



Qualification Pack



Chemist - Retail Pharmacy

Regulated Business Operations

QP Code: LFS/Q0615

Version: 1.0

NSQF Level: 5

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LFS/Q0615: Chemist - Retail Pharmacy

Brief Job Description

Chemist - Retail Pharmacy is responsible for the storage, dispensing, and sale of drug products in compliance with regulations and legal guidelines. The job holder is expected to monitor and solve service concerns also.

Personal Attributes

The individual should have knowledge of different materials and chemicals along with the storing and selling appropriate pharma product. He must be able to identify defects, select appropriate storage areas, and handle inventory/stock. He should have the ability to do quality assurance, inventory control, manufacturing dispensing .

Applicable National Occupational Standards (NOS)

Compulsory NOS:

1. [LFS/N0602: Carry out reporting and documentation for appropriate storage of material/products](#)
2. [LFS/N0118: Coordinate with supervisor, teammates, and cross-functional teams](#)
3. [LFS/N0113: Ensure a hygienic and clean work area to avoid contamination](#)
4. [LFS/N0101: Follow Environment ,health and safety guidelines in GMP/GLP controlled areas and laboratory](#)
5. [LFS/N0656: Supervise waste disposal as per environment sustainable practices](#)
6. [LFS/N0668: Supervise warehouse operations for storage, dispensing and sale of drug products](#)
7. [DGT/VSQ/N0103: Employability Skills \(90 Hours\)](#)

Options(Not mandatory):

Option : Regulated Business Operations

1. [LFS/N0120: Establish own enterprise and perform various entrepreneurial activities to run the business operations in Life Sciences Sector](#)
2. [LFS/N0121: Maintain the critical business documents as Entrepreneur in Life Sciences Sector](#)



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Qualification Pack (QP) Parameters

Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Supply Chain Management
Country	India
NSQF Level	5
Credits	21
Aligned to NCO/ISCO/ISIC Code	NCO-2015/3213.0100 NCO-2015/3213.9900
Minimum Educational Qualification & Experience	B.Pharma (8th semester) OR M.Pharma OR D.Pharma with 2 Years of experience OR Certificate-NSQF (Associate- Retail Pharmacy Operations (Level 4)) with 3 Years of experience
Minimum Level of Education for Training in School	
Pre-Requisite License or Training	Pharmacist registration with State Pharmacy Council for securing an employment is MUST
Minimum Job Entry Age	21 Years
Last Reviewed On	NA
Next Review Date	28/07/2025
NSQC Approval Date	28/07/2022
Version	1.0
Reference code on NQR	QM-05-LS-00256-2023-V1.1-LSSSDC
NQR Version	1.0



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LFS/N0602: Carry out reporting and documentation for appropriate storage of material/products

Description

This NOS unit is about the job holder to carry out reporting and documentation for appropriate storage of material/products

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
- PC2.** report to the appropriate authority as laid down by the company
- PC3.** follow reporting procedures as prescribed by the company and cGMP

Recording and documentation

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

- PC4.** Prepare and submit daily/weekly/monthly reports on receipt and dispatch performance, pending activities, worker productivity and others as per SOP.
- PC5.** Review and monitor the work of the assistants, executives and contractual workforce, and check for accuracy of documentation and task performance.
- PC6.** Maintain documents regarding stock received and stock rotation.
- PC7.** Maintain documents regarding damaged goods and disposal methods.
- PC8.** Maintain documents regarding storage techniques.
- PC9.** Identify documentation to be completed relating to one's role as per cGMP.
- PC10.** Record details accurately in an appropriate format.
- PC11.** Accurately document the results of the inspections and testing.
- PC12.** Maintain all controlled document files and test records in a timely and accurate manner.
- PC13.** Ensure that the final document meets regulatory and compliance requirements.
- PC14.** Make sure documents are available to all appropriate authorities to inspect.
- PC15.** Update tracker of stored inventory.
- PC16.** Evaluate problems and make initial recommendations for possible corrective action to supervise.
- PC17.** Perform review of records and other documentation for compliance to established procedures and good documentation practices.



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PC18. Write and update the inspection procedures, protocols and checklists.

PC19. Prepare inspection reports as per the inspection activity performed.

