/2024 |

# LFS/N0561: Coordinate with chemist/researchers and cross-functional teams

## Description

This NOS is about coordination with supervisor and other cross-functional teams to perform various activities

## Scope

The scope covers the following :

- Coordination with chemist/ researchers
- Coordination with cross-functional teams
- Sensitivity towards all genders and people with disability

## Elements and Performance Criteria

*Coordination with chemist/ researchers*

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

**PC1.** work as per the instructions given by chemist/ researcher

**PC2.** communicate to chemist/ researcher about test operations running in a laboratory

**PC3.** inform about the available stock in the lab to chemist / researcher

**PC4.** intimate chemist/ researcher about required repairs and maintenance of equipment

**PC5.** communicate the deviations in the wet lab / scale up lab work to chemist/ researcher

**PC6.** inform chemist/researcher about potential hazards or expected test disruptions

**PC7.** handover complete daily work report to reporting manager

**PC8.** assist chemist/researchers in the cleaning validation of the equipment in the presence of designated authorized personnel and QA inspector in a cGMP/ NABL compliance lab

*Coordination with Cross-functional Teams*

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

**PC9.** coordinate with store supervisor to fulfil the stock of chemicals/ equipment/ instruments/ machines in the laboratory

**PC10.** coordinate with the maintenance team to fulfill lab maintenance requirements

**PC11.** coordinate with Environment, Health and Safety team for quenching activities and in case of accidental hazard

*Sensitivity towards all genders and people with disability*

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

**PC12.** respect all the genders, religions, and caste

**PC13.** empathize with the people with disability

**PC14.** offer support or help to a person with disability only when asked

**PC15.** adhere to the guidelines laid in POSH Act

**PC16.** 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 company's policies on the preferred language of communication, reporting and escalation policy
**KU2.** the reporting structure of the organization
**KU3.** types of audits in the life sciences sector
**KU4.** the guidelines for Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal Act)
**KU5.** the methods of workplace communication
**KU6.** the methods of team coordination
**KU7.** the types of possible disabilities among people with disability (PwD)
**KU8.** the challenges faced by PwD
**KU9.** the importance of displaying empathy towards PwD
**KU10.** the right way to use the laws acts, and provisions defined for PWD by the statutory bodies
**KU11.** the importance of awareness of gender sensitization and prevention of sexual harassment (POSH) act
**KU12.** the importance of respect for all religion, caste, and culture
**KU13.** types of maintenance in the lab and concerned stakeholders for coordination
**KU14.** concerned stakeholders for cleaning validation and stock replenishment

## Generic Skills (GS)

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

**GS1.** use written communication skills to record and report the incidences accurately as per SOP and GMP guidelines in the English language
**GS2.** use written communication skills to maintain proper and concise records as per given format and in compliance with ALCOA principle
**GS3.** use reading and comprehension skills for interpreting various coding systems and to read instructions, guidelines, procedures, rules, and signage to interpret the procedure to be followed
**GS4.** use listening skills to interpret the instructions and procedures to be followed
**GS5.** use verbal communication skills to interact with teammates, researchers, chemists, lab in charge and cross functional teams for coordination and to communicate confidential and sensitive information discretely to the authorized person
**GS6.** use team-building skills during interaction with teammates and while managing the difficult/stressful or emotional situations at work
**GS7.** apply problem-solving skills to find solutions for workflow-related difficulties

**GS8.** apply planning and organizing skills to plan and organize tools and material required to fulfil work requirements

