



Qualification Pack



Supervisor- Maintenance (Pharma, Biologics and Medical Device Facility)

Electives: Water System

QP Code: LFS/Q0802 Instantiated QP Code: LFS/Q0802-SI003

Version: 3.0

NSQF Level: 5

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LFS/Q0802-SI003: Supervisor- Maintenance (Pharma, Biologics and Medical Device Facility)

Brief Job Description

Supervisor-Maintenance (Pharma, Biologics and Medical Device Facility) is responsible for supervising Maintenance Technician and Assistant and oversee the maintenance activities of the plant/ facility in a regulated/ semi-regulated plant/ research center. The job role holder is responsible for identifying and resolving critical issues related to installation, operation, maintenance or break down of specialized utility like electrical, HVAC, water, gases or steam. The individual is responsible for overseeing current Good Manufacturing Practices (cGMP) critical engineering functions and ensuring the adherence to regulatory/ GMP and Environment, Health, and Safety(EHS) guidelines.

Personal Attributes

The person should have good written and verbal communication skills. The individual should possess good problem solving, decision making, analytical, and critical thinking skills within the permissible boundaries. The person is expected to be emotionally balanced and good in interpersonal relationships and handling conflicts. The job holder should be good in resource and time management.

Applicable National Occupational Standards (NOS)

Compulsory NOS:

1. [LFS/N0821: Discuss about life sciences industry and Essential concepts for manufacturing design and maintenance](#)
2. [LFS/N0805: Ensure smooth maintenance of utilities as per cGMP guidelines](#)
3. [LFS/N0111: Ensure adherence to Environment, health and safety guidelines in production facility and cGMP controlled areas](#)
4. [LFS/N0806: Perform maintenance related documentation](#)
5. [LFS/N0807: Coordinate with a manager and cross-functional teams and manage the maintenance team](#)
6. [DGT/VSQ/N0103: Employability Skills \(90 Hours\)](#)

Electives (mandatory to select at least one):

Elective : Water System

This Supervisor- Maintenance (Pharma, Biologics and Medical Device Facility) is considered to be a Water Utility specialist.



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1. [LFS/N0810: Monitor assembly, installation, operation and maintenance of Water system utility](#)

Qualification Pack (QP) Parameters

Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Engineering and Maintenance
Country	India
NSQF Level	5
Credits	20
Aligned to NCO/ISCO/ISIC Code	NCO-2015/2144.0600 NCO-2015/3122.5600
Minimum Educational Qualification & Experience	Completed 2nd year of UG (UG Diploma) (Instrumentation & Electronics / Mechanical/ Civil/ relevant Field) OR Diploma (Diploma in Engineering (Instrumentation & Electronics / Mechanical/ Civil/ relevant Field)) OR Certificate-NSQF (Level 4 Technician- Maintenance (Level 4)) with 3 Years of experience Experience in Life Sciences sector OR Certificate-NSQF (Certificate NSQF Level 3 Assistant-Maintenance (Pharma, Biologics and Medical Device Facility)) with 6 Years of experience Experience in Life Sciences sector
Minimum Level of Education for Training in School	
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	3.0



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Reference code on NQR	QG-05-LS-03410-2024-V2-LSSSDC
NQR Version	2.0



Qualification Pack

LFS/N0821: Discuss about life sciences industry and Essential concepts for manufacturing design and maintenance

Description

This NOS is to Discuss about life sciences industry and Essential concepts for manufacturing design and maintenance

Scope

The scope covers the following :

- Discuss about Life Sciences industry
- Essential concepts for manufacturing design and 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 the key segments within the Life Sciences industry (pharma, biologics, medical devices) in both the Indian and global contexts.
- PC2.** Demonstrate understanding of regulatory frameworks such as WHO, FDA, and EU guidelines for GLP, cGMP, and GDP in a cleanroom setting
- PC3.** Identify the essential technical and interpersonal skills required to perform maintenance in a pharmaceutical, biologics, or medical device manufacturing facility
- PC4.** Demonstrate understanding of terms related to maintenance documentation, such as Work Orders, Maintenance Logs, and Standard Operating Procedures (SOPs).

Essential concepts for manufacturing design and maintenance

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

- PC5.** discuss how maintenance activities contribute to product quality, equipment efficiency, and adherence to current Good Manufacturing Practices (cGMP).
- PC6.** identify preventive maintenance in reducing equipment downtime and minimizing unexpected breakdowns.
- PC7.** analyze the impact of equipment breakdowns on production timelines, product quality, and compliance with regulatory standards
- PC8.** apply root cause analysis to identify underlying issues leading to equipment breakdown or process failure.
- PC9.** assess potential process deviations and material defects that can lead to non-conforming products.
- PC10.** conduct risk assessments to identify potential hazards during maintenance shutdowns, including project and annual shutdowns.
- PC11.** perform statistical analysis during maintenance activities to monitor performance and identify areas for improvement.

Knowledge and Understanding (KU)



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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
- 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:



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- 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
- 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>	10	10	5	5
PC1. Discuss the key segments within the Life Sciences industry (pharma, biologics, medical devices) in both the Indian and global contexts.	-	-	-	-
PC2. Demonstrate understanding of regulatory frameworks such as WHO, FDA, and EU guidelines for GLP, cGMP, and GDP in a cleanroom setting	-	-	-	-
PC3. Identify the essential technical and interpersonal skills required to perform maintenance in a pharmaceutical, biologics, or medical device manufacturing facility	-	-	-	-
PC4. Demonstrate understanding of terms related to maintenance documentation, such as Work Orders, Maintenance Logs, and Standard Operating Procedures (SOPs).	-	-	-	-
<i>Essential concepts for manufacturing design and maintenance</i>	20	30	10	10
PC5. discuss how maintenance activities contribute to product quality, equipment efficiency, and adherence to current Good Manufacturing Practices (cGMP).	-	-	-	-
PC6. identify preventive maintenance in reducing equipment downtime and minimizing unexpected breakdowns.	-	-	-	-
PC7. analyze the impact of equipment breakdowns on production timelines, product quality, and compliance with regulatory standards	-	-	-	-
PC8. apply root cause analysis to identify underlying issues leading to equipment breakdown or process failure.	-	-	-	-
PC9. assess potential process deviations and material defects that can lead to non-conforming products.	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC10. conduct risk assessments to identify potential hazards during maintenance shutdowns, including project and annual shutdowns.	-	-	-	-
PC11. perform statistical analysis during maintenance activities to monitor performance and identify areas for improvement.	-	-	-	-
NOS Total	30	40	15	15



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0821
NOS Name	Discuss about life sciences industry and Essential concepts for manufacturing design and maintenance
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Engineering and Maintenance
NSQF Level	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



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LFS/N0805: Ensure smooth maintenance of utilities as per cGMP guidelines

Description

This job function is about a Supervisor- Maintenance (Pharma, Biologics and Medical Device Facility) preparing and communicating maintenance schedules and managing maintenance operations.

