









Associate- Warehouse (Pharma, Bio Pharma, Medical Devices)

QP Code: LFS/Q0604 Instantiated QP Code: LFS/Q0604-SI001

Version: 4.0

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LFS/Q0604-SI001: Associate- Warehouse (Pharma, Bio Pharma, Medical Devices)

Brief Job Description

Associate- Warehouse (Pharma, Bio Pharma, Medical Devices) is responsible for inspecting the broad level physical characteristics of the material, placing them in correct storage area, reporting and documenting, housekeeping, disposing waste packaging material, and maintaining a safe working environment in compliance with regulatory standards and current Good Manufacturing Practices (cGMP).

Personal Attributes

The individual should possess basic reading and writing skills. Quality centricity and detail orientation, along with a motivated frame of mind are desirable for the role.

Applicable National Occupational Standards (NOS)

Compulsory NOS:

- 1. LFS/N0673: Discuss about Life Sciences industry and basics of supply chain management
- 2. LFS/N0657: Receive and store goods in a store/ warehouse
- 3. <u>LFS/N0632</u>: Carry out packaging material inspection and waste disposal as per regulatory standards
- 4. LFS/N0633: Carry out reporting and documentation to meet storing and stocking requirements
- 5. <u>LFS/N0112</u>: Adherence to Environment, health and safety guidelines in a production facility and GMP controlled area
- 6. LFS/N0118: Coordinate with supervisor, teammates, and cross-functional teams
- 7. LFS/N0659: Verify GST applicability and accuracy of GST in invoices
- 8. DGT/VSQ/N0101: Employability Skills (30 Hours)

Qualification Pack (QP) Parameters

Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research









Occupation	Supply Chain Management
Country	India
NSQF Level	3
Credits	12
Aligned to NCO/ISCO/ISIC Code	NCO-2015/7233.9902
Minimum Educational Qualification & Experience	10th Class OR D.Pharma OR Certificate-NSQF (Level 2 (Assistant- Secondary & Tertiary Packaging)) with 3 Years of experience
Minimum Level of Education for Training in School	8th Class
Pre-Requisite License or Training	NA
Minimum Job Entry Age	18 Years
Last Reviewed On	NA
Next Review Date	17/12/2027
NSQC Approval Date	17/12/2024
Version	4.0
Reference code on NQR	QG-03-LS-03408-2024-V2-LSSSDC
NQR Version	2.0

Remarks:

NA	
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LFS/N0673: Discuss about Life Sciences industry and basics of supply chain management

Description

This NOS is about introducing related to life sciences Industry and basic of supply chain management

Scope

The scope covers the following:

- Life Sciences industry and supply chain management
- Environmental Sustainability

Elements and Performance Criteria

Life Sciences industry and supply chain management

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

- **PC1.** elaborate the major segments within the life sciences industry (pharmaceuticals, biotechnology, medical devices, etc.).
- **PC2.** describe the regulatory authorities, regulations, legislation, and good practices such as cGMP, GLP, and GDP that are relevant to supply chain management in a life sciences manufacturing facility
- **PC3.** Illustrate the basic skills required to perform supply chain management tasks, including inventory control, procurement, and vendor management
- **PC4.** discuss the role of government policies and initiatives in promoting the growth of the life sciences industry in India.
- **PC5.** use basic terminologies in the supply chain department, including procurement, logistics, and distribution
- **PC6.** analyze the impact of non-compliance with regulatory requirements on the quality of the product and the environment, and propose measures to mitigate such risks.