**GS9.** 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

**GS10.** apply customer centricity while responding to auditors, customer representatives and QA personnel

**GS11.** apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations with clear choices and written instructions

## Assessment Criteria

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| *Coordination with chemist/ researchers* | **15** | **25** | **-** | **5** |
| **PC1.** work as per the instructions given by chemist/ researcher | - | - | - | - |
| **PC2.** communicate to chemist/ researcher about test operations running in a laboratory | - | - | - | - |
| **PC3.** inform about the available stock in the lab to chemist / researcher | - | - | - | - |
| **PC4.** intimate chemist/ researcher about required repairs and maintenance of equipment | - | - | - | - |
| **PC5.** communicate the deviations in the wet lab / scale up lab work to chemist/ researcher | - | - | - | - |
| **PC6.** inform chemist/researcher about potential hazards or expected test disruptions | - | - | - | - |
| **PC7.** handover complete daily work report to reporting manager | - | - | - | - |
| **PC8.** assist chemist/researchers in the cleaning validation of the equipment in the presence of designated authorized personnel and QA inspector in a cGMP/ NABL compliance lab | - | - | - | - |
| *Coordination with Cross-functional Teams* | **15** | **20** | **-** | **5** |
| **PC9.** coordinate with store supervisor to fulfil the stock of chemicals/ equipment/ instruments/ machines in the laboratory | - | - | - | - |
| **PC10.** coordinate with the maintenance team to fulfill lab maintenance requirements | - | - | - | - |
| **PC11.** coordinate with Environment, Health and Safety team for quenching activities and in case of accidental hazard | - | - | - | - |
| *Sensitivity towards all genders and people with disability* | **5** | **10** | **-** | **-** |
| **PC12.** respect all the genders, religions, and caste | - | - | - | - |

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| **PC13.** empathize with the people with disability | - | - | - | - |
| **PC14.** offer support or help to a person with disability only when asked | - | - | - | - |
| **PC15.** adhere to the guidelines laid in POSH Act | - | - | - | - |
| **PC16.** report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee | - | - | - | - |
| **NOS Total** | **35** | **55** | **-** | **10** |

## National Occupational Standards (NOS) Parameters

| | |
|---|---|
| **NOS Code** | LFS/N0561 |
| **NOS Name** | Coordinate with chemist/researchers and cross-functional teams |
| **Sector** | Life Sciences |
| **Sub-Sector** | Pharmaceutical, Bio Pharmaceutical, Contract Research |
| **Occupation** | Research and Development |
| **NSQF Level** | 3.5 |
| **Credits** | 1.00 |
| **Version** | 3.0 |
| **Last Reviewed Date** | 17/12/2024 |
| **Next Review Date** | 17/12/2027 |
| **NSQC Clearance Date** | 17/12/2024 |

# DGT/VSQ/N0101: Employability Skills (30 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
- 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 job requirements

*Constitutional values – Citizenship*

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

**PC2.** identify constitutional values, civic rights, duties, personal values and ethics and environmentally sustainable practices

*Becoming a Professional in the 21st Century*

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

**PC3.** explain 21st Century Skills such as Self-Awareness, Behavior Skills, Positive attitude, self-motivation, problem-solving, creative thinking, time management, social and cultural awareness, emotional awareness, continuous learning mindset etc.

*Basic English Skills*

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

**PC4.** speak with others using some basic English phrases or sentences

*Communication Skills*

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

**PC5.** follow good manners while communicating with others

**PC6.** work with others in a team

*Diversity & Inclusion*

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

**PC7.** communicate and behave appropriately with all genders and PwD

**PC8.** report any issues related to sexual harassment

*Financial and Legal Literacy*

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

**PC9.** use various financial products and services safely and securely

**PC10.** calculate income, expenses, savings etc.

**PC11.** approach the concerned authorities for any exploitation as per legal rights and laws

*Essential Digital Skills*

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

**PC12.** operate digital devices and use its features and applications securely and safely

**PC13.** use internet and social media platforms securely and safely

*Entrepreneurship*

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

**PC14.** identify and assess opportunities for potential business

**PC15.** identify sources for arranging money and associated financial and legal challenges

*Customer Service*

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

**PC16.** identify different types of customers

**PC17.** identify customer needs and address them appropriately

**PC18.** follow appropriate hygiene and grooming standards

*Getting ready for apprenticeship & Jobs*

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

**PC19.** create a basic biodata

**PC20.** search for suitable jobs and apply

**PC21.** identify and register apprenticeship opportunities as per requirement

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

**KU1.** need for employability skills

**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 basic spoken English language

**KU6.** Do and dont of effective communication

**KU7.** inclusivity and its importance

**KU8.** different types of disabilities and appropriate communication and behaviour towards PwD

**KU9.** different types of financial products and services

**KU10.** how to compute income and expenses
**KU11.** importance of maintaining safety and security in financial transactions
**KU12.** different legal rights and laws
**KU13.** how to operate digital devices and applications safely and securely
**KU14.** ways to identify business opportunities
**KU15.** types of customers and their needs
**KU16.** how to apply for a job and prepare for an interview
**KU17.** apprenticeship scheme and the process of registering on apprenticeship portal