Scope

The scope covers the following :

- Maintenance schedule management
- Maintenance operations management
- cGMP related critical activities
- Environmental sustainability

Elements and Performance Criteria

Maintenance Schedules Management

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

- PC1.** prepare a list of areas in production or manufacturing facility where maintenance is to be done
- PC2.** plan and schedule the maintenance activities (preventive/periodic shutdown maintenance)
- PC3.** ensure zero impact or disturbance in planned production activities due to scheduled maintenance
- PC4.** update the maintenance plan as part of new equipment introduction
- PC5.** identify the manpower requirement based on the maintenance required and their specialized field of utility
- PC6.** plan maintenance as per the vacation schedule for all employees and ensure that work is not affected adversely
- PC7.** assign the required workmen/workforce for maintenance activities as per planned schedule
- PC8.** monitor and ensure the punctuality of workmen at the workplace as per the maintenance schedule

Maintenance Operations Management

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

- PC9.** ensure availability and adherence of maintenance team with Material Safety Data Sheets (MSDS), maintenance and relevant production/ lab procedures, work instructions and manufacturer's instructions for all maintenance activities at the workplace
- PC10.** ensure the maintenance team is trained and competent to follow maintenance-related procedures
- PC11.** ensure that all the documented procedures are followed by self and team during the changeover, project shutdown and annual shut down
- PC12.** provide technical guidance to the maintenance team for any troubleshooting and severe risk/hazard



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PC13. deal with accidental damage, if any, caused during maintenance activity

PC14. report to the impacted stakeholders, production planning team and QA for any disturbances in material flow or equipment

GMP Related Critical Activities

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

PC15. analyze the risks for the working environment in the area where maintenance is to be performed

PC16. assess the impact of every new spare part/ lubricant/chemical on machine/ utility performance, clean room state, and product quality

PC17. approve the job analysis and risk assessment analysis for every maintenance technician

PC18. provide line clearance for starting of maintenance activity in consultation with the impacted area in charge and QA team

PC19. oversee cleaning validation and ensure maintenance work does not impact the cleanroom state of the area under maintenance or product quality

Environmental sustainability

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

PC20. create awareness in the team about organizational environment sustainability guidelines and procedures

PC21. ensure energy conservation by following energy-efficient work procedures and maintenance tools and appliances

PC22. ensure no leakage of water at work premises

PC23. ensure that waste disposal is done by environment-friendly methods as per SOPs

PC24. ensure that the waste garnered from the activity is disposed of with zero impact on the environment in compliance to defined procedures

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. importance of time management

KU2. concepts of project management

KU3. fundamental concepts of 5S

KU4. importance of team management

KU5. how to resolve team conflicts without affecting work

KU6. importance of manpower management and how it is forecasted

KU7. cGMP guidelines

KU8. importance of training team members on the maintenance operations in adherence to safety guidelines

KU9. common causes of variation and corrective action required

KU10. operational health and safety (OHS) hazards and controls, including limitations of protective clothing and equipment relevant to the work process

KU11. requirements of different shutdowns and procedures to be followed in the event of a power outage



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- KU12.** environmental issues and controls relevant to the process, including waste/rework collection and handling procedures related to the process

Generic Skills (GS)

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

- GS1.** use verbal communication skills to communicate work schedules clearly and precisely
- GS2.** apply problem-solving skills to resolve workplace conflicts
- GS3.** analyze past data and apply critical thinking skills to identify resource needed for maintenance activities required in future
- GS4.** apply planning and organizing skills to plan and organize resources to ensure that maintenance activities lead to production efficiency
- GS5.** use verbal communication skills to interact with teammates and with other production teams for identifying appropriate maintenance schedules
- GS6.** apply problem-solving skills to solve conflicts within the team on work schedules and adherence
- GS7.** apply critical thinking skills to identify alternate approaches/resource deployment/equipment utilization to ensure schedule adherence
- GS8.** apply analytical skill to analyze operations data and information to identify assembly, installation and maintenance needs
- GS9.** apply critical thinking skills to prevent faults and anomalies before the breakdown

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Maintenance Schedules Management</i>	5	10	-	-
PC1. prepare a list of areas in production or manufacturing facility where maintenance is to be done	-	-	-	-
PC2. plan and schedule the maintenance activities (preventive/periodic shutdown maintenance)	-	-	-	-
PC3. ensure zero impact or disturbance in planned production activities due to scheduled maintenance	-	-	-	-
PC4. update the maintenance plan as part of new equipment introduction	-	-	-	-
PC5. identify the manpower requirement based on the maintenance required and their specialized field of utility	-	-	-	-
PC6. plan maintenance as per the vacation schedule for all employees and ensure that work is not affected adversely	-	-	-	-
PC7. assign the required workmen/workforce for maintenance activities as per planned schedule	-	-	-	-
PC8. monitor and ensure the punctuality of workmen at the workplace as per the maintenance schedule	-	-	-	-
<i>Maintenance Operations Management</i>	15	25	-	5
PC9. ensure availability and adherence of maintenance team with Material Safety Data Sheets (MSDS), maintenance and relevant production/ lab procedures, work instructions and manufacturer's instructions for all maintenance activities at the workplace	-	-	-	-
PC10. ensure the maintenance team is trained and competent to follow maintenance-related procedures	-	-	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC11. ensure that all the documented procedures are followed by self and team during the changeover, project shutdown and annual shut down	-	-	-	-
PC12. provide technical guidance to the maintenance team for any troubleshooting and severe risk/ hazard	-	-	-	-
PC13. deal with accidental damage, if any, caused during maintenance activity	-	-	-	-
PC14. report to the impacted stakeholders, production planning team and QA for any disturbances in material flow or equipment	-	-	-	-
<i>GMP Related Critical Activities</i>	10	15	-	5
PC15. analyze the risks for the working environment in the area where maintenance is to be performed	-	-	-	-
PC16. assess the impact of every new spare part/ lubricant/chemical on machine/ utility performance, clean room state, and product quality	-	-	-	-
PC17. approve the job analysis and risk assessment analysis for every maintenance technician	-	-	-	-
PC18. provide line clearance for starting of maintenance activity in consultation with the impacted area in charge and QA team	-	-	-	-
PC19. oversee cleaning validation and ensure maintenance work does not impact the cleanroom state of the area under maintenance or product quality	-	-	-	-
<i>Environmental sustainability</i>	5	5	-	-
PC20. create awareness in the team about organizational environment sustainability guidelines and procedures	-	-	-	-
PC21. ensure energy conservation by following energy-efficient work procedures and maintenance tools and appliances	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC22. ensure no leakage of water at work premises	-	-	-	-
PC23. ensure that waste disposal is done by environment-friendly methods as per SOPs	-	-	-	-
PC24. ensure that the waste garnered from the activity is disposed of with zero impact on the environment in compliance to defined procedures	-	-	-	-
NOS Total	35	55	-	10



