

## Qualification Pack



# Assistant- Maintenance (Pharma, Biologics and Medical Device Facility)

Electives: Utility

QP Code: LFS/Q0801 Instantiated QP Code: LFS/Q0801-SI002

Version: 3.0

NSQF Level: 3

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# LFS/Q0801-SI002: Assistant- Maintenance (Pharma, Biologics and Medical Device Facility)

## Brief Job Description

Assistant- Maintenance (Pharma, Biologics and Medical Device Facility) assists maintenance technician and supervisor in carrying out maintenance activities and performing basic machining, fitting and assembling activities of machinery and utilities like Heating, Ventilation, and Air Conditioning (HVAC), Water, Gases, Steam, and Electricity. The individual is responsible for carrying out reporting and documentation for maintenance activities as per current Good Manufacturing Practices (cGMP). The job holder is also responsible for maintaining a healthy, hygienic, safe and secure working environment.

## Personal Attributes

The individual should have good communication skills, problem solving and mathematical skills. The person should be honest and good team player and must have patience. The job holder is expected to work in adverse conditions hence needs to be physically fit and strong

## Applicable National Occupational Standards (NOS)

### Compulsory NOS:

1. [LFS/N0820: Discuss about life sciences industry and essential concepts of Maintenance](#)
2. [LFS/N0112: Adherence to Environment, health and safety guidelines in a production facility and GMP controlled area](#)
3. [LFS/N0802: Prepare for maintenance in compliance with schedule and job safety guidelines](#)
4. [LFS/N0113: Ensure a hygienic and clean work area to avoid contamination](#)
5. [LFS/N0801: Coordinate with reporting manager, teammates, and cross-functional teams](#)
6. [DGT/VSQ/N0101: Employability Skills \(30 Hours\)](#)

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

#### Elective : Utility

This Assistant- Maintenance (Pharma, Biologics and Medical Device Facility) is considered to be specialized in maintaining the utilities.

1. [LFS/N0804: Assist Maintenance Technician/Supervisor to carry out specialized maintenance in compliance with cGMP and regulatory guidelines](#)



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### Qualification Pack (QP) Parameters

<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceutical, Bio Pharmaceutical, Contract Research, Medical Devices and In Vitro Diagnostic (IVD)
<b>Occupation</b>	Engineering and Maintenance
<b>Country</b>	India
<b>NSQF Level</b>	3
<b>Credits</b>	14
<b>Aligned to NCO/ISCO/ISIC Code</b>	NCO-2015/7233.9900, NCO-2015/7233.0101
<b>Minimum Educational Qualification &amp; Experience</b>	10th Class OR Grade 8 pass with 2 years of (NTC/ NAC) after 8th
<b>Minimum Level of Education for Training in School</b>	8th Class
<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>	3.0
<b>Reference code on NQR</b>	QG-03-LS-03411-2024-V2-LSSSDC
<b>NQR Version</b>	2.0

### Remarks:

NA



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# LFS/N0820: Discuss about life sciences industry and essential concepts of Maintenance

## Description

This NOS is to discuss about life sciences industry and essential concepts of Maintenance

## Scope

The scope covers the following :

- Discuss about Life Sciences industry
- Essential concepts of Maintenance

## Elements and Performance Criteria

### *Discuss about Life Sciences industry*

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

- PC1.** discuss key insights related major segments within the life sciences industry (pharmaceuticals, biotechnology, medical devices, etc.).
- PC2.** apply the standards of GLP, cGMP, and GDP in relevant scenarios in maintenance department.
- PC3.** interpret various guidelines and demonstrate their application in Life Sciences processes.
- PC4.** perform essential maintenance tasks.

### *Essential concepts of Maintenance*

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

- PC5.** perform basic mathematical calculations related to maintenance tasks.
- PC6.** identify the consequences of delays in maintenance on production and operations.
- PC7.** demonstrate how to Investigate the most likely caused of the fault during equipment checks.
- PC8.** apply 5S principles in the maintenance of machines.
- PC9.** Identify right tools and materials based on the maintenance task requirements.

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** basics of mathematical calculations and measurement
- KU2.** application of cutting fluids and compounds with regard to a range of different materials, and why some materials do not require cutting fluids to be used
- KU3.** how to check the workpiece and the selection of the right measuring equipment
- KU4.** how to check that the measuring equipment is within current calibration dates and that the instruments are correctly zeroed
- KU5.** various mechanical fastening devices that are used. Fastening devices: nuts; bolts; machine screws; cap screws; clips; pins; locking and retaining devices; rivets
- KU6.** basics of different types of locking devices used in machines



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- KU7.** generic protocols to be adopted for dismantling/re-assembly of various types of equipment
- KU8.** methods of identification, application, fitting and removal of different types of bearings and gears
- KU9.** how to make adjustments to components/assemblies to ensure they function correctly. Adjustments: setting working clearance, setting travel, setting backlash in gears, preloading bearings, bearing pressing
- KU10.** how components are to be aligned, adjusted and positioned before securing them, and the operating procedure of relevant tools and equipment used
- KU11.** sterilization requirements for maintenance tools and guidelines to maintain the sterility
- KU12.** methods of visual inspection and sound observation during maintenance
- KU13.** common machines in life sciences facilities
- KU14.** equipment operation and control procedures to be applied during the maintenance activity
- KU15.** health and safety requirements and safe working practices and procedures required for the maintenance activities undertaken
- KU16.** hazards associated with the mechanical maintenance activities and how they can be minimized
- KU17.** basics of cleaning and waste disposal guidelines
- KU18.** basics of Good Manufacturing practices applicable to engineering and maintenance function and basic concepts of shop-floor work productivity including waste reduction, efficient material usage and optimization of time
- KU19.** basic guidelines for documentation in compliance with ALCOA principles and Data Integrity rules
- KU20.** importance of maintenance documentation following the maintenance activity, critical documents to be generated by Assistant- Maintenance (Pharma, Biologics and Medical Device Facility)
- KU21.** environmental sustainable procedures to save water and energy
- KU22.** eco-friendly waste disposal procedures