## Generic Skills (GS)

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

**GS1.** communicate effectively using appropriate language
**GS2.** behave politely and appropriately with all
**GS3.** perform basic calculations
**GS4.** solve problems effectively
**GS5.** be careful and attentive at work
**GS6.** use time effectively
**GS7.** maintain hygiene and sanitisation to avoid infection

## Assessment Criteria

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| *Introduction to Employability Skills* | **1** | **1** | **-** | **-** |
| **PC1.** understand the significance of employability skills in meeting the job requirements | - | - | - | - |
| *Constitutional values – Citizenship* | **1** | **1** | **-** | **-** |
| **PC2.** identify constitutional values, civic rights, duties, personal values and ethics and environmentally sustainable practices | - | - | - | - |
| *Becoming a Professional in the 21st Century* | **1** | **3** | **-** | **-** |
| **PC3.** explain 21st Century Skills such as Self-Awareness, Behavior Skills, Positive attitude, self-motivation, problem-solving, creative thinking, time management, social and cultural awareness, emotional awareness, continuous learning mindset etc. | - | - | - | - |
| *Basic English Skills* | **2** | **3** | **-** | **-** |
| **PC4.** speak with others using some basic English phrases or sentences | - | - | - | - |
| *Communication Skills* | **1** | **1** | **-** | **-** |
| **PC5.** follow good manners while communicating with others | - | - | - | - |
| **PC6.** work with others in a team | - | - | - | - |
| *Diversity & Inclusion* | **1** | **1** | **-** | **-** |
| **PC7.** communicate and behave appropriately with all genders and PwD | - | - | - | - |
| **PC8.** report any issues related to sexual harassment | - | - | - | - |
| *Financial and Legal Literacy* | **3** | **4** | **-** | **-** |
| **PC9.** use various financial products and services safely and securely | - | - | - | - |

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| **PC10.** calculate income, expenses, savings etc. | - | - | - | - |
| **PC11.** approach the concerned authorities for any exploitation as per legal rights and laws | - | - | - | - |
| *Essential Digital Skills* | **4** | **6** | **-** | **-** |
| **PC12.** operate digital devices and use its features and applications securely and safely | - | - | - | - |
| **PC13.** use internet and social media platforms securely and safely | - | - | - | - |
| *Entrepreneurship* | **3** | **5** | **-** | **-** |
| **PC14.** identify and assess opportunities for potential business | - | - | - | - |
| **PC15.** identify sources for arranging money and associated financial and legal challenges | - | - | - | - |
| *Customer Service* | **2** | **2** | **-** | **-** |
| **PC16.** identify different types of customers | - | - | - | - |
| **PC17.** identify customer needs and address them appropriately | - | - | - | - |
| **PC18.** follow appropriate hygiene and grooming standards | - | - | - | - |
| *Getting ready for apprenticeship & Jobs* | **1** | **3** | **-** | **-** |
| **PC19.** create a basic biodata | - | - | - | - |
| **PC20.** search for suitable jobs and apply | - | - | - | - |
| **PC21.** identify and register apprenticeship opportunities as per requirement | - | - | - | - |
| **NOS Total** | **20** | **30** | **-** | **-** |

## National Occupational Standards (NOS) Parameters

| | |
|---|---|
| **NOS Code** | DGT/VSQ/N0101 |
| **NOS Name** | Employability Skills (30 Hours) |
| **Sector** | Cross Sectoral |
| **Sub-Sector** | Professional Skills |
| **Occupation** | Employability |
| **NSQF Level** | 2 |
| **Credits** | 1 |
| **Version** | 1.0 |
| **Last Reviewed Date** | 08/05/2025 |
| **Next Review Date** | 08/05/2028 |
| **NSQC Clearance Date** | 08/05/2025 |