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0805
NOS Name	Ensure smooth maintenance of utilities as per cGMP guidelines
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Engineering and Maintenance
NSQF Level	5
Credits	6.0
Version	3.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024



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LFS/N0111: Ensure adherence to Environment, health and safety guidelines in production facility and cGMP controlled areas

Description

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

Scope

The scope covers the following :

- Follow health and hygiene protocols
- Adherence to safety and security procedures
- Adherence to emergency procedures

Elements and Performance Criteria

Follow health and hygiene protocols

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

- PC1.** comply with health and personal hygiene-related protocols as per WHO standards, revised GMP and ICH GMP guidelines
- PC2.** wash hands before entering in the production area with soap/alcohol based sanitisers
- PC3.** report any allergy, sickness or any other environment-related breach before or after entering the work premises to the designated person
- PC4.** take preventive actions on the report of any allergy, sickness or any other environment-related breach reported by subordinates
- PC5.** follow gowning procedures while entering an environment controlled work area and ensure the adherence of the same by others

Adherence to safety and security procedures

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

- PC6.** comply with safety and security policies and procedures
- PC7.** ensure the use of appropriate safety gears like headgear, masks, gloves and other accessories as mentioned in the guidelines, by self and subordinates while carrying out work
- PC8.** take preventive and corrective actions based on the report of any identified breaches in safety and security policies and procedures by subordinates
- PC9.** ensure that discipline for material segregation and 5S system is followed at the storage area
- PC10.** comply with material handling, segregation, and storage guidelines for hazardous material
- PC11.** take corrective actions for reported hazards in consultation with EHS personnel
- PC12.** complete the records of safety drills and trainings undertaken by self and subordinates

Adherence to emergency procedures

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



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- PC13.** report any hazards that he/she is not competent to deal with the relevant EHS personnel and warn other people who may be affected
- PC14.** raise the alarm and inform the concerned person immediately for action in the cases of spill, fall, injury, toxic inhale, fire or explosion
- PC15.** follow emergency protocols for any alarms and ensure the safety of subordinates in the area under supervision
- PC16.** follow emergency procedures efficiently
- PC17.** ensure injured employees are provided appropriate first aid and medical aid

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** company's procedures for the environment, health, and safety
- KU2.** implications that any non-compliance with health, safety and security may have on individuals and the organization
- KU3.** workplace hazards in the manufacturing facility in the life sciences sector, how and when to report hazards
- KU4.** limits of individual responsibility for dealing with hazards
- KU5.** chemical substances, their characteristics, and required precaution and safety measures
- KU6.** gowning procedure
- KU7.** the organization's emergency procedures for different emergencies and the importance of following these
- KU8.** evacuation procedures for employees, contract staff and visitors
- KU9.** how to summon medical assistance and the emergency services, where necessary
- KU10.** health, safety and accident reporting procedures and the importance of reporting in GMP
- KU11.** different types of breaches in the environment, health, safety and security and how and when to report these
- KU12.** WHO guidelines for personal hygiene
- KU13.** type of safety gears and procedure to use them
- KU14.** the importance of material segregation and 5S system
- KU15.** WHO guidelines for handling and storing hazardous material

Generic Skills (GS)

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

- GS1.** use reading and comprehension skills to understand the various coding systems and to read instructions, guidelines, procedures, rules, and signages to understand the procedure to be followed
- GS2.** use listening skills to follow the instructions and procedures during emergency alarms
- GS3.** use written communication skills to accurately record every information required to be reported as per SOP and GMP guidelines in the prescribed language



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- GS4.** apply planning and organizing skills to plan and organize tools and material required for work to fulfil environment, health, safety and security requirements
- GS5.** use critical thinking skills to take relevant actions on the accidents and breach in compliance with EHS protocols
- GS6.** apply decision-making skills to make balanced judgments within the authority while dealing with hazards and breaches
- GS7.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS8.** use verbal communication skills to communicate with supervisor/ manager/ EHS Incharge or any other concerned authority clearly for escalating any emergency or hazard