## Generic Skills (GS)

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

- GS1.** use written communication skills to fill up appropriate technical forms, process charts, activity logs as per the organizational format in English and/or regional language
- GS2.** use reading and comprehension skills to read and interpret information correctly from various job specification documents, manuals, health and safety instructions, memos, etc. applicable to the job in English and/or regional language
- GS3.** use communication skills to convey and share technical information clearly using appropriate language and to liaise with appropriate authorities using the correct protocol for any escalations
- GS4.** apply decision making skills to take decisions with respect to his/her work without affecting other's work/ action plan
- GS5.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS6.** apply planning and organizing skills to plan, prioritize and sequence work operations as per job requirements





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- GS7.** apply critical thinking skills to analyze information relevant to work
- GS8.** apply time management skills to manage own time for achieving better results
- GS9.** apply computational skills to undertake basic numerical computations and calculations



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### Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Discuss about Life Sciences industry</i>	<b>10</b>	<b>15</b>	<b>-</b>	<b>5</b>
<b>PC1.</b> discuss key insights related major segments within the life sciences industry (pharmaceuticals, biotechnology, medical devices, etc.).	-	-	-	-
<b>PC2.</b> apply the standards of GLP, cGMP, and GDP in relevant scenarios in maintenance department.	-	-	-	-
<b>PC3.</b> interpret various guidelines and demonstrate their application in Life Sciences processes.	-	-	-	-
<b>PC4.</b> perform essential maintenance tasks.	-	-	-	-
<i>Essential concepts of Maintenance</i>	<b>20</b>	<b>30</b>	<b>10</b>	<b>10</b>
<b>PC5.</b> perform basic mathematical calculations related to maintenance tasks.	-	-	-	-
<b>PC6.</b> identify the consequences of delays in maintenance on production and operations.	-	-	-	-
<b>PC7.</b> demonstrate how to Investigate the most likely caused of the fault during equipment checks.	-	-	-	-
<b>PC8.</b> apply 5S principles in the maintenance of machines.	-	-	-	-
<b>PC9.</b> Identify right tools and materials based on the maintenance task requirements.	-	-	-	-
<b>NOS Total</b>	<b>30</b>	<b>45</b>	<b>10</b>	<b>15</b>





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### National Occupational Standards (NOS) Parameters

<b>NOS Code</b>	LFS/N0820
<b>NOS Name</b>	Discuss about life sciences industry and essential concepts of Maintenance
<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceutical, Bio Pharmaceutical, Contract Research
<b>Occupation</b>	Engineering and Maintenance
<b>NSQF Level</b>	3
<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/N0112: Adherence to Environment, health and safety guidelines in a production facility and GMP controlled area

#### Description

This NOS unit is about adhering with the rules and regulations related to health, safety, environment, and security in a manufacturing facility or testing/ research laboratory in life sciences sector

#### Scope

The scope covers the following :

- Follow health and personal hygiene protocols
- Follow safety and security procedures
- Follow emergency procedures

#### Elements and Performance Criteria

##### *Follow health and personal 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 guidelines
- PC2.** wash hands before entering in the production area 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.** follow gowning procedures while entering an environment controlled work area

##### *Follow safety and security procedures*

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

- PC5.** comply with safety and security policies and procedures
- PC6.** use appropriate safety gears like headgear, masks, gloves and other relevant safety accessories as mentioned in the guidelines, while carrying out work
- PC7.** use helmets, ropes, harness, and ladders while working at heights
- PC8.** use pulleys/ forklift (if available) to transport the material/ spares/ heavy assembly and tools
- PC9.** report any identified breaches in safety and security policies and procedures to the designated person
- PC10.** segregate material and follow the 5S system at the storage area
- PC11.** adhere to storage and handling guidelines for hazardous material
- PC12.** identify and correct any hazards that one can deal with safely, competently and within the limits of authority
- PC13.** record the details of completed safety drills and training

##### *Follow emergency procedures*

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



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- PC14.** 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
- PC15.** inform the concerned person immediately about every unsafe act/ incident
- PC16.** follow emergency procedures efficiently

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** individual's role and responsibilities in maintaining healthy, hygienic, safe and secure working environment
- KU2.** company's procedures and protocols for the environment, health and safety
- KU3.** relevant legislative requirements as per local laws
- KU4.** implications that any non-compliance with health, safety and security may have on individuals and the organization
- KU5.** workplace hazards in the manufacturing/ research facility in the life sciences sector and reporting procedures for unhealthy/ unsafe act/incidents, hazards and accident as per GMP
- KU6.** limits of individual responsibility for dealing with hazards
- KU7.** chemical substances, their characteristics, and required precaution and safety measures
- KU8.** gowning procedure
- KU9.** the organization's emergency procedures for different emergency situations and the importance of following these
- KU10.** evacuation procedures for employees, contract staff and visitors
- KU11.** procedure to summon medical assistance and the emergency services, where necessary
- KU12.** different types of breaches in the environment, health, safety and security and how and when to report these
- KU13.** WHO guidelines for personal hygiene
- KU14.** types of safety gears and procedure to use them
- KU15.** importance of material segregation and 5S system
- KU16.** WHO guidelines for handling and storing hazardous material