Environmental Sustainability

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

- **PC7.** ensure energy conservation by switching off the machine and equipment post operations
- **PC8.** identify ways to optimize the usage of electricity/energy in various tasks/activities/processes and also by optimizing the lab machine/ equipment performance
- **PC9.** ensure no leakage of water in the warehouse area
- PC10. identify recyclable and non-recyclable, and hazardous waste generated
- PC11. segregate waste into different categories to achieve zero pollution of land and water

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. requirements for maintaining security and safety during delivery and storage of goods









- **KU2.** organization's SOP for receiving and storing a range of products as per specifications
- **KU3.** administrative procedures required for receiving and storing goods
- **KU4.** levels of hygiene required by storage area and importance of maintaining the same
- **KU5.** different quality management systems (ISO-9000, ISO-14001, OHSAS-18000), good laboratory and manufacturing practices
- **KU6.** organizational coding system of finished materials, compounds and company manual
- **KU7.** quality and damage checks to be done and importance of the same
- **KU8.** correct methods of storage of goods according to good manufacturing practices
- **KU9.** importance of identifying non-conforming goods
- **KU10.** risk and impact of not following defined procedures/work instructions
- **KU11.** procedures for receiving raw material and identified stock
- **KU12.** methods of identifying and maintaining safe storage areas/locations and secure storage environments
- **KU13.** storage requirements for different types of products and why they are important

Generic Skills (GS)

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

- **GS1.** use reading and comprehension skills to extract the relevant information from manuals, SOPs, health and safety instructions, memos, reports, job cards, and notes/comments
- **GS2.** use written communication skills to maintain proper and concise records as per given format and compliant with ALCOA principle
- **GS3.** use verbal communication skills in communicating the details of work done to appropriate people and during interaction with regulatory inspectors and other teammates
- **GS4.** use planning and organizing skills in every activity planned and to achieve resource optimization
- **GS5.** apply problem-solving skills to find solutions for workflow-related difficulties
- **GS6.** apply critical thinking skills to analyze and identify when to report an issue/concern to the supervisor and to deal with a colleague individually, depending on the type of concern
- **GS7.** use critical thinking skills to analyze impact of deviations, wastage and rejects to the environment and efficiency
- **GS8.** apply customer-centricity while responding to auditors and QA personnel









Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Life Sciences industry and supply chain management	20	-	5	5
PC1. elaborate the major segments within the life sciences industry (pharmaceuticals, biotechnology, medical devices, etc.).	-	-	-	-
PC2. describe the regulatory authorities, regulations, legislation, and good practices such as cGMP, GLP, and GDP that are relevant to supply chain management in a life sciences manufacturing facility	-	-	-	-
PC3. Illustrate the basic skills required to perform supply chain management tasks, including inventory control, procurement, and vendor management	-	-	-	-
PC4. discuss the role of government policies and initiatives in promoting the growth of the life sciences industry in India.	-	-	-	-
PC5. use basic terminologies in the supply chain department, including procurement, logistics, and distribution	-	-	-	-
PC6. analyze the impact of non-compliance with regulatory requirements on the quality of the product and the environment, and propose measures to mitigate such risks.	-	-	-	-
Environmental Sustainability	20	30	10	10
PC7. ensure energy conservation by switching off the machine and equipment post operations	-	-	-	-
PC8. identify ways to optimize the usage of electricity/energy in various tasks/activities/processes and also by optimizing the lab machine/ equipment performance	-	-	-	-
PC9. ensure no leakage of water in the warehouse area	-	-	-	-
PC10. identify recyclable and non-recyclable, and hazardous waste generated	-	-	-	-









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









National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0673
NOS Name	Discuss about Life Sciences industry and basics of supply chain management
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Supply Chain Management
NSQF Level	3
Credits	1.00
Version	1.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024









LFS/N0657: Receive and store goods in a store/ warehouse

Description

This NOS is about a receiving incoming goods and checking the material safety in the store or a warehouse.

Scope

The scope covers the following:

- · Receive goods
- Material safety

Elements and Performance Criteria

Receive goods

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

- **PC1.** identify the quantity and nature of goods to be received in a Life Sciences facility
- PC2. confirm appropriate storage space availability for the goods received
- **PC3.** check and confirm that all equipment required for receipt and movement of goods is available and in good working order
- **PC4.** complete all the required paperwork for the goods/materials received
- **PC5.** ensure that the area for receiving goods is clean, tidy and free from obstruction and perils
- **PC6.** report any shortfall in space or malfunction with equipment in store to the supervisor
- PC7. check that all goods as detailed in the delivery note have been received
- **PC8.** record refusals accurately following the organisation's SOP
- **PC9.** update stock control systems to reflect receipt of goods