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Follow health and hygiene protocols</i>	10	15	-	5
PC1. comply with health and personal hygiene-related protocols as per WHO standards, revised GMP and ICH GMP guidelines	-	-	-	-
PC2. wash hands before entering in the production area with soap/alcohol based sanitisers	-	-	-	-
PC3. report any allergy, sickness or any other environment-related breach before or after entering the work premises to the designated person	-	-	-	-
PC4. take preventive actions on the report of any allergy, sickness or any other environment-related breach reported by subordinates	-	-	-	-
PC5. follow gowning procedures while entering an environment controlled work area and ensure the adherence of the same by others	-	-	-	-
<i>Adherence to safety and security procedures</i>	10	25	-	5
PC6. comply with safety and security policies and procedures	-	-	-	-
PC7. ensure the use of appropriate safety gears like headgear, masks, gloves and other accessories as mentioned in the guidelines, by self and subordinates while carrying out work	-	-	-	-
PC8. take preventive and corrective actions based on the report of any identified breaches in safety and security policies and procedures by subordinates	-	-	-	-
PC9. ensure that discipline for material segregation and 5S system is followed at the storage area	-	-	-	-
PC10. comply with material handling, segregation, and storage guidelines for hazardous material	-	-	-	-
PC11. take corrective actions for reported hazards in consultation with EHS personnel	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. complete the records of safety drills and trainings undertaken by self and subordinates	-	-	-	-
<i>Adherence to emergency procedures</i>	10	15	-	5
PC13. report any hazards that he/she is not competent to deal with the relevant EHS personnel and warn other people who may be affected	-	-	-	-
PC14. raise the alarm and inform the concerned person immediately for action in the cases of spill, fall, injury, toxic inhale, fire or explosion	-	-	-	-
PC15. follow emergency protocols for any alarms and ensure the safety of subordinates in the area under supervision	-	-	-	-
PC16. follow emergency procedures efficiently	-	-	-	-
PC17. ensure injured employees are provided appropriate first aid and medical aid	-	-	-	-
NOS Total	30	55	-	15



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0111
NOS Name	Ensure adherence to Environment, health and safety guidelines in production facility and cGMP controlled areas
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Generic
NSQF Level	5
Credits	1.00
Version	3.0
Last Reviewed Date	08/04/2025
Next Review Date	08/04/2028
NSQC Clearance Date	08/04/2025



Qualification Pack

LFS/N0806: Perform maintenance related documentation

Description

This NOS is about a Supervisor- Maintenance (Pharma, Biologics and Medical Device Facility) performing documentation for maintenance operations in compliance with GMP and regulatory guidelines

Scope

The scope covers the following :

- Reporting of maintenance activities
- Maintain engineering and maintenance-related documents
- Manage the Computerized Maintenance Management System (CMMS)/ computerized hybrid system

Elements and Performance Criteria

Reporting of maintenance activities

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

- PC1.** follow ALCOA PLUS guidelines for documentation
- PC2.** perform root cause analysis based on review of every reported breakdown incident/job work action and report to production and QA for further consultation
- PC3.** identify and document Corrective Action and Preventive Action (CAPA) for every incident and deviations in compliance with GMP and other regulatory guidelines
- PC4.** perform risk analysis and develop a contingency plan for each reported and unprecedented cause or error or critical incident
- PC5.** maintain the equipment master and its qualification, validation, and calibration records
- PC6.** review and approve the logbook entries and trial run records

Maintain engineering and maintenance related document

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

- PC7.** maintain Operation and Maintenance (O&M) manuals, schematic drawings, procedures, protocols, reports, and log of system revisions for every equipment/ machine under the scope of work
- PC8.** maintain checklists for breakdown maintenance based on experience, maintenance manuals and manufacture's recommendations for every equipment
- PC9.** determine the procedures for maintenance, installation, modification/repair of equipment and provide inputs to QA for drafting the SOPs
- PC10.** record the trial run readings in a logbook, before and after every activity
- PC11.** ensure the appropriate status labels are placed on the machine/ equipment/ part, post every maintenance completion
- PC12.** coordinate with QA personnel for documentation of qualification/ re-qualification records of the machine/ equipment/part
- PC13.** record risk assessment analysis for every new spare part/ lubricant/ any changes in machine parameters during maintenance and seek approval from QA team



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PC14. review and approve the change control request in case of change of any spare part in consultation with QA, production and regulatory team and document the details of same

PC15. ensure all GMP critical documents and source records are maintained as per ALCOA PLUS guidelines and are made available promptly for audits

Manage the Computerized Maintenance Management System (CMMS)/ computerized hybrid system

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

PC16. ensure the logs and entries are made in a computerized maintenance management system (CMMS)/ a hybrid system if available in the organization

PC17. ensure recording of the calibration records for equipment in the CMMS/ a hybrid system

PC18. maintain the master list of tools, equipment, and spare parts

PC19. sort tools, equipment, and spare parts into various categories like critical, general, special purpose, etc

PC20. maintain the status of tools and equipment in a CMMS/ hybrid system

PC1. approve the request of spare part/ replacement in a computerized indent system if applicable

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. basics of ALCOA PLUS Principles used in the Life Sciences Sector

KU2. basics of Good Documentation Practices (GDP) followed in the Life Sciences Sector

KU3. common formats and processes followed for filling machine/ equipment master, risk deviations, incident reporting, calibration records, and CAPA related information

KU4. management of the CMMS/Hybrid computerized system

KU5. operating procedure of computerized indent system for spare parts

KU6. maintenance-related labelling and tagging guidelines as per WHO/ GMP

KU7. steps to be taken in a change control procedure

KU8. list of GMP critical documents in a regulated facility

KU9. process of recording the outcome of Design Qualifications (DQ), Installation Qualification (IQ) Operation Qualification (OQ), and Performance Qualification (PQ)

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/ or computer-based record/electronic mail

GS2. use listening skills to understand the instructions and procedures to be followed

GS3. use verbal communication skills to communicate with cross-functional teams and supervisor effectively

GS4. apply decision making skills to disclose information only to those who have the right and need to know it



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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 problem-solving skills to find solutions for workflow-related difficulties
- GS7.** use verbal communication to respond to audit queries and participate in audit interviews as and when required