## Generic Skills (GS)

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

- GS1.** use reading and comprehension skills to read instructions, guidelines, procedures, rules, and signages
- GS2.** use written communication skills to accurately record every information required to be reported as per SOP and GMP guidelines in the language prescribed by the company's SOP
- GS3.** apply planning and organizing skills to plan and organize tools and material required for work to fulfil environment, health, safety and security requirements
- GS4.** use critical thinking skills to ascertain the breach/ compliance of EHS protocols



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- GS5.** apply customer centricity to remain compliant with data integrity rules, GMP guidelines and to evaluate impact of wrongdoings
- GS6.** apply decision-making skills to make balanced judgments within the authority in different situations while dealing with hazards and breaches
- GS7.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS8.** use verbal communication skills to communicate with supervisor/ manager/ EHS Incharge or any other concerned authority clearly for escalating any emergency situation or hazard

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### Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Follow health and personal hygiene protocols</i>	<b>10</b>	<b>10</b>	<b>5</b>	<b>5</b>
<b>PC1.</b> comply with health and personal hygiene-related protocols as per WHO standards, , revised GMP and ICH GMP guidelines	-	-	-	-
<b>PC2.</b> wash hands before entering in the production area 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> follow gowning procedures while entering an environment controlled work area	-	-	-	-
<i>Follow safety and security procedures</i>	<b>10</b>	<b>20</b>	<b>5</b>	<b>5</b>
<b>PC5.</b> comply with safety and security policies and procedures	-	-	-	-
<b>PC6.</b> use appropriate safety gears like headgear, masks, gloves and other relevant safety accessories as mentioned in the guidelines, while carrying out work	-	-	-	-
<b>PC7.</b> use helmets, ropes, harness, and ladders while working at heights	-	-	-	-
<b>PC8.</b> use pulleys/ forklift (if available) to transport the material/ spares/ heavy assembly and tools	-	-	-	-
<b>PC9.</b> report any identified breaches in safety and security policies and procedures to the designated person	-	-	-	-
<b>PC10.</b> segregate material and follow the 5S system at the storage area	-	-	-	-
<b>PC11.</b> adhere to storage and handling guidelines for hazardous material	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<b>PC12.</b> identify and correct any hazards that one can deal with safely, competently and within the limits of authority	-	-	-	-
<b>PC13.</b> record the details of completed safety drills and training	-	-	-	-
<i>Follow emergency procedures</i>	<b>10</b>	<b>10</b>	<b>5</b>	<b>5</b>
<b>PC14.</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>PC15.</b> inform the concerned person immediately about every unsafe act/ incident	-	-	-	-
<b>PC16.</b> follow emergency procedures efficiently	-	-	-	-
<b>NOS Total</b>	<b>30</b>	<b>40</b>	<b>15</b>	<b>15</b>



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### National Occupational Standards (NOS) Parameters

<b>NOS Code</b>	LFS/N0112
<b>NOS Name</b>	Adherence to Environment, health and safety guidelines in a production facility and GMP controlled area
<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceutical, Bio Pharmaceutical, Contract Research
<b>Occupation</b>	Generic
<b>NSQF Level</b>	4
<b>Credits</b>	1.00
<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

### LFS/N0802: Prepare for maintenance in compliance with schedule and job safety guidelines

#### Description

This job function is about preparing for maintenance of utilities in compliance with schedule and job safety guidelines

#### Scope

The scope covers the following :

- Prepare for maintenance activities

#### Elements and Performance Criteria

##### *Prepare for maintenance activities*

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

- PC1.** obtain job specifications and requirements from valid sources and assist technician/supervisor to find out the fault in any instrument
- PC2.** interpret the schedule for initiating the preparation of maintenance, (including preventive maintenance activities)
- PC3.** perform pre-maintenance job safety analysis as per the defined checklist.
- PC4.** Ensure instruments are thoroughly cleaned to remove any visible soil or residual debris.
- PC5.** ensure availability of the relevant tools, spares and materials to be used for repair or preventive maintenance
- PC6.** ensure sanitization/ sterilization and cleaning validation of the tools and spares, to be used for repair or maintenance, in accordance with SOPs
- PC7.** check the maintenance area for proper ventilation, light and safety equipment
- PC8.** place the tags/ labels/ signages for indicating that the machines and area is under maintenance as per the instructions by maintenance technician

#### Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** company values, ethics, and culture
- KU2.** about maintenance and cleaning procedures and protocols
- KU3.** risk and impact of not following defined procedures/work instructions
- KU4.** basic maintenance functions and types, types of faults, and maintenance activities for them
- KU5.** operational characteristics of the materials, equipment, and process, sufficient to recognize out of specification products, process problems, and materials faults
- KU6.** use and correct selection of equipment, materials, processes, and procedures
- KU7.** good practices to work on machines