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** company manual , SOP , types of documentation used in the organization and its importance
- KU2.** risk and impact of not following defined procedures/work instructions
- KU3.** impact of various documentations practices on cost, quality, productivity, delivery and safety
- KU4.** how to carry out good stock management
- KU5.** importance of complete and accurate documentation
- KU6.** relevant legislative responsibilities and workplace systems for recording information on dispensed pharmaceutical materials and related workplace coding and labelling systems and purpose
- KU7.** principles of good documentation practices and visual standards applied in the workplace
- KU8.** escalation matrix for reporting identified issues
- KU9.** importance of identifying non-conforming materials
- KU10.** 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 ,prescription, 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, cross-functional teams and customers as applicable
- GS5.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS6.** apply planning and organizing skills to plan and organize tools and material required to fulfil documentation related requirements
- GS7.** apply critical thinking skills to analyze and identify what and when to report an issue/concern to the supervisor/ QA team / any other stakeholder
- GS8.** apply customer-centricity while generating and securing documents
- GS9.** apply customer-centricity to remain compliant with data integrity rules, GMP guidelines and to evaluate the impact of errors
- GS10.** apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Reporting quality issues and test results</i>	10	25	7	6
PC1. report defects/ problem/ incidents /quality issues/ test results as applicable in a timely manner	-	-	-	-
PC2. report to the appropriate authority as laid down by the company	-	-	-	-
PC3. follow reporting procedures as prescribed by the company and cGMP	-	-	-	-
<i>Recording and documentation</i>	15	20	8	9
PC4. Prepare and submit daily/weekly/monthly reports on receipt and dispatch performance, pending activities, worker productivity and others as per SOP.	-	-	-	-
PC5. Review and monitor the work of the assistants, executives and contractual workforce, and check for accuracy of documentation and task performance.	-	-	-	-
PC6. Maintain documents regarding stock received and stock rotation.	-	-	-	-
PC7. Maintain documents regarding damaged goods and disposal methods.	-	-	-	-
PC8. Maintain documents regarding storage techniques.	-	-	-	-
PC9. Identify documentation to be completed relating to one's role as per cGMP.	-	-	-	-
PC10. Record details accurately in an appropriate format.	-	-	-	-
PC11. Accurately document the results of the inspections and testing.	-	-	-	-
PC12. Maintain all controlled document files and test records in a timely and accurate manner.	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC13. Ensure that the final document meets regulatory and compliance requirements.	-	-	-	-
PC14. Make sure documents are available to all appropriate authorities to inspect.	-	-	-	-
PC15. Update tracker of stored inventory.	-	-	-	-
PC16. Evaluate problems and make initial recommendations for possible corrective action to supervise.	-	-	-	-
PC17. Perform review of records and other documentation for compliance to established procedures and good documentation practices.	-	-	-	-
PC18. Write and update the inspection procedures, protocols and checklists.	-	-	-	-
PC19. Prepare inspection reports as per the inspection activity performed.	-	-	-	-
NOS Total	25	45	15	15



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0602
NOS Name	Carry out reporting and documentation for appropriate storage of material/products
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Supply Chain Management
NSQF Level	4
Credits	2.00
Version	2.0
Last Reviewed Date	NA
Next Review Date	28/07/2025
NSQC Clearance Date	28/07/2022



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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.** communicate workflow related difficulties 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 GMP 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 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



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- 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 queries 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 GMP 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

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Coordination with the supervisor</i>	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	-	-	-	-
<i>Coordination with functional teams</i>	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. communicate workflow related difficulties to find solutions	-	-	-	-
<i>Coordination with cross-functional teams and other stakeholders</i>	5	10	5	5
PC6. follow the instructions of QA team for any GMP 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	-	-	-	-
<i>Sensitivity towards all genders and people with disability</i>	5	10	5	5
PC10. respect all genders, religions, caste, and cultures	-	-	-	-
PC11. empathize with the people with disability	-	-	-	-



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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



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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	2.0
Last Reviewed Date	30/12/2021
Next Review Date	30/12/2024
NSQC Clearance Date	28/07/2022



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

Description

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

Scope

The scope covers the following :

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

Elements and Performance Criteria

sanitation activities before starting the work

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

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

Sanitation activities during work

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

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

Sanitation activities after completion of work

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

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



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

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

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

Generic Skills (GS)

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

- GS1.** use written communication skills to record and communicate details of work done to appropriate people using written/typed report and electronic mail
- GS2.** use verbal communication skills to communicate with supervisor, cross-functional teams and auditors effectively
- GS3.** use critical thinking skills to interpret the various coding systems as per company norms and in identifying the non-compliance while performing the area inspection
- GS4.** apply customer centricity at work
- GS5.** apply problem-solving and decision making while dealing with any deviation

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Assessment Criteria

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



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



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0113
NOS Name	Ensure a hygienic and clean work area to avoid contamination
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Generic
NSQF Level	4
Credits	1.00
Version	2.0
Last Reviewed Date	30/09/2021
Next Review Date	30/12/2024
NSQC Clearance Date	30/12/2021



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

Description

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

Scope

The scope covers the following :