Qualification Pack

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Reporting of maintenance activities</i>	10	15	-	5
PC1. follow ALCOA PLUS guidelines for documentation	-	-	-	-
PC2. perform root cause analysis based on review of every reported breakdown incident/job work action and report to production and QA for further consultation	-	-	-	-
PC3. identify and document Corrective Action and Preventive Action (CAPA) for every incident and deviations in compliance with GMP and other regulatory guidelines	-	-	-	-
PC4. perform risk analysis and develop a contingency plan for each reported and unprecedented cause or error or critical incident	-	-	-	-
PC5. maintain the equipment master and its qualification, validation, and calibration records	-	-	-	-
PC6. review and approve the logbook entries and trial run records	-	-	-	-
<i>Maintain engineering and maintenance related document</i>	10	20	-	5
PC7. maintain Operation and Maintenance (O&M) manuals, schematic drawings, procedures, protocols, reports, and log of system revisions for every equipment/ machine under the scope of work	-	-	-	-
PC8. maintain checklists for breakdown maintenance based on experience, maintenance manuals and manufacture's recommendations for every equipment	-	-	-	-
PC9. determine the procedures for maintenance, installation, modification/repair of equipment and provide inputs to QA for drafting the SOPs	-	-	-	-
PC10. record the trial run readings in a logbook, before and after every activity	-	-	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC11. ensure the appropriate status labels are placed on the machine/ equipment/ part, post every maintenance completion	-	-	-	-
PC12. coordinate with QA personnel for documentation of qualification/ re-qualification records of the machine/ equipment/part	-	-	-	-
PC13. record risk assessment analysis for every new spare part/ lubricant/ any changes in machine parameters during maintenance and seek approval from QA team	-	-	-	-
PC14. review and approve the change control request in case of change of any spare part in consultation with QA, production and regulatory team and document the details of same	-	-	-	-
PC15. ensure all GMP critical documents and source records are maintained as per ALCOA PLUS guidelines and are made available promptly for audits	-	-	-	-
<i>Manage the Computerized Maintenance Management System (CMMS)/ computerized hybrid system</i>	10	20	-	5
PC16. ensure the logs and entries are made in a computerized maintenance management system (CMMS)/ a hybrid system if available in the organization	-	-	-	-
PC17. ensure recording of the calibration records for equipment in the CMMS/ a hybrid system	-	-	-	-
PC18. maintain the master list of tools, equipment, and spare parts	-	-	-	-
PC19. sort tools, equipment, and spare parts into various categories like critical, general, special purpose, etc	-	-	-	-
PC20. maintain the status of tools and equipment in a CMMS/ hybrid system	-	-	-	-
PC1. approve the request of spare part/ replacement in a computerized indent system if applicable	-	-	-	-



Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
NOS Total	30	55	-	15



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0806
NOS Name	Perform maintenance related documentation
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Engineering and Maintenance
NSQF Level	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



Qualification Pack

LFS/N0807: Coordinate with a manager and cross-functional teams and manage the maintenance team

Description

This job function is about communicating with colleagues (both within team & cross-functional) and seniors to achieve smooth and hazard-free workflow during production

Scope

The scope covers the following :

- Coordination with manager
- Coordination with cross-functional teams
- Manage the maintenance team
- Sensitivity towards gender and people with disability

Elements and Performance Criteria

Coordinate with manager

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

- PC1.** follow the regulatory guidelines received from the manager
- PC2.** plan the maintenance operations to meet the objective, timelines and cost optimization targets in coordination with manager
- PC3.** ensure timely intimation to the manager about planned absence and the backup plan for smooth operations during the absence
- PC4.** escalate the critical issues/ alarming situations to the manager
- PC5.** inform the identified cause and effect relationships for deviations and assist management in the development of CAPA and contingency plans
- PC6.** seek work or behavioral feedback from the manager
- PC7.** coordinate with the manager on learning goals and seek guidance on team's performance improvement

Coordinate with cross-functional teams

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

- PC8.** provide inputs to cross-functional teams for estimation of time and cost for installation and maintenance
- PC9.** coordinate with warehouse and QA to replenish any necessary supplies/ consumables and spares
- PC10.** follow the protocols of cross-functional sections to ensure compliance with procedural and regulatory guidelines
- PC11.** coordinate with production, quality, and supply chain teams to derive the maintenance schedules for zero impact on productivity
- PC12.** coordinate with production, quality team for line clearance, change control approvals as well as calibration and validation activities
- PC13.** respect other's time and ensure to meet timelines for any cross-functional deliverable



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PC14. collaborate with the cross-function team and resolve interpersonal conflicts at work, if any

PC15. coordinate with QA and regulatory auditors for audit of electrical maintenance work

PC16. answer the queries of auditors in an appropriate way

Manage the maintenance team

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

PC17. ensure completion of technical and behavioral training of maintenance team members before the start of work and completion of their training records

PC18. ensure communication of organizational objective and regulatory guidelines to the team and set the key performance indicator for each team member

PC19. evaluate the performance of team members periodically and engage them in performance assessment dialogue and provide work-related and behavioral feedback

PC20. guide team members on the learning goals and provide opportunities to perform, learn, and grow

PC21. guide team members for managing their time effectively

Sensitivity towards all genders and people with disability

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

PC22. respect all genders, religions, and caste

PC23. empathize with the people with disability

PC24. offer support or help to a person with disability only when asked

PC25. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act

PC26. 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 policies on preferred language of communication, reporting and escalation policy, quality delivery standards, and personnel management

KU2. reporting structure

KU3. importance of team management in team building

KU4. emotions and stress management strategies

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 right way to use the laws acts, and provisions defined for PwD by the statutory bodies

KU9. the guidelines laid on Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act

KU10. importance of respecting all genders, religion, caste, and culture

KU11. how to develop a collaborative culture for cross-culture and gender-inclusive team

KU12. various cost optimization strategies

KU13. process of developing CAPA and contingency plans



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KU14. various approach to define key performance indicators and methods to evaluate performance at work

KU15. time management strategies

Generic Skills (GS)

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

GS1. use reading and comprehension skills to read job sheets and interpret technical details mentioned in the job-sheet

GS2. how to use written communication skills to write e-mails to communicate any job-related information to supervisor or colleagues

GS3. how to use reading skills to read notes/comments from the supervisor

GS4. apply team-building skills while interacting with teammates and while managing the difficult/stressful or emotional situations at work

GS5. use verbal communication skills to communicate with colleagues and supervisor to maintain an effective and smooth interpersonal relationship

GS6. apply critical thinking skills to analyze and identify when to report an issue/concern to the manager and when to deal with a colleague individually, depending on the type of concern

GS7. apply team-building skills to improve work processes by interacting with others and adopting best practices