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**KU8.** implications of delays in the maintenance process

**KU9.** the current Good Manufacturing Practices(GMP) and other regulatory guidelines

### 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 in regional language or English/Hindi
- GS2.** use reading and comprehension skills to understand instructions/manuals, SOPs, health and safety instructions, memos, reports, job cards, schedules, etc.
- GS3.** use verbal communication skills to report deviation or to communicate relevant information to authorized person as per the SOP
- GS4.** apply critical thinking skills to analyze past trends and experience for defining action and decisions
- GS5.** apply critical thinking skills to understand and identify causes for lack of adherence to the maintenance schedule and highlight the same
- GS6.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS7.** plan individual work in order to achieve specified deadlines and align with the maintenance schedules



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### Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Prepare for maintenance activities</i>	35	50	-	15
<b>PC1.</b> obtain job specifications and requirements from valid sources and assist technician/supervisor to find out the fault in any instrument	-	-	-	-
<b>PC2.</b> interpret the schedule for initiating the preparation of maintenance, (including preventive maintenance activities)	-	-	-	-
<b>PC3.</b> perform pre-maintenance job safety analysis as per the defined checklist.	-	-	-	-
<b>PC4.</b> Ensure instruments are thoroughly cleaned to remove any visible soil or residual debris.	-	-	-	-
<b>PC5.</b> ensure availability of the relevant tools, spares and materials to be used for repair or preventive maintenance	-	-	-	-
<b>PC6.</b> ensure sanitization/ sterilization and cleaning validation of the tools and spares, to be used for repair or maintenance, in accordance with SOPs	-	-	-	-
<b>PC7.</b> check the maintenance area for proper ventilation, light and safety equipment	-	-	-	-
<b>PC8.</b> place the tags/ labels/ signages for indicating that the machines and area is under maintenance as per the instructions by maintenance technician	-	-	-	-
<b>NOS Total</b>	<b>35</b>	<b>50</b>	<b>-</b>	<b>15</b>



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### National Occupational Standards (NOS) Parameters

<b>NOS Code</b>	LFS/N0802
<b>NOS Name</b>	Prepare for maintenance in compliance with schedule and job safety guidelines
<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceutical, Bio Pharmaceutical, Contract Research
<b>Occupation</b>	Engineering and Maintenance
<b>NSQF Level</b>	3
<b>Credits</b>	2.00
<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



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### LFS/N0113: Ensure a hygienic and clean work area to avoid contamination

#### Description

This NOS unit is about maintaining hygienic and clean work area to avoid contamination

#### Scope

The scope covers the following :

- Sanitation activities before starting the work
- Sanitation activities during work
- Sanitation activities post completion of work

#### Elements and Performance Criteria

##### *sanitation activities before starting the work*

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

- PC1.** inspect the area and machine, taking into account various surfaces
- PC2.** check for cleaning validation tag on machines and accessories
- PC3.** ensure to clean the area or machine part as per SOP, in case of any stain on floor or machine
- PC4.** perform the cleaning validation in the presence of authorized personnel or QA inspector
- PC5.** ensure that there is adequate ventilation for the work being carried out
- PC6.** handle the cleaning material/reagent only after wearing the personal protective equipment required for the cleaning method
- PC7.** segregate and store the chemicals/ material with an appropriate label in designated places to avoid contamination

##### *Sanitation activities during work*

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

- PC8.** deal with accidental spillage, if any, caused while carrying out the work and clean as per SOP
- PC9.** segregate and store the intermediate material with an appropriate label in designated places to avoid contamination
- PC10.** report any additional cleaning requirement that is outside one's purview, to the appropriate person
- PC11.** segregate, store and dispose of the rejected products or generated waste as per SOP under the supervision of supervisor and EHS personnel

##### *Sanitation activities after completion of work*

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

- PC12.** ensure that there is no oily substance on the floor to avoid slippage
- PC13.** ensure that no scrap material is lying around
- PC14.** perform the cleaning of the equipment after every batch production as per SOP
- PC15.** perform the cleaning validation of the equipment in the presence of designated authorized personnel and QA inspector



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- PC16.** ensure that, on completion of the work, the area is left clean and dry and meets WHO and cGMP requirements of sanitized premises
- PC17.** place the trolley, equipment, materials and personal protective equipment at the designated place after use, ensuring they are clean and securely stored
- PC18.** dispose of the waste garnered from the activity as per SOP
- PC19.** dispose of used and un-used solutions according to manufacturer's instructions, and clean the equipment thoroughly

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** levels of hygiene required by production area and the importance of maintaining the same
- KU2.** methodology for production area inspection with methods and materials required for cleaning a variety of surfaces and equipment
- KU3.** the method to check the treated surface and equipment on completion of cleaning
- KU4.** procedures for reporting any unidentified soiling or any deviation for cleaning validation
- KU5.** role of different materials, chemicals, and equipment in cleaning and sanitation of production area
- KU6.** current Good Manufacturing Practices (cGMP) and WHO guidelines for cleaning/ sanitation activity and maintaining hygiene
- KU7.** cleaning validation process
- KU8.** waste disposal guidelines as per WHO and cGMP and relevant organizational SOPs

## 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/typed report and electronic mail
- GS2.** use verbal communication skills to communicate with supervisor, cross-functional teams and auditors effectively
- GS3.** use critical thinking skills to interpret the various coding systems as per company norms and in identifying the non-compliance while performing the area inspection
- GS4.** apply customer centricity at work
- GS5.** apply problem-solving and decision making while dealing with any deviation