Material safety

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

- **PC10.** check the material specification for proper storage conditions
- PC11. follow all the guidelines related to material safety

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1. requirements for maintaining security and safety during delivery and storage of goods
- **KU2.** organization's SOP for receiving and storing a range of products as per specifications
- **KU3.** administrative procedures required for receiving and storing goods
- **KU4.** levels of hygiene required by storage area and importance of maintaining the same
- **KU5.** different quality management systems (ISO-9000, ISO-14001, OHSAS-18000), good laboratory and manufacturing practices
- **KU6.** organizational coding system of finished materials, compounds and company manual









- **KU7.** quality and damage checks to be done and importance of the same
- **KU8.** correct methods of storage of goods according to good manufacturing practices
- KU9. importance of identifying non-conforming goods
- **KU10.** risk and impact of not following defined procedures/work instructions
- **KU11.** procedures for receiving raw material and identified stock
- **KU12.** methods of identifying and maintaining safe storage areas/locations and secure storage environments
- **KU13.** storage requirements for different types of products and why they are important

Generic Skills (GS)

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

- **GS1.** use reading and comprehension skills to extract the relevant information from manuals, SOPs, health and safety instructions, memos, reports, job cards, and notes/comments
- **GS2.** use written communication skills to maintain proper and concise records as per given format and compliant with ALCOA principle
- **GS3.** use verbal communication skills in communicating the details of work done to appropriate people and during interaction with regulatory inspectors and other teammates
- **GS4.** use planning and organizing skills in every activity planned and to achieve resource optimization
- **GS5.** apply problem-solving skills to find solutions for workflow-related difficulties
- **GS6.** apply critical thinking skills to analyze and identify when to report an issue/concern to the supervisor and to deal with a colleague individually, depending on the type of concern
- **GS7.** use critical thinking skills to analyze impact of deviations, wastage and rejects to the environment and efficiency
- **GS8.** apply customer-centricity while responding to auditors and QA personnel









Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Receive goods	15	30	10	10
PC1. identify the quantity and nature of goods to be received in a Life Sciences facility	-	-	-	-
PC2. confirm appropriate storage space availability for the goods received	-	-	-	-
PC3. check and confirm that all equipment required for receipt and movement of goods is available and in good working order	-	-	-	-
PC4. complete all the required paperwork for the goods/materials received	-	-	-	-
PC5. ensure that the area for receiving goods is clean, tidy and free from obstruction and perils	-	-	-	-
PC6. report any shortfall in space or malfunction with equipment in store to the supervisor	-	-	-	-
PC7. check that all goods as detailed in the delivery note have been received	-	-	-	-
PC8. record refusals accurately following the organisation's SOP	-	-	-	-
PC9. update stock control systems to reflect receipt of goods	-	-	-	-
Material safety	10	15	5	5
PC10. check the material specification for proper storage conditions	-	-	-	_
PC11. follow all the guidelines related to material safety	-	-	-	-
NOS Total	25	45	15	15









National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0657
NOS Name	Receive and store goods in a store/ warehouse
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Supply Chain Management
NSQF Level	3
Credits	3.00
Version	3.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024









LFS/N0632: Carry out packaging material inspection and waste disposal as per regulatory standards

Description

This NOS unit is about carrying out inspection of packaging material ,disposal of defective or waste packaging material and reporting the deviations according to current good manufacturing practices.