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Coordinate with manager</i>	10	15	-	3
PC1. follow the regulatory guidelines received from the manager	-	-	-	-
PC2. plan the maintenance operations to meet the objective, timelines and cost optimization targets in coordination with manager	-	-	-	-
PC3. ensure timely intimation to the manager about planned absence and the backup plan for smooth operations during the absence	-	-	-	-
PC4. escalate the critical issues/ alarming situations to the manager	-	-	-	-
PC5. inform the identified cause and effect relationships for deviations and assist management in the development of CAPA and contingency plans	-	-	-	-
PC6. seek work or behavioral feedback from the manager	-	-	-	-
PC7. coordinate with the manager on learning goals and seek guidance on team's performance improvement	-	-	-	-
<i>Coordinate with cross-functional teams</i>	10	15	-	5
PC8. provide inputs to cross-functional teams for estimation of time and cost for installation and maintenance	-	-	-	-
PC9. coordinate with warehouse and QA to replenish any necessary supplies/ consumables and spares	-	-	-	-
PC10. follow the protocols of cross-functional sections to ensure compliance with procedural and regulatory guidelines	-	-	-	-
PC11. coordinate with production, quality, and supply chain teams to derive the maintenance schedules for zero impact on productivity	-	-	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. coordinate with production, quality team for line clearance, change control approvals as well as calibration and validation activities	-	-	-	-
PC13. respect other's time and ensure to meet timelines for any cross-functional deliverable	-	-	-	-
PC14. collaborate with the cross-function team and resolve interpersonal conflicts at work, if any	-	-	-	-
PC15. coordinate with QA and regulatory auditors for audit of electrical maintenance work	-	-	-	-
PC16. answer the queries of auditors in an appropriate way	-	-	-	-
<i>Manage the maintenance team</i>	10	15	-	5
PC17. ensure completion of technical and behavioral training of maintenance team members before the start of work and completion of their training records	-	-	-	-
PC18. ensure communication of organizational objective and regulatory guidelines to the team and set the key performance indicator for each team member	-	-	-	-
PC19. evaluate the performance of team members periodically and engage them in performance assessment dialogue and provide work-related and behavioral feedback	-	-	-	-
PC20. guide team members on the learning goals and provide opportunities to perform, learn, and grow	-	-	-	-
PC21. guide team members for managing their time effectively	-	-	-	-
<i>Sensitivity towards all genders and people with disability</i>	5	5	-	2
PC22. respect all genders, religions, and caste	-	-	-	-
PC23. empathize with the people with disability	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC24. offer support or help to a person with disability only when asked	-	-	-	-
PC25. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act	-	-	-	-
PC26. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee	-	-	-	-
NOS Total	35	50	-	15



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0807
NOS Name	Coordinate with a manager and cross-functional teams and manage the maintenance team
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Engineering and Maintenance
NSQF Level	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



Qualification Pack

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

Description

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

Scope

The scope covers the following :

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

Elements and Performance Criteria

Introduction to Employability Skills

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

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

Constitutional values – Citizenship

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

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

Becoming a Professional in the 21st Century

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

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



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

Basic English Skills

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

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

Career Development & Goal Setting

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

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

Communication Skills

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

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

Diversity & Inclusion

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

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

Financial and Legal Literacy

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

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

Essential Digital Skills

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

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



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

Entrepreneurship

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

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

Customer Service

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

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

Getting ready for apprenticeship & Jobs

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

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

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

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



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

Generic Skills (GS)

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

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

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Introduction to Employability Skills</i>	1	1	-	-
PC1. understand the significance of employability skills in meeting the current job market requirement and future of work	-	-	-	-
PC2. identify and explore learning and employability relevant portals	-	-	-	-
PC3. research about the different industries, job market trends, latest skills required and the available opportunities	-	-	-	-
<i>Constitutional values – Citizenship</i>	1	1	-	-
PC4. recognize the significance of constitutional values, including civic rights and duties, citizenship, responsibility towards society etc. and personal values and ethics such as honesty, integrity, caring and respecting others, etc.	-	-	-	-
PC5. follow environmentally sustainable practices	-	-	-	-
<i>Becoming a Professional in the 21st Century</i>	1	3	-	-
PC6. recognize the significance of 21st Century Skills for employment	-	-	-	-
PC7. practice the 21st Century Skills such as Self-Awareness, Behaviour Skills, time management, critical and adaptive thinking, problem-solving, creative thinking, social and cultural awareness, emotional awareness, learning to learn for continuous learning etc. in personal and professional life	-	-	-	-
PC8. adopt a continuous learning mindset for personal and professional development	-	-	-	-
<i>Basic English Skills</i>	3	4	-	-
PC9. use basic English for everyday conversation in different contexts, in person and over the telephone	-	-	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC10. read and understand routine information, notes, instructions, mails, letters etc. written in English	-	-	-	-
PC11. write short messages, notes, letters, e-mails etc. in English	-	-	-	-
<i>Career Development & Goal Setting</i>	1	2	-	-
PC12. identify career goals based on the skills, interests, knowledge, and personal attributes	-	-	-	-
PC13. prepare a career development plan with short- and long-term goals	-	-	-	-
<i>Communication Skills</i>	2	2	-	-
PC14. follow verbal and non-verbal communication etiquette while communicating in professional and public settings	-	-	-	-
PC15. use active listening techniques for effective communication	-	-	-	-
PC16. communicate in writing using appropriate style and format based on formal or informal requirements	-	-	-	-
PC17. work collaboratively with others in a team	-	-	-	-
<i>Diversity & Inclusion</i>	1	1	-	-
PC18. communicate and behave appropriately with all genders and PwD	-	-	-	-
PC19. escalate any issues related to sexual harassment at workplace according to POSH Act	-	-	-	-
<i>Financial and Legal Literacy</i>	2	3	-	-
PC20. identify and select reliable institutions for various financial products and services such as bank account, debit and credit cards, loans, insurance etc.	-	-	-	-
PC21. carry out offline and online financial transactions, safely and securely, using various methods and check the entries in the passbook	-	-	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC22. identify common components of salary and compute income, expenses, taxes, investments etc	-	-	-	-
PC23. identify relevant rights and laws and use legal aids to fight against legal exploitation	-	-	-	-
<i>Essential Digital Skills</i>	3	5	-	-
PC24. operate digital devices and use their features and applications securely and safely	-	-	-	-
PC25. carry out basic internet operations by connecting to the internet safely and securely, using the mobile data or other available networks through Bluetooth, Wi-Fi, etc.	-	-	-	-
PC26. display responsible online behaviour while using various social media platforms	-	-	-	-
PC27. create a personal email account, send and process received messages as per requirement	-	-	-	-
PC28. carry out basic procedures in documents, spreadsheets and presentations using respective and appropriate applications	-	-	-	-
PC29. utilize virtual collaboration tools to work effectively	-	-	-	-
<i>Entrepreneurship</i>	2	3	-	-
PC30. identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research	-	-	-	-
PC31. develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion	-	-	-	-
PC32. identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity	-	-	-	-
<i>Customer Service</i>	1	2	-	-
PC33. identify different types of customers and ways to communicate with them	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC34. identify and respond to customer requests and needs in a professional manner	-	-	-	-
PC35. use appropriate tools to collect customer feedback	-	-	-	-
PC36. follow appropriate hygiene and grooming standards	-	-	-	-
<i>Getting ready for apprenticeship & Jobs</i>	2	3	-	-
PC37. create a professional Curriculum vitae (Résumé)	-	-	-	-
PC38. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively	-	-	-	-
PC39. apply to identified job openings using offline /online methods as per requirement	-	-	-	-
PC40. answer questions politely, with clarity and confidence, during recruitment and selection	-	-	-	-
PC41. identify apprenticeship opportunities and register for it as per guidelines and requirements	-	-	-	-
NOS Total	20	30	-	-