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### Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>sanitation activities before starting the work</i>	<b>10</b>	<b>10</b>	<b>5</b>	<b>5</b>
<b>PC1.</b> inspect the area and machine, taking into account various surfaces	-	-	-	-
<b>PC2.</b> check for cleaning validation tag on machines and accessories	-	-	-	-
<b>PC3.</b> ensure to clean the area or machine part as per SOP, in case of any stain on floor or machine	-	-	-	-
<b>PC4.</b> perform the cleaning validation in the presence of authorized personnel or QA inspector	-	-	-	-
<b>PC5.</b> ensure that there is adequate ventilation for the work being carried out	-	-	-	-
<b>PC6.</b> handle the cleaning material/reagent only after wearing the personal protective equipment required for the cleaning method	-	-	-	-
<b>PC7.</b> segregate and store the chemicals/ material with an appropriate label in designated places to avoid contamination	-	-	-	-
<i>Sanitation activities during work</i>	<b>10</b>	<b>20</b>	<b>5</b>	<b>5</b>
<b>PC8.</b> deal with accidental spillage, if any, caused while carrying out the work and clean as per SOP	-	-	-	-
<b>PC9.</b> segregate and store the intermediate material with an appropriate label in designated places to avoid contamination	-	-	-	-
<b>PC10.</b> report any additional cleaning requirement that is outside one's purview, to the appropriate person	-	-	-	-
<b>PC11.</b> segregate, store and dispose of the rejected products or generated waste as per SOP under the supervision of supervisor and EHS personnel	-	-	-	-
<i>Sanitation activities after completion of work</i>	<b>10</b>	<b>10</b>	<b>5</b>	<b>5</b>





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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<b>PC12.</b> ensure that there is no oily substance on the floor to avoid slippage	-	-	-	-
<b>PC13.</b> ensure that no scrap material is lying around	-	-	-	-
<b>PC14.</b> perform the cleaning of the equipment after every batch production as per SOP	-	-	-	-
<b>PC15.</b> perform the cleaning validation of the equipment in the presence of designated authorized personnel and QA inspector	-	-	-	-
<b>PC16.</b> ensure that, on completion of the work, the area is left clean and dry and meets WHO and cGMP requirements of sanitized premises	-	-	-	-
<b>PC17.</b> place the trolley, equipment, materials and personal protective equipment at the designated place after use, ensuring they are clean and securely stored	-	-	-	-
<b>PC18.</b> dispose of the waste garnered from the activity as per SOP	-	-	-	-
<b>PC19.</b> dispose of used and un-used solutions according to manufacturer's instructions, and clean the equipment thoroughly	-	-	-	-
<b>NOS Total</b>	<b>30</b>	<b>40</b>	<b>15</b>	<b>15</b>



## Qualification Pack

### National Occupational Standards (NOS) Parameters

<b>NOS Code</b>	LFS/N0113
<b>NOS Name</b>	Ensure a hygienic and clean work area to avoid contamination
<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceutical, Bio Pharmaceutical, Contract Research
<b>Occupation</b>	Generic
<b>NSQF Level</b>	4
<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/N0801: Coordinate with reporting manager, teammates, and cross-functional teams

#### Description

This NOS unit is about communicating with colleagues (both within team & cross-functional) and seniors in order to achieve smooth and hazard-free workflow

#### Scope

The scope covers the following :

- Interact with reporting manager
- Interact with colleagues and cross-functional teams
- Sensitivity towards all genders and people with disability

#### Elements and Performance Criteria

##### *Interact with reporting manager*

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

- PC1.** comprehend the work instructions given by supervisor/ reporting manager
- PC2.** ensure to meet goals and timelines set by the supervisor/ reporting manager and report any anticipated reasons for delays
- PC3.** ensure timely intimation to supervisor/ reporting manager about his/ her planned absence as well as any illness/ dizziness during work
- PC4.** inform supervisor/ reporting manager on critical issues, requiring his/her intervention, proactively
- PC5.** engage with supervisor/ reporting manager on work-related and behavioral feedback

##### *Interact with colleagues and cross-functional teams*

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

- PC6.** takeover/ handover from colleagues in previous shift/ to colleagues in the next shift as per defined guidelines
- PC7.** coordinate with concerned personnel in stores for replenishing required material and spares
- PC8.** follow the protocols of cross-functional sections
- PC9.** plan the work in consultation with impacted cross-functional teams
- PC10.** respect others time and meet timelines for any cross-functional deliverable
- PC11.** resolve interpersonal conflicts at work with other colleagues, if any

##### *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 with the guidelines laid in POSH Act



## Qualification Pack

- 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.** company's vision, policies on preferred language of communication, quality delivery standards, time office rules, handover policies
- KU2.** reporting structure and escalation policy
- KU3.** basics of effective communication
- KU4.** importance of building team coordination
- KU5.** the types of possible disabilities among people with disability (PwD)
- KU6.** the challenges faced by PwD (Person with Disability)
- KU7.** importance of displaying empathy towards PwD
- KU8.** the laws, acts, and provisions defined for PwD by the statutory bodies
- KU9.** the guidelines for Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal Act)
- KU10.** importance of respecting all gender, religion, caste, and culture