Scope

The scope covers the following:

- Packaging material inspection
- Waste disposal
- Reporting and escalation of deviations

Elements and Performance Criteria

Packaging material inspection

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

- **PC1.** ensure that total range of checks are regularly and consistently performed on the packaging material
- **PC2.** use appropriate measuring instruments, equipment, tools, accessories etc. as required for the checks
- **PC3.** ensure the status and accuracy of instruments used for measurement
- **PC4.** identify material's non-conformities to quality assurance standards
- **PC5.** identify impact on final product due to non-conformance to regulatory standards

Waste disposal

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

- **PC6.** dispose the non-conforming packaging material as per SOP
- **PC7.** follow the standards and procedures as mentioned in cGMP while disposing non-conforming material
- **PC8.** identify and analyse any problems that may arise while disposing the materials
- **PC9.** suggest corrective action to address problems to the supervisor

Reporting and escalation of deviations

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

- **PC10.** interpret the results of the quality checks correctly
- **PC11.** take up results of the findings with the appropriate authority and within stipulated time
- PC12. record results of action taken in a standard format
- PC13. record adjustments not covered by established procedures for future reference
- **PC14.** review effectiveness of action taken
- **PC15.** record the disposal methods used and the types of defects or reasons for disposal









Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- **KU1.** company manual and the SOP
- KU2. correct methods of disposal of waste according to cGMP
- **KU3.** proper procedure for performing quality checks without affecting the material
- **KU4.** characteristics of the packaging material
- **KU5.** use of monitoring and measuring devices
- **KU6.** implications of inaccurate measuring and testing instruments and equipment
- **KU7.** implications of defective materials on production of final products
- **KU8.** importance of complete and accurate documentation
- **KU9.** procedure for reporting incidents where standard operating procedures are not followed
- **KU10.** principles of good inspection practices and visual standards applied in the workplace
- **KU11.** different techniques/inspection methods used to identify defects
- KU12. methods of using testing equipment, related test methods and purpose of tests
- **KU13.** importance of quality checks along with quality and production targets

Generic Skills (GS)

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

- **GS1.** use written communication skills to record information accurately in compliance with ALCOA principles as per SOP and cGMP guidelines in the English language
- **GS2.** use reading and comprehension skills to read the various coding systems, instructions, guidelines, procedures, rules, and signage
- **GS3.** use listening skills to understand the instructions, procedures and alarms
- **GS4.** use verbal communication skills to interact with supervisor, teammates, and cross-functional teams
- **GS5.** use team-building skills while dealing with teammates and while managing the difficult/stressful or emotional situations at work
- **GS6.** apply problem-solving skills to find solutions for workflow-related difficulties
- **GS7.** apply planning and organizing skills to plan and organize tools and material required to fulfil documentation related requirements
- **GS8.** apply critical thinking skills to analyze and identify what and when to report an issue/concern to the supervisor/ QA team / any other stakeholder
- **GS9.** apply customer-centricity while generating and securing documents
- **GS10.** apply customer-centricity to remain compliant with data integrity rules, cGMP guidelines and to evaluate the impact of errors
- **GS11.** apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations









Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Packaging material inspection	10	15	5	5
PC1. ensure that total range of checks are regularly and consistently performed on the packaging material	-	-	-	-
PC2. use appropriate measuring instruments, equipment, tools, accessories etc. as required for the checks	-	-	-	-
PC3. ensure the status and accuracy of instruments used for measurement	-	-	-	-
PC4. identify material's non-conformities to quality assurance standards	-	-	-	-
PC5. identify impact on final product due to nonconformance to regulatory standards	-	-	-	-
Waste disposal	10	10	5	5
PC6. dispose the non-conforming packaging material as per SOP	-	-	-	-
PC7. follow the standards and procedures as mentioned in cGMP while disposing nonconforming material	-	-	-	-
PC8. identify and analyse any problems that may arise while disposing the materials	-	-	-	-
PC9. suggest corrective action to address problems to the supervisor	-	-	-	-
Reporting and escalation of deviations	10	15	5	5
PC10. interpret the results of the quality checks correctly	-	-	-	-
PC11. take up results of the findings with the appropriate authority and within stipulated time	-	-	-	-
PC12. record results of action taken in a standard format	-	-	-	-









Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC13. record adjustments not covered by established procedures for future reference	-	-	-	-
PC14. review effectiveness of action taken	-	-	-	-
PC15. record the disposal methods used and the types of defects or reasons for disposal	-	-	-	-
NOS Total	30	40	15	15









National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0632
NOS Name	Carry out packaging material inspection and waste disposal as per regulatory standards
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Supply Chain Management
NSQF Level	3
Credits	2.00
Version	4.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024









LFS/N0633: Carry out reporting and documentation to meet storing and stocking requirements

Description

This NOS unit is about a Associate- warehouse (Pharma/ Bio Pharma / Medical Devices) performing reporting and documentation to meet storing and stocking requirements.