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	DGT/VSQ/N0103
NOS Name	Employability Skills (90 Hours)
Sector	Cross Sectoral
Sub-Sector	Professional Skills
Occupation	Employability
NSQF Level	5
Credits	3
Version	1.0
Last Reviewed Date	30/05/2024
Next Review Date	30/05/2027
NSQC Clearance Date	30/05/2024



Qualification Pack

LFS/N0810: Monitor assembly, installation, operation and maintenance of Water system utility

Description

This job function is about a Supervisor- Maintenance(Pharma, Biologics and Medical Device Facility) - Water System monitoring assembly, installation, operation, and maintenance while performing troubleshooting for critical issues.

Scope

The scope covers the following :

- Oversee installation activities
- Supervise water system utility maintenance and perform troubleshooting

Elements and Performance Criteria

Oversee installation activities

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

- PC1.** provide inputs to quality and production department to prepare and review design qualifications (DQ), installation qualification (IQ) operation qualification (OQ) performance qualification (PQ) protocols for Water utility system especially for Water for Pharmaceutical Use (WPU), Purified Water (PW), Highly Purified Water (HPW) and Water for Injection (WFI)
- PC2.** ensure the design specification of water production and distribution system is followed during the installation and assembly of the water system to meet the required water quality grade parameters for specified purposes
- PC3.** secure approvals from concerned internal stakeholders (QA, production, and EHS) before the start of installation activity
- PC4.** ensure that the installation of electrical utility is done by approved vendor through a competent team as per design specification
- PC5.** oversee the installation activities for water system utility and its components to ensure any non-compliance with cleanroom state and regulatory guidelines
- PC6.** provide inputs to the installation team for troubleshooting during installation
- PC7.** support QA in applying design qualifications (DQ), installation qualification (IQ) operation qualification (OQ) performance qualification (PQ) protocols for Water utility system especially for Water for Pharmaceutical Use (WPU) and Water for Injection (WFI)

Supervise water system utility maintenance and perform troubleshooting

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

- PC8.** ensure the cleanroom requirements like cleaning decontamination, etc. are met for the tools and tool kits
- PC9.** troubleshoot during equipment breakdown and check for the water leakage/ loose pipes and gaskets, rusted joints, short circuit, damage to wires, clamps, alignment of the pipeline, motor pump, RO system, water filters, reagents, erratic/ problematic performance or any other problem mentioned in the complaint



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- PC10.** examine Water for Pharmaceutical (WPU), Purified Water (PW), Highly Purified Water (HPW) and Water for Injection (WFI) system and water filters and storage tanks for appropriate working conditions
- PC11.** identify the root cause of the problem and follow work instructions or OEM manuals to rectify the problems
- PC12.** evaluate the solution of the problem in light of the impact on productivity/ regulatory compliance/ cleanroom state
- PC13.** assess the impact on product quality for any changes in the parameters of the WPU, WFI and get the approval from production and quality team
- PC14.** ensure the replacement parts are compliant to and compatible with the production requirement and have no impact on product quality
- PC15.** maintain the records of Water system maintenance jobs and water filter changing and cleaning pattern and assign tasks to appropriate personnel
- PC16.** recommend procedure revisions based on the history of breakdown and equipment maintenance logs
- PC17.** take inputs/ assistance from other maintenance specialists like Electrical/ Gases system etc./ Civil) while performing the troubleshooting
- PC18.** coordinate with OEM/ empaneled specialist's services for troubleshooting and maintenance in case of any error/ critical issue beyond the scope of written procedures
- PC19.** oversee the maintenance work being performed by personnel from OEM/ empaneled specialist's service providers on Water system utility
- PC20.** supervise the calibration, validation, and re-qualification activities post-maintenance for water system utility in consultation with the quality team and production team
- PC21.** ensure to maintain the water storage tank and filter change logs and history and review the trend for any deviations/ OOS reading for reporting to management

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** the maintenance protocols and required chain of approval for line clearance
- KU2.** procedure to be followed in response to breakdown calls from the shop floor
- KU3.** risk and impact of not following defined procedures/work instructions
- KU4.** cleanroom guidelines and basics of relevant current Good Manufacturing Practices(GMP) and other regulatory guidelines
- KU5.** various tools and related safety protocols used in water maintenance
- KU6.** WPU, PW, HPW and WFI production system maintenance functions, common faults, and troubleshooting procedure
- KU7.** operational characteristics of the materials, equipment, and process, sufficient to recognize out of specification products, process problems, and materials faults
- KU8.** water system design and plant utility distribution system drawing, civil work drawing and various type of water filters and water purification process and their use in maintaining difference grade of water for different purposes
- KU9.** process of job safety analysis and how to use risk assessment matrix