### Generic Skills (GS)

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

- GS1.** use reading and comprehension skills to read job sheets, in interpreting technical details mentioned in the job sheet and to read notes/comments received from the technician/supervisor
- GS2.** use verbal communication and listening skills to interact with team members, to establish effective working relationships with different team members and other cross-functional teams to deliver planned work
- GS3.** apply planning and organizing skills to plan and organize assigned work in order to achieve specified targets and deadlines
- GS4.** apply critical thinking skills to spot process disruptions and delays

## Qualification Pack

### Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Interact with reporting manager</i>	<b>10</b>	<b>15</b>	-	<b>5</b>
<b>PC1.</b> comprehend the work instructions given by supervisor/ reporting manager	-	-	-	-
<b>PC2.</b> ensure to meet goals and timelines set by the supervisor/ reporting manager and report any anticipated reasons for delays	-	-	-	-
<b>PC3.</b> ensure timely intimation to supervisor/ reporting manager about his/ her planned absence as well as any illness/ dizziness during work	-	-	-	-
<b>PC4.</b> inform supervisor/ reporting manager on critical issues, requiring his/her intervention, proactively	-	-	-	-
<b>PC5.</b> engage with supervisor/ reporting manager on work-related and behavioral feedback	-	-	-	-
<i>Interact with colleagues and cross-functional teams</i>	<b>10</b>	<b>20</b>	-	<b>5</b>
<b>PC6.</b> takeover/ handover from colleagues in previous shift/ to colleagues in the next shift as per defined guidelines	-	-	-	-
<b>PC7.</b> coordinate with concerned personnel in stores for replenishing required material and spares	-	-	-	-
<b>PC8.</b> follow the protocols of cross-functional sections	-	-	-	-
<b>PC9.</b> plan the work in consultation with impacted cross-functional teams	-	-	-	-
<b>PC10.</b> respect others time and meet timelines for any cross-functional deliverable	-	-	-	-
<b>PC11.</b> resolve interpersonal conflicts at work with other colleagues, if any	-	-	-	-
<i>Sensitivity towards all genders and people with disability</i>	<b>10</b>	<b>20</b>	-	<b>5</b>



## Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<b>PC12.</b> respect all the genders, religions, and caste	-	-	-	-
<b>PC13.</b> empathize with the people with disability	-	-	-	-
<b>PC14.</b> offer support or help to a person with disability only when asked	-	-	-	-
<b>PC15.</b> adhere with the guidelines laid in POSH Act	-	-	-	-
<b>PC16.</b> report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee	-	-	-	-
<b>NOS Total</b>	<b>30</b>	<b>55</b>	<b>-</b>	<b>15</b>



## Qualification Pack

### National Occupational Standards (NOS) Parameters

<b>NOS Code</b>	LFS/N0801
<b>NOS Name</b>	Coordinate with reporting manager, teammates, and cross-functional teams
<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceutical, Bio Pharmaceutical, Contract Research
<b>Occupation</b>	Engineering and Maintenance
<b>NSQF Level</b>	4
<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

### 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



## Qualification Pack

### *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



## Qualification Pack

- 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

## 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 job requirements	-	-	-	-
<i>Constitutional values – Citizenship</i>	<b>1</b>	<b>1</b>	-	-
<b>PC2.</b> identify constitutional values, civic rights, duties, personal values and ethics and environmentally sustainable practices	-	-	-	-
<i>Becoming a Professional in the 21st Century</i>	<b>1</b>	<b>3</b>	-	-
<b>PC3.</b> 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.	-	-	-	-
<i>Basic English Skills</i>	<b>2</b>	<b>3</b>	-	-
<b>PC4.</b> speak with others using some basic English phrases or sentences	-	-	-	-
<i>Communication Skills</i>	<b>1</b>	<b>1</b>	-	-
<b>PC5.</b> follow good manners while communicating with others	-	-	-	-
<b>PC6.</b> work with others in a team	-	-	-	-
<i>Diversity &amp; Inclusion</i>	<b>1</b>	<b>1</b>	-	-
<b>PC7.</b> communicate and behave appropriately with all genders and PwD	-	-	-	-
<b>PC8.</b> report any issues related to sexual harassment	-	-	-	-
<i>Financial and Legal Literacy</i>	<b>3</b>	<b>4</b>	-	-
<b>PC9.</b> use various financial products and services safely and securely	-	-	-	-

## Qualification Pack

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



## Qualification Pack

### National Occupational Standards (NOS) Parameters

<b>NOS Code</b>	DGT/VSQ/N0101
<b>NOS Name</b>	Employability Skills (30 Hours)
<b>Sector</b>	Cross Sectoral
<b>Sub-Sector</b>	Professional Skills
<b>Occupation</b>	Employability
<b>NSQF Level</b>	2
<b>Credits</b>	1
<b>Version</b>	1.0
<b>Last Reviewed Date</b>	08/05/2025
<b>Next Review Date</b>	06/05/2028
<b>NSQC Clearance Date</b>	08/05/2025



## Qualification Pack

# LFS/N0804: Assist Maintenance Technician/Supervisor to carry out specialized maintenance in compliance with cGMP and regulatory guidelines

## Description

The job function is about assisting maintenance technician/ supervisor to carry out utility maintenance in compliance with cGMP and regulatory guidelines

## Scope

The scope covers the following :