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

Elements and Performance Criteria

Follow health and hygiene protocols

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

- PC1.** comply with health and personal hygiene-related protocols as per WHO standards and ICH GMP/GLP guidelines
- PC2.** sanitize hands with soap/alcohol based sanitizers before entering in laboratory and production area as per SOP
- PC3.** ensure to wear a lab coat while working in the laboratory
- PC4.** follow gowning procedures while entering in an environment-controlled work area like production shop floor, warehouse etc.
- PC5.** report any environment-related breach while working in laboratory to the lab in-charge or EHS personnel
- PC6.** disinfect the instruments and equipment before and after work as per workplace health and sanitization guidelines

Follow safety and security procedures

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

- PC7.** comply with safety and security policies and procedures
- PC8.** use appropriate safety gears like headgear, masks, gloves and other accessories as mentioned in the guidelines, while carrying out work
- PC9.** report any identified breaches/ incidents/ accidents to the designated person
- PC10.** segregate and store sample/ chemicals/ waste material as per 5S system and SOP
- PC11.** adhere to storage and handling guidelines for hazardous material as per MSDS
- PC12.** take preventive actions against hazards in laboratory by following the safety instructions/guidelines as per MSDS and inform the concerned authority for the same
- PC13.** perform quenching of waste/unused and expired reagents and chemicals using environment sustainable methods under supervision of lab in charge and EHS personnel
- PC14.** complete training records with accuracy for all the attended safety drills and training



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Follow emergency procedures

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

- PC15.** inform the concerned designated person immediately about every unsafe act/ incident (spill, fall, injury, toxic inhale, fire or explosion) for suitable action
- PC16.** follow emergency procedures efficiently
- PC17.** raise alarm and warn other people who may be affected by hazard/unsafe incident

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** individual's role and responsibilities in relation to compliance with environment, health, hygiene and safety rules
- KU2.** the relevant laws and procedures related to the environment, health, and safety regulations
- KU3.** the implications that any non-compliance with health, safety and security may have on individuals and the organization
- KU4.** the limits of individual responsibility for dealing with hazards
- KU5.** workplace hazards in life sciences facility and reporting procedure for accident/ hazard as per GMP guidelines
- KU6.** the characteristics of chemical substances, precaution and safety measures required while handling them
- KU7.** the gowning procedure for controlled areas
- KU8.** the organization's emergency procedures for different situations and the importance of following these
- KU9.** the evacuation procedures for employees, contract staff and visitors
- KU10.** the procedure to summon medical assistance and the emergency services in case of necessity
- KU11.** the types of breaches in the environment, health, safety, and security and their reporting procedures
- KU12.** the type of safety gears and procedure to use them
- KU13.** the importance of material segregation and 5S system
- KU14.** the WHO guidelines for personal hygiene, handling and storing hazardous material
- KU15.** the ALCOA principles for documentation and data integrity

Generic Skills (GS)

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

- GS1.** use written communication skills to accurately record the required information to be reported as per SOP
- GS2.** use reading and comprehension skills for interpreting the various coding systems and to read instructions, guidelines, procedures, rules, and signage to understand the procedure to be followed
- GS3.** use listening skills to act appropriately on the emergency alarms



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- GS4.** use verbal communication skills to interact with teammates, lab in charge and cross-functional teams to communicate about hazards, safety instructions and accidents
- GS5.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS6.** apply planning and organizing skills to plan and organize tools and material required for work to fulfil environment, health, safety and security requirements
- GS7.** apply critical thinking skills to analyze and identify when to report an issue/concern to the lab in charge and when to deal with a colleague individually, depending on the type of concern
- GS8.** use critical thinking skills to ascertain the breach/ compliance of EHS protocols
- GS9.** apply customer centricity to remain compliant with data integrity rules, GMP guidelines
- GS10.** apply decision-making skills to make balanced judgments within the authority in different situations while dealing with the hazards and breaches

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



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



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0101
NOS Name	Follow Environment ,health and safety guidelines in GMP/GLP controlled areas and laboratory
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Generic
NSQF Level	4
Credits	1.00
Version	3.0
Last Reviewed Date	NA
Next Review Date	30/12/2024
NSQC Clearance Date	30/12/2021



Qualification Pack

LFS/N0656: Supervise waste disposal as per environment sustainable practices

Description

This NOS is about a person who Supervises waste disposal as per environment sustainable practices

Scope

The scope covers the following :