# LFS/N0562: Perform Scale-up operations under the supervision of researchers in the Synthesis R&D/Kilo lab

## Description

This NOS unit is about a Lab Technician-Pharma, Biologics and Medical devices performing the various scale-up operations in adherence to safety standards

## Scope

The scope covers the following :

- Scale-up Operations
- Storage and disposal of bulk chemicals

## Elements and Performance Criteria

*Scale-up Operations*

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

**PC1.** ensure not to enter the scale-up lab without wearing the appropriate PPE

**PC2.** setup instruments and equipment required for scale-up operations under the supervision of researchers

**PC3.** perform scale-up operations of various compounds, solvents, and chemicals under the supervision of researchers using different techniques like distillation of solvents, filtration of compounds, and crystallization by following Standard Test Protocol (STP)

**PC4.** maintain the reaction conditions like temperature, pressure, etc. as instructed by researchers

**PC5.** operate the reactors for scale-up reactions as per SOP

**PC6.** perform routine upkeep and maintenance of reactors in scale up/kilo lab

**PC7.** wash reactors and large-sized glassware under the supervision of researchers

*Storage and disposal of bulk chemicals*

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

**PC8.** handle and store a large quantity of solvent containers and material in a lab safely

**PC9.** manage the material logs for stored solvents, chemicals, and glassware as per cGMP

**PC10.** perform quenching of the bulk chemical wastages under the supervision of researchers and EHS personnel

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

**KU1.** types of pharmaceutical labs and their functions

**KU2.** about life sciences scale-up lab and the instrument/equipment used in it

**KU3.** type of PPEs used in a scale-up lab and their selection and use

**KU4.** properties and handling guidelines of chemicals as per Material Safety Data Sheet (MSDS) and the hazards caused by them

**KU5.** the techniques, principles, and working of instruments used in a scale-up lab

**KU6.** essential GLP and GMP guidelines

**KU7.** types of biohazards and their corrective and preventive actions

**KU8.** washing methods of large-sized glassware and different types of reactors

**KU9.** procedures for reporting any unresolved issues and hazards

**KU10.** procedures to report incidents where standard operating procedures are not followed

## 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 in compliance with ALCOA principle

**GS3.** use reading and comprehension skills to interpret the various coding systems and to read instructions, guidelines, procedures, rules, and signage to understand the procedure to be followed

**GS4.** use verbal communication skills to interact with teammates, researchers, chemists, lab in charge and cross functional teams

**GS5.** apply problem-solving skills to find solutions for workflow-related difficulties using concepts of basic sciences (chemistry), mathematics, statistics

**GS6.** apply planning and organizing skills to plan and organize tools and material required to fulfil own work requirements in timely manner

**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.** apply customer centricity to remain compliant with data integrity rules, GMP/GLP guidelines and to evaluate impact of wrongdoings

**GS9.** apply decision making skills to make balanced judgments within the authority while dealing with daily work-life situations with clear choices and written instruction

## Assessment Criteria

| Assessment Criteria for Outcomes | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---|---|---|---|---|
| *Scale-up Operations* | **20** | **30** | **-** | **10** |
| **PC1.** ensure not to enter the scale-up lab without wearing the appropriate PPE | - | - | - | - |
| **PC2.** setup instruments and equipment required for scale-up operations under the supervision of researchers | - | - | - | - |
| **PC3.** perform scale-up operations of various compounds, solvents, and chemicals under the supervision of researchers using different techniques like distillation of solvents, filtration of compounds, and crystallization by following Standard Test Protocol (STP) | - | - | - | - |
| **PC4.** maintain the reaction conditions like temperature, pressure, etc. as instructed by researchers | - | - | - | - |
| **PC5.** operate the reactors for scale-up reactions as per SOP | - | - | - | - |
| **PC6.** perform routine upkeep and maintenance of reactors in scale up/kilo lab | - | - | - | - |
| **PC7.** wash reactors and large-sized glassware under the supervision of researchers | - | - | - | - |
| *Storage and disposal of bulk chemicals* | **15** | **25** | **-** | **-** |
| **PC8.** handle and store a large quantity of solvent containers and material in a lab safely | - | - | - | - |
| **PC9.** manage the material logs for stored solvents, chemicals, and glassware as per cGMP | - | - | - | - |
| **PC10.** perform quenching of the bulk chemical wastages under the supervision of researchers and EHS personnel | - | - | - | - |
| **NOS Total** | **35** | **55** | **-** | **10** |