- Maintenance of Heating, Ventilation, and Air Conditioning (HVAC) Utility
- Maintenance of Electric Utility
- Maintenance of Gas Utility
- Maintenance of Water Utility
- Maintenance of Steam Utility
- Environment sustainability

## Elements and Performance Criteria

### *Maintenance of HVAC Utility*

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

- PC1.** disconnect the electric supply from mains
- PC2.** tag the HVAC Unit/ relevant section as “under maintenance”
- PC3.** tighten up nut bolts/screw of HVAC and Ultraviolet (UV) cabinet as per instructions by the technician
- PC4.** Ensure the use of appropriate personal protective equipment (PPE) while handling HVAC components, especially in confined or high-temperature areas
- PC5.** follow working instruction to replace gasket of joints under supervision of technician
- PC6.** assist the technician in preparing preventive maintenance checklists, based on the past experience, maintenance manuals, and original equipment manuals by manufacturer as per cGMP
- PC7.** assist in maintenance, and/or modification in the HVAC system
- PC8.** clean tools/scrap material post maintenance activities

### *Maintenance of Electric Utility*

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

- PC9.** ensure to wear appropriate PPE before entering into the electrical utility area
- PC10.** Follow electrical safety protocols, including avoiding direct contact with live wires and using insulated tools when working near electrical systems.
- PC11.** disconnect the supply of electricity in the utility area
- PC12.** assist the technician in verifying the phases of electricity utility and voltage in the main PCC for the transformer’s electricity line





## Qualification Pack

**PC13.** assist in identifying defect/problem in the electrical utility system

### *Maintenance of Gas Utility*

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

**PC14.** support in the receipt, unloading, handling, and storage of gas cylinders

**PC15.** assist in monitoring of compressed air and gases in different plant/R&D facilities

**PC16.** assist in testing the frequency of various gases and its utility

**PC17.** identify gas leakage and escalate the faults to technician/ appropriate person for preventive actions

### *Maintenance of Water Utility*

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

**PC18.** check the availability of water in the plant

**PC19.** support in maintaining purified water, distilled water, tap water and water for injection as per the required specifications

**PC20.** assist maintenance technician/supervisor in the inspection of the water system for leakage, rusting, contamination etc.

### *Maintenance of Steam Utility*

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

**PC21.** assist the technician in the operation and cleaning of steam sterilizer

**PC22.** Monitor pressure levels and ensure all steam safety valves are functioning properly before operation, under the supervision of a certified technician.

**PC23.** check the connectivity of all the utilities such as compressed air, water with boiler

**PC24.** check the cleaning status of steam utility, also the water level in the boiler of the autoclave under the supervision of a certified boiler operator or maintenance technician

### *Environment Sustainability*

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

**PC25.** ensure energy conservation by switching off the tools, machine and equipment post operation

**PC26.** identify ways to optimize the usage of electricity/energy in various tasks/activities/processes

**PC27.** ensure no leakage of water at work premises

**PC28.** identify and segregate recyclable and non-recyclable, and hazardous waste generated

**PC29.** select and apply environment-friendly methods given in SOPs for waste disposal to achieve minimum pollution of land and water

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

**KU1.** basic principles of HVAC, gases, electric, steam and, water utilities

**KU2.** parts/ components of utilities (HVAC, gases, electric, steam and, water utilities) and their functions

**KU3.** about various tools and equipment required for various utilities

**KU4.** basic maintenance functions of HVAC, gases, electric, steam and, water

**KU5.** reporting incidents where standard operating procedures are not followed



## Qualification Pack

- KU6.** the importance of quality control procedures
- KU7.** importance of following cGMP guidelines
- KU8.** good practices to work on machines, guidelines of 5S and TPM
- KU9.** implications of delays in-process and maintenance
- KU10.** basics of cleanroom guidelines
- KU11.** environment sustainable methods to save energy and water
- KU12.** eco-friendly methods to dispose waste

## 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 in regional language or English/Hindi
- GS2.** use reading and comprehension skills to understand instructions/manuals, SOPs, health and safety instructions, memos, reports, job cards, etc.
- GS3.** use communication skills to convey and share technical information clearly using appropriate language, to report any disruptions and delays and any relevant information to concerned authority
- GS4.** apply critical thinking skills to identifying malfunctions and faults in various utilities
- GS5.** apply problem-solving skills to diagnose common problems in the machine based on visual inspection, sound, temperature, etc.
- GS6.** plan and organize assigned work in order to achieve specified deadlines as per the schedule provided
- GS7.** apply problem-solving skills to find solutions for workflow-related difficulties

## Qualification Pack

### Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Maintenance of HVAC Utility</i>	<b>5</b>	<b>10</b>	-	<b>5</b>
<b>PC1.</b> disconnect the electric supply from mains	-	-	-	-
<b>PC2.</b> tag the HVAC Unit/ relevant section as “under maintenance”	-	-	-	-
<b>PC3.</b> tighten up nut bolts/screw of HVAC and Ultraviolet (UV) cabinet as per instructions by the technician	-	-	-	-
<b>PC4.</b> Ensure the use of appropriate personal protective equipment (PPE) while handling HVAC components, especially in confined or high-temperature areas	-	-	-	-
<b>PC5.</b> follow working instruction to replace gasket of joints under supervision of technician	-	-	-	-
<b>PC6.</b> assist the technician in preparing preventive maintenance checklists, based on the past experience, maintenance manuals, and original equipment manuals by manufacturer as per cGMP	-	-	-	-
<b>PC7.</b> assist in maintenance, and/or modification in the HVAC system	-	-	-	-
<b>PC8.</b> clean tools/scrap material post maintenance activities	-	-	-	-
<i>Maintenance of Electric Utility</i>	<b>5</b>	<b>10</b>	-	<b>5</b>
<b>PC9.</b> ensure to wear appropriate PPE before entering into the electrical utility area	-	-	-	-
<b>PC10.</b> Follow electrical safety protocols, including avoiding direct contact with live wires and using insulated tools when working near electrical systems.	-	-	-	-
<b>PC11.</b> disconnect the supply of electricity in the utility area	-	-	-	-

## Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<b>PC12.</b> assist the technician in verifying the phases of electricity utility and voltage in the main PCC for the transformer's electricity line	-	-	-	-
<b>PC13.</b> assist in identifying defect/problem in the electrical utility system	-	-	-	-
<i>Maintenance of Gas Utility</i>	<b>5</b>	<b>10</b>	-	<b>5</b>
<b>PC14.</b> support in the receipt, unloading, handling, and storage of gas cylinders	-	-	-	-
<b>PC15.</b> assist in monitoring of compressed air and gases in different plant/R&D facilities	-	-	-	-
<b>PC16.</b> assist in testing the frequency of various gases and its utility	-	-	-	-
<b>PC17.</b> identify gas leakage and escalate the faults to technician/ appropriate person for preventive actions	-	-	-	-
<i>Maintenance of Water Utility</i>	<b>5</b>	<b>10</b>	-	<b>5</b>
<b>PC18.</b> check the availability of water in the plant	-	-	-	-
<b>PC19.</b> support in maintaining purified water, distilled water, tap water and water for injection as per the required specifications	-	-	-	-
<b>PC20.</b> assist maintenance technician/supervisor in the inspection of the water system for leakage, rusting, contamination etc.	-	-	-	-
<i>Maintenance of Steam Utility</i>	<b>5</b>	<b>10</b>	-	<b>5</b>
<b>PC21.</b> assist the technician in the operation and cleaning of steam sterilizer	-	-	-	-
<b>PC22.</b> Monitor pressure levels and ensure all steam safety valves are functioning properly before operation, under the supervision of a certified technician.	-	-	-	-
<b>PC23.</b> check the connectivity of all the utilities such as compressed air, water with boiler	-	-	-	-



## Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<b>PC24.</b> check the cleaning status of steam utility, also the water level in the boiler of the autoclave under the supervision of a certified boiler operator or maintenance technician	-	-	-	-
<i>Environment Sustainability</i>	-	-	-	-
<b>PC25.</b> ensure energy conservation by switching off the tools, machine and equipment post operation	-	-	-	-
<b>PC26.</b> identify ways to optimize the usage of electricity/energy in various tasks/activities/processes	-	-	-	-
<b>PC27.</b> ensure no leakage of water at work premises	-	-	-	-
<b>PC28.</b> identify and segregate recyclable and non-recyclable, and hazardous waste generated	-	-	-	-
<b>PC29.</b> select and apply environment-friendly methods given in SOPs for waste disposal to achieve minimum pollution of land and water	-	-	-	-
<b>NOS Total</b>	<b>25</b>	<b>50</b>	<b>-</b>	<b>25</b>



## Qualification Pack

### National Occupational Standards (NOS) Parameters

<b>NOS Code</b>	LFS/N0804
<b>NOS Name</b>	Assist Maintenance Technician/Supervisor to carry out specialized maintenance in compliance with cGMP and regulatory guidelines
<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceutical, Bio Pharmaceutical, Contract Research
<b>Occupation</b>	Engineering and Maintenance
<b>NSQF Level</b>	3
<b>Credits</b>	7.00
<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

## 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 an assessment and awarding body will create unique evaluations for each assessment component i.e. theory, practical, project and viva for every student at each examination/training center based on this criterion.
6. Wherever any assessment component is not applicable/ feasible, the balance assessment components will be used to assess the candidate and accordingly the total marks will be calculated only for the applied



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assessment component.

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

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

### Minimum Aggregate Passing % at QP Level : 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/N0820.Discuss about life sciences industry and essential concepts of Maintenance	30	45	10	15	100	10
LFS/N0112.Adherence to Environment, health and safety guidelines in a production facility and GMP controlled area	30	40	15	15	100	10
LFS/N0802.Prepare for maintenance in compliance with schedule and job safety guidelines	35	50	-	15	100	25
LFS/N0113.Ensure a hygienic and clean work area to avoid contamination	30	40	15	15	100	10
LFS/N0801.Coordinate with reporting manager, teammates, and cross-functional teams	30	55	-	15	100	10



### Qualification Pack

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
DGT/VSQ/N0101.Employability Skills (30 Hours)	20	30	-	-	50	5
<b>Total</b>	<b>175</b>	<b>260</b>	<b>40</b>	<b>75</b>	<b>550</b>	<b>70</b>

Elective: 1 Utility

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0804.Assist Maintenance Technician/Supervisor to carry out specialized maintenance in compliance with cGMP and regulatory guidelines	25	50	-	25	100	30
<b>Total</b>	<b>25</b>	<b>50</b>	<b>-</b>	<b>25</b>	<b>100</b>	<b>30</b>