Scope

The scope covers the following:

- Reporting quality issues and test results
- Recording and documentation

Elements and Performance Criteria

Reporting quality issues and test results

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

- **PC1.** report defects/problem/incidents/quality issues/test results as applicable in a timely manner to the appropriate authority
- **PC2.** follow reporting procedures as prescribed by the company

Recording and documentation

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

- **PC3.** maintain records regarding stock received and stock rotation
- PC4. maintain records regarding damaged materials and disposal methods
- **PC5.** maintain records regarding storage techniques
- **PC6.** document the results of the inspections and testing
- PC7. maintain all controlled document files and test records in a timely and accurate manner
- **PC8.** ensure that the final document meets with the regulatory requirements
- **PC9.** ensure that documents are available to all appropriate authorities to inspect
- **PC10.** perform review of records and other documentation for compliance to established procedures and good documentation practices
- **PC11.** prepare inspection reports as per the inspection activity performed

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- **KU1.** importance of complete and accurate documentation
- **KU2.** importance of identifying non-conforming materials
- **KU3.** risk and impact of not following defined procedures/work instructions
- **KU4.** escalation matrix for reporting identified issues









- **KU5.** how to carry out good stock management, including the rotation of stock, and checking expiry dates of goods
- **KU6.** principles of good inspection practices and visual standards applied in the workplace
- **KU7.** use of computer applications/software

Generic Skills (GS)

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

- **GS1.** use written communication skills to record information accurately in compliance with ALCOA principles as per SOP and GMP guidelines in the English language
- **GS2.** use reading and comprehension skills to read the various coding systems, instructions, guidelines, procedures, rules, and signage
- **GS3.** use listening skills to interpret the instructions, procedures and alarms
- **GS4.** use verbal communication skills to interact with supervisor, teammates, and cross-functional teams
- **GS5.** use team-building skills while dealing with teammates and while managing the difficult/stressful or emotional situations at work
- GS6. apply problem-solving skills to find solutions for workflow-related difficulties
- **GS7.** apply planning and organizing skills to plan and organize tools and material required to fulfil documentation related requirements
- **GS8.** apply critical thinking skills to analyze and identify what and when to report an issue/concern to the supervisor/ QA team / any other stakeholder
- **GS9.** apply customer-centricity while generating and securing documents
- **GS10.** apply customer-centricity to remain compliant with data integrity rules, GMP guidelines and to evaluate the impact of errors
- **GS11.** apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations









Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Reporting quality issues and test results	10	15	10	5
PC1. report defects/problem/incidents/quality issues/test results as applicable in a timely manner to the appropriate authority	-	-	-	-
PC2. follow reporting procedures as prescribed by the company	-	-	-	-
Recording and documentation	15	30	10	5
PC3. maintain records regarding stock received and stock rotation	-	-	-	-
PC4. maintain records regarding damaged materials and disposal methods	-	-	-	-
PC5. maintain records regarding storage techniques	-	-	-	-
PC6. document the results of the inspections and testing	-	-	-	-
PC7. maintain all controlled document files and test records in a timely and accurate manner	-	-	-	-
PC8. ensure that the final document meets with the regulatory requirements	-	-	-	-
PC9. ensure that documents are available to all appropriate authorities to inspect	-	-	-	-
PC10. perform review of records and other documentation for compliance to established procedures and good documentation practices	-	-	-	-
PC11. prepare inspection reports as per the inspection activity performed	-	-	-	-
NOS Total	25	45	20	10









National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0633
NOS Name	Carry out reporting and documentation to meet storing and stocking requirements
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Supply Chain Management
NSQF Level	3
Credits	2.00
Version	4.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024









LFS/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:









- **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









- **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









Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Follow health and personal hygiene protocols	10	10	5	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 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	10	20	5	5
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	-	-	_	-









Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
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	10	10	5	5
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	-	-	-	-
NOS Total	30	40	15	15









National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0112
NOS Name	Adherence to Environment, health and safety guidelines in a production facility and GMP controlled area
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Generic
NSQF Level	4
Credits	1.00
Version	4.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024









LFS/N0118: Coordinate with supervisor, teammates, and cross-functional teams

Description

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

Scope

The scope covers the following:

- Coordination with the supervisor
- Coordination with functional teams
- Coordination with Cross-functional teams and other stakeholders
- · Sensitivity towards all genders and people with disability

Elements and Performance Criteria

Coordination with the supervisor

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

- **PC1.** coordinate with the reporting manager to obtain work instructions
- PC2. report problems related to facility, equipment, and material availability to the supervisor
- **PC3.** provide the requisite information, documents, clarifications to manager regarding the work done

Coordination with functional teams

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

- **PC4.** perform shift takeover/ handover from colleagues in previous shift/ to colleagues in the next shift as per defined guidelines
- **PC5.** discuss workflow related difficulties with the team to find solutions

Coordination with cross-functional teams and other stakeholders

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

- **PC6.** follow the instructions of QA team for any cGMP compliant process
- **PC7.** coordinate with the store supervisor for the stocks of materials required
- **PC8.** coordinate with Environment, Health and Safety team for safety incidents and accidental hazard in the work area
- **PC9.** ensure to provide requested information, documents, clarifications during audits

Sensitivity towards all genders and people with disability

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

- **PC10.** respect all the genders, religions, caste, and cultures
- PC11. empathize with the people with disability
- PC12. offer support or help to a person with disability only when asked
- **PC13.** adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act









PC14. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- **KU1.** the company's policies on the preferred language of communication, reporting and escalation policy
- **KU2.** the methods of workplace communication
- **KU3.** the method of responding to audit gueries for own work
- **KU4.** the shift handover/ takeover procedure in life sciences manufacturing units
- **KU5.** the guidelines laid on Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act
- **KU6.** the methods of team coordination
- **KU7.** the types of possible disabilities among people with disability (PwD)
- KU8. the challenges faced by PWD
- **KU9.** the importance of displaying empathy towards PwD
- **KU10.** the right way to use the laws acts, and provisions defined for PWD by the statutory bodies
- **KU11.** the importance of awareness for gender sensitization and prevention of sexual harassment (POSH) act
- **KU12.** the importance of respect for gender identities, all religion, caste, and culture

Generic Skills (GS)

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

- **GS1.** use written communication skills to accurately record the information required to be reported as per SOP and cGMP guidelines in the english/ local language
- **GS2.** use reading and comprehension skills to interpret the various coding systems, instructions, guidelines, procedures, rules, and signages
- **GS3.** use listening skills to interpret the instructions and procedures to be followed
- **GS4.** use verbal communication skills to interact with teammates, supervisor, and cross-functional teams
- **GS5.** use team-building skills while interacting with teammates and while managing the difficult/stressful or emotional situations at work
- **GS6.** apply problem-solving skills to find solutions for workflow-related difficulties
- **GS7.** apply planning and organizing skills to plan and organize tools and material required to fulfil work requirements
- **GS8.** apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations with clear choices and written instructions









Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Coordination with the supervisor	5	10	5	5
PC1. coordinate with the reporting manager to obtain work instructions	-	-	-	-
PC2. report problems related to facility, equipment, and material availability to the supervisor	-	-	-	-
PC3. provide the requisite information, documents, clarifications to manager regarding the work done	-	-	-	-
Coordination with functional teams	5	15	3	2
PC4. perform shift takeover/ handover from colleagues in previous shift/ to colleagues in the next shift as per defined guidelines	-	-	-	-
PC5. discuss workflow related difficulties with the team to find solutions	-	-	-	-
Coordination with cross-functional teams and other stakeholders	5	10	5	5
PC6. follow the instructions of QA team for any cGMP compliant process	-	-	-	-
PC7. coordinate with the store supervisor for the stocks of materials required	-	-	-	-
PC8. coordinate with Environment, Health and Safety team for safety incidents and accidental hazard in the work area	-	-	-	-
PC9. ensure to provide requested information, documents, clarifications during audits	-	-	-	-
Sensitivity towards all genders and people with disability	5	10	5	5
PC10. respect all the genders, religions, caste, and cultures	-	-	-	-
PC11. empathize with the people with disability	-	-	-	-









Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. offer support or help to a person with disability only when asked	-	-	-	-
PC13. adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act	-	-	-	-
PC14. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee	-	-	-	-
NOS Total	20	45	18	17









National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0118
NOS Name	Coordinate with supervisor, teammates, and cross-functional teams
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Generic
NSQF Level	3
Credits	1.00
Version	3.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024









LFS/N0659: Verify GST applicability and accuracy of GST in invoices

Description

This unit is about checking applicability of GST and verifying invoice accuracy of GST and other amount

Scope

The scope covers the following:

- · Check applicability of GST
- Verify invoice

Elements and Performance Criteria

Check applicability of GST

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

- **PC1.** identify location of service recipient and place of supply of services
- **PC2.** identify proper classification of the transaction (i.e. Intra-State or Inter-state) and determine the applicable GST: Central Goods and Services Tax (CGST), Integrated Goods and Services Tax (IGST), State Goods and Services Tax (SGST)
- **PC3.** identify if GST is payable under reverse charge in case the Service provider is unregistered party

Verify invoice

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

- **PC4.** obtain name, address, GST Identification Number (GSTIN), Permanent account number (PAN) number, email id of service/shipment provider and recipient
- **PC5.** obtain description of service, Service accounting code (SAC)/Harmonized System of Nomenclature (HSN) code
- **PC6.** receive unique identification number (UIN) for multilateral entity
- **PC7.** check for relevant notification in case of exempt clients
- PC8. calculate taxable value considering applicable rate of GST based on SAC/HSN
- PC9. check for vendor invoices for all mandatory particulars and applicable GST

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- **KU1.** reporting structure to support and expedite assigned activities
- **KU2.** company's policy and work instructions on quality standards for sales and support to customer
- **KU3.** company's products and services
- **KU4.** organizational guidelines for dealing with receipts and payments
- KU5. company's policy on mode of receipts









- **KU6.** company's policy on processes and methods of collection and payments
- **KU7.** basic financial concepts such as calculation of interest and taxes
- **KU8.** Concept and current prevailing GST rules
- **KU9.** bifurcation of taxes
- **KU10.** reverse charge mechanism
- **KU11.** current prevailing exemptions under GST
- **KU12.** refund process
- KU13. use of MS office (Excel, Word), Internet, Point of sales Software
- **KU14.** CGST Act, 2017 (preferable not mandatory)

Generic Skills (GS)

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

- **GS1.** how to read and understand various forms ,policies, directives and vendor invoices
- **GS2.** how to maintain , record of invoices verified
- **GS3.** coordinate with colleagues and seniors
- **GS4.** decide on applicability of tax rates
- **GS5.** plan and organize information for verifying invoice
- **GS6.** ensure tax indicated is correct
- **GS7.** inform about any errors or refunds to be sought and extra taxes to be paid
- **GS8.** resolve tax related issues with accounts department and vendors
- **GS9.** analyze invoices for tax calculation
- **GS10.** check for error in invoice









Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Check applicability of GST	10	15	3	5
PC1. identify location of service recipient and place of supply of services	-	-	-	-
PC2. identify proper classification of the transaction (i.e. Intra-State or Inter-state) and determine the applicable GST: Central Goods and Services Tax (CGST), Integrated Goods and Services Tax (IGST), State Goods and Services Tax (SGST)	-	-	-	-
PC3. identify if GST is payable under reverse charge in case the Service provider is unregistered party	-	-	-	-
Verify invoice	20	37	5	5
PC4. obtain name, address, GST Identification Number (GSTIN), Permanent account number (PAN) number, email id of service/shipment provider and recipient	-	-	-	-
PC5. obtain description of service, Service accounting code (SAC)/Harmonized System of Nomenclature (HSN) code	-	-	-	-
PC6. receive unique identification number (UIN) for multilateral entity	-	-	-	-
PC7. check for relevant notification in case of exempt clients	-	-	-	-
PC8. calculate taxable value considering applicable rate of GST based on SAC/HSN	-	-	-	-
PC9. check for vendor invoices for all mandatory particulars and applicable GST	-	-	-	-
NOS Total	30	52	8	10









National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0659
NOS Name	Verify GST applicability and accuracy of GST in invoices
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Supply Chain Management
NSQF Level	3
Credits	1.00
Version	2.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024









DGT/VSQ/N0101: Employability Skills (30 Hours)

Description

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

Scope

The scope covers the following:

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

Elements and Performance Criteria

Introduction to Employability Skills

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

PC1. understand the significance of employability skills in meeting the job requirements

Constitutional values - Citizenship

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

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

Becoming a Professional in the 21st Century

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

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

Basic English Skills

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

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

Communication Skills

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

PC5. follow good manners while communicating with others

PC6. work with others in a team









Diversity & Inclusion

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

PC7. communicate and behave appropriately with all genders and PwD

PC8. report any issues related to sexual harassment

Financial and Legal Literacy

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

PC9. use various financial products and services safely and securely

PC10. calculate income, expenses, savings etc.

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

Essential Digital Skills

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

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

PC13. use internet and social media platforms securely and safely

Entrepreneurship

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

PC14. identify and assess opportunities for potential business

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

Customer Service

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

PC16. identify different types of customers

PC17. identify customer needs and address them appropriately

PC18. follow appropriate hygiene and grooming standards

Getting ready for apprenticeship & Jobs

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

PC19. create a basic biodata

PC20. search for suitable jobs and apply

PC21. identify and register apprenticeship opportunities as per requirement

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. need for employability skills

KU2. various constitutional and personal values

KU3. different environmentally sustainable practices and their importance

KU4. Twenty first (21st) century skills and their importance

KU5. how to use basic spoken English language

KU6. Do and dont of effective communication

KU7. inclusivity and its importance

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

KU9. different types of financial products and services









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

Generic Skills (GS)

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

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









Assessment Criteria

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









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









National Occupational Standards (NOS) Parameters

NOS Code	DGT/VSQ/N0101
NOS Name	Employability Skills (30 Hours)
Sector	Cross Sectoral
Sub-Sector	Professional Skills
Occupation	Employability
NSQF Level	2
Credits	1
Version	1.0
Last Reviewed Date	24/10/2024
Next Review Date	24/10/2029
NSQC Clearance Date	24/10/2024

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 via for every student at each examination/training center based on this criterion.
- 6. Wherever any assessment component is not applicable/ feasible, the balance assessment components will be used to assess the candidate, and accordingly the total marks will be calculated only for the applied









assessment component.

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

Minimum Aggregate Passing % at QP Level: 50

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

Minimum Passing % at NOS Level: 50

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

Assessment Weightage

Compulsory NOS

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0673.Discuss about Life Sciences industry and basics of supply chain management	40	30	15	15	100	5
LFS/N0657.Receive and store goods in a store/ warehouse	25	45	15	15	100	20
LFS/N0632.Carry out packaging material inspection and waste disposal as per regulatory standards	30	40	15	15	100	20
LFS/N0633.Carry out reporting and documentation to meet storing and stocking requirements	25	45	20	10	100	20
LFS/N0112.Adherence to Environment, health and safety guidelines in a production facility and GMP controlled area	30	40	15	15	100	10









National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0118.Coordinate with supervisor, teammates, and cross-functional teams	20	45	18	17	100	10
LFS/N0659.Verify GST applicability and accuracy of GST in invoices	30	52	8	10	100	10
DGT/VSQ/N0101.Employability Skills (30 Hours)	20	30	-	-	50	5
Total	220	327	106	97	750	100