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- KU10.** importance of environmental sustainability and good practices for environmental sustainability for a maintenance technician
- KU11.** implications of delays in the maintenance process
- KU12.** process of design qualifications (DQ), installation qualification (IQ), operation qualification (OQ), performance qualification (PQ) for a water system utility
- KU13.** process of writing SOPs as per GMP guidelines
- KU14.** basic statistical tools and process of root cause analysis
- KU15.** different quality management systems (ISO-9000, TS16949, ISO-14001)
- KU16.** operational health and safety (OHS) hazards and controls, including limitations of protective clothing and equipment relevant to the work process
- KU17.** use of monitoring and measuring devices
- KU18.** requirements of different shutdowns as appropriate to the process and workplace production requirements, including emergency and routine shutdowns and procedures to follow in the event of a power outage
- KU19.** methods, materials, and equipment used in installing, repairing and maintaining water production and purification system

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 read and understand instructions/manuals, SOPs, health and safety instructions, memos, reports, job cards, schedules, machine history/ logs, etc.
- GS3.** use verbal communication skills to communicate with maintenance and cross-functional team for instructions and coordination to share confidential and sensitive information discretely 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 analyze the situations and the associated risk and be able to categorize them for decision making
- GS6.** apply decision-making skills to take decisions with the help of pre-defined matrix and procedural guidelines
- GS7.** apply critical skills to use process understanding to identify causes for lack of deviations
- GS8.** apply planning and organizing skills to plan individual work to achieve specified deadlines

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Oversee installation activities</i>	10	20	-	10
PC1. provide inputs to quality and production department to prepare and review design qualifications (DQ), installation qualification (IQ) operation qualification (OQ) performance qualification (PQ) protocols for Water utility system especially for Water for Pharmaceutical Use (WPU), Purified Water (PW), Highly Purified Water (HPW) and Water for Injection (WFI)	-	-	-	-
PC2. ensure the design specification of water production and distribution system is followed during the installation and assembly of the water system to meet the required water quality grade parameters for specified purposes	-	-	-	-
PC3. secure approvals from concerned internal stakeholders (QA, production, and EHS) before the start of installation activity	-	-	-	-
PC4. ensure that the installation of electrical utility is done by approved vendor through a competent team as per design specification	-	-	-	-
PC5. oversee the installation activities for water system utility and its components to ensure any non-compliance with cleanroom state and regulatory guidelines	-	-	-	-
PC6. provide inputs to the installation team for troubleshooting during installation	-	-	-	-
PC7. support QA in applying design qualifications (DQ), installation qualification (IQ) operation qualification (OQ) performance qualification (PQ) protocols for Water utility system especially for Water for Pharmaceutical Use (WPU) and Water for Injection (WFI)	-	-	-	-
<i>Supervise water system utility maintenance and perform troubleshooting</i>	20	30	-	10

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC8. ensure the cleanroom requirements like cleaning decontamination, etc. are met for the tools and tool kits	-	-	-	-
PC9. troubleshoot during equipment breakdown and check for the water leakage/ loose pipes and gaskets, rusted joints, short circuit, damage to wires, clamps, alignment of the pipeline, motor pump, RO system, water filters, reagents, erratic/ problematic performance or any other problem mentioned in the complaint	-	-	-	-
PC10. examine Water for Pharmaceutical (WPU), Purified Water (PW), Highly Purified Water (HPW) and Water for Injection (WFI) system and water filters and storage tanks for appropriate working conditions	-	-	-	-
PC11. identify the root cause of the problem and follow work instructions or OEM manuals to rectify the problems	-	-	-	-
PC12. evaluate the solution of the problem in light of the impact on productivity/ regulatory compliance/ cleanroom state	-	-	-	-
PC13. assess the impact on product quality for any changes in the parameters of the WPU, WFI and get the approval from production and quality team	-	-	-	-
PC14. ensure the replacement parts are compliant to and compatible with the production requirement and have no impact on product quality	-	-	-	-
PC15. maintain the records of Water system maintenance jobs and water filter changing and cleaning pattern and assign tasks to appropriate personnel	-	-	-	-
PC16. recommend procedure revisions based on the history of breakdown and equipment maintenance logs	-	-	-	-
PC17. take inputs/ assistance from other maintenance specialists like Electrical/ Gases system etc./ Civil) while performing the troubleshooting	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC18. coordinate with OEM/ empaneled specialist's services for troubleshooting and maintenance in case of any error/ critical issue beyond the scope of written procedures	-	-	-	-
PC19. oversee the maintenance work being performed by personnel from OEM/ empaneled specialist's service providers on Water system utility	-	-	-	-
PC20. supervise the calibration, validation, and re-qualification activities post-maintenance for water system utility in consultation with the quality team and production team	-	-	-	-
PC21. ensure to maintain the water storage tank and filter change logs and history and review the trend for any deviations/ OOS reading for reporting to management	-	-	-	-
NOS Total	30	50	-	20



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0810
NOS Name	Monitor assembly, installation, operation and maintenance of Water system utility
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Engineering and Maintenance
NSQF Level	5
Credits	7.00
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 viva for every student at each examination/training center based on this criterion.
6. Wherever any assessment component is not applicable/ feasible, the balance assessment components will be used to assess the candidate and accordingly the total marks will be calculated only for the applied



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assessment component.

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

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

Minimum Aggregate Passing % at QP Level : 70

(Please note: Every Trainee should score a minimum aggregate passing percentage as specified above, to successfully clear the Qualification Pack assessment.)

Minimum Passing % at NOS Level: 70

(Please note: A Trainee must score the minimum percentage for each NOS separately as well as on the QP as a whole.)

Assessment Weightage

Compulsory NOS

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0821.Discuss about life sciences industry and Essential concepts for manufacturing design and maintenance	30	40	15	15	100	10
LFS/N0805.Ensure smooth maintenance of utilities as per cGMP guidelines	35	55	0	10	100	15
LFS/N0111.Ensure adherence to Environment, health and safety guidelines in production facility and cGMP controlled areas	30	55	0	15	100	10
LFS/N0806.Perform maintenance related documentation	30	55	0	15	100	15
LFS/N0807.Coordinate with a manager and cross-functional teams and manage the maintenance team	35	50	0	15	100	10



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National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
DGT/VSQ/N0103.Employability Skills (90 Hours)	20	30	-	-	50	10
Total	180	285	15	70	550	70

Elective: 1 Water System

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0810.Monitor assembly, installation, operation and maintenance of Water system utility	30	50	0	20	100	30
Total	30	50	-	20	100	30