## National Occupational Standards (NOS) Parameters

| | |
|---|---|
| **NOS Code** | LFS/N0562 |
| **NOS Name** | Perform Scale-up operations under the supervision of researchers in the Synthesis R&D/Kilo lab |
| **Sector** | Life Sciences |
| **Sub-Sector** | Pharmaceutical, Bio Pharmaceutical, Contract Research |
| **Occupation** | Research and Development |
| **NSQF Level** | 3.5 |
| **Credits** | 3.00 |
| **Version** | 3.0 |
| **Last Reviewed Date** | 17/12/2024 |
| **Next Review Date** | 17/12/2027 |
| **NSQC Clearance Date** | 17/12/2024 |

# Assessment Guidelines and Assessment Weightage

## Assessment Guidelines

1. Criteria for assessment for each Qualification Pack will be created by Life Sciences Sector Skill Development Council (LSSSDC)

2. Each Element will be assigned marks proportional to its importance in NOS. LSSSDC will also lay down the proportion of marks for Theory, Practical, Project, and Viva for each Element.

3. The assessment for the theory part will be based on the knowledge bank of questions created by the LSSSDC.

4. Assessment will be conducted for all compulsory NOS, and where applicable, on the selected elective/option NOS/set of NOS.

5. LSSSDC as assessment and awarding body will create unique evaluations for each assessment component i.e. theory, practical, project and via for every student at each examination/training center based on this criterion.

6. Wherever any assessment component is not applicable/ feasible, the balance assessment components will be used to assess the candidate and accordingly the total marks will be calculated only for the applied

assessment component.

7. To pass the Qualification Pack, every trainee should score a minimum of 50%-70% of marks in each NOS (depending on NSQF Level) to successfully clear the assessment. In the case of a Govt funded program, the program guidelines will be overarching on the pass percentage rules.

8. In case of unsuccessful completion, the trainee may seek re-assessment on the Qualification Pack.

**Minimum Aggregate Passing % at QP Level : 50**

(**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: 50**

(**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/N0581.Discuss about life sciences industry and basic of Research and Development | 40 | 30 | 15 | 15 | 100 | 10 |
| LFS/N0531.Process the laboratory glassware/ plasticware for experimentation | 25 | 40 | 20 | 15 | 100 | 10 |
| LFS/N0533.Store & handle laboratory chemicals and maintain records | 35 | 55 | 0 | 10 | 100 | 10 |
| LFS/N0109.Ensure hygienic, clean and contamination-free work area and hoods in laboratory | 30 | 55 | 0 | 15 | 100 | 10 |
| LFS/N0101.Follow Environment ,health and safety guidelines in cGMP/GLP controlled areas and laboratory | 30 | 55 | 0 | 15 | 100 | 10 |

**Qualification Pack**

| National Occupational Standards | Theory Marks | Practical Marks | Project Marks | Viva Marks | Total Marks | Weightage |
|---|---|---|---|---|---|---|
| LFS/N0561.Coordinate with chemist/researchers and cross-functional teams | 35 | 55 | 0 | 10 | 100 | 10 |
| DGT/VSQ/N0101.Employability Skills (30 Hours) | 20 | 30 | - | - | 50 | 10 |
| **Total** | **215** | **320** | **35** | **80** | **650** | **70** |

Elective: 1 Scale-up/Kilo Lab

| National Occupational Standards | Theory Marks | Practical Marks | Project Marks | Viva Marks | Total Marks | Weightage |
|---|---|---|---|---|---|---|
| LFS/N0562.Perform Scale-up operations under the supervision of researchers in the Synthesis R&D/Kilo lab | 35 | 55 | 0 | 10 | 100 | 30 |
| **Total** | **35** | **55** | **-** | **10** | **100** | **30** |