- Supervise Non-conforming waste material

Elements and Performance Criteria

Supervise Non-conforming waste material

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

- PC1.** Dispose the non-conforming waste material
- PC2.** Follow the standards and procedures as mentioned in GMP while disposing defective materials
- PC3.** Identify and analyze any problems that may arise while disposing the materials
- PC4.** Suggest corrective action to address problems
- PC5.** Review effectiveness of corrective action
- PC6.** Undertake safe disposal of damaged goods and its documentation based on inputs from client and directions from manager
- PC7.** Dispose the waste garnered from the activity as per SOP
- PC8.** Maintain documents regarding damaged goods and disposal methods
- PC9.** Undertake safe disposal of damaged goods and its documentation based on inputs from client and directions from manager

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** the WHO guidelines and ICH-cGMP rules for waste disposal and waste management
- KU2.** implications of defective goods on production of final products
- KU3.** relevant legislative responsibilities and workplace systems for recording information on dispensed pharmaceutical materials
- KU4.** principles of good inspection practices and visual standards applied in the workplace
- KU5.** different techniques/inspection methods used to identify defects
- KU6.** disposal of non-conforming and rejected samples
- KU7.** purpose and basic principles of the dispensing process, including the characteristics of finished goods and related handling requirements

Generic Skills (GS)



Qualification Pack

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 understand the instructions, procedures and alarms
- GS4.** use verbal communication skills to interact with teammates, cross-functional teams and higher authorities
- 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 decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations



Qualification Pack

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Supervise Non-conforming waste material</i>	30	50	10	10
PC1. Dispose the non-conforming waste material	-	-	-	-
PC2. Follow the standards and procedures as mentioned in GMP while disposing defective materials	-	-	-	-
PC3. Identify and analyze any problems that may arise while disposing the materials	-	-	-	-
PC4. Suggest corrective action to address problems	-	-	-	-
PC5. Review effectiveness of corrective action	-	-	-	-
PC6. Undertake safe disposal of damaged goods and its documentation based on inputs from client and directions from manager	-	-	-	-
PC7. Dispose the waste garnered from the activity as per SOP	-	-	-	-
PC8. Maintain documents regarding damaged goods and disposal methods	-	-	-	-
PC9. Undertake safe disposal of damaged goods and its documentation based on inputs from client and directions from manager	-	-	-	-
NOS Total	30	50	10	10



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0656
NOS Name	Supervise waste disposal as per environment sustainable practices
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical and Contract Research
Occupation	Supply Chain Management
NSQF Level	4
Credits	2.00
Version	2.0
Last Reviewed Date	NA
Next Review Date	28/07/2025
NSQC Clearance Date	28/07/2022



Qualification Pack

LFS/N0668: Supervise warehouse operations for storage, dispensing and sale of drug products

Description

This NOS is about a person who supervises warehouse operations for storage, dispensing and sale of drug products

Scope

The scope covers the following :

- Prepare daily plan and allocate resources
- Storage and dispensing
- Sale of drug product

Elements and Performance Criteria

Prepare daily plan and allocate resources

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

- PC1.** Obtain receipt, storage and dispatch details
- PC2.** Develop daily work plan factoring in priority cases, and cases requiring exceptional handling.
- PC3.** Check for correct segregation of items.
- PC4.** Check for contamination or leakage of items.
- PC5.** Check and facilitate disposal of contaminated or leakage items as per policy.
- PC6.** Update tracker of stored inventory.

Storage and dispensing

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

- PC7.** Storage and dispensing
- PC8.** Maintain proper drugs storage, rack layout, cold chain, refrigeration, and upkeep of the pharmacy.
- PC9.** Maintain inventory of the stores, stock checking and inventory replenishment.
- PC10.** Perform visual inspection of inbound and outbound goods.
- PC11.** Check prescription of the patient and dispense medication to inpatient and outpatient pharmacy.
- PC12.** Check expiry of the medication while dispensing.
- PC13.** Follow First in and First Out protocols for dispensing medicines to the customer.
- PC14.** Check the mandatory documentation on receipt of stock and before unloading and ensure right quantity is received as per the documentation.
- PC15.** Supervise segregation of damaged goods and act as per SOP and in consultation with Manager.

Sale of drug product

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



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- PC16.** Handle queries of the patient for medications.
- PC17.** Sale of Drug Products
- PC18.** Maintain records of purchase and sale of the drugs.
- PC19.** Ensure inventory status is updated in the ERP concurrently based on transactions and inventory counts.
- PC20.** Sell of the OTC Drugs/ Increase the OTC Sale.
- PC21.** Maintain records of Cash register.
- PC22.** Comply with regulatory laws of Pharmacy.
- PC23.** Build customer relationship to increase sale of the stores.

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.** levels of hygiene required by storage area and importance of maintaining the same
- KU4.** risk and impact of not following defined procedures/work instructions
- KU5.** escalation matrix for reporting identified issues
- KU6.** how to carry out good stock management, including the rotation of stock, and checking expiry dates of goods
- KU7.** use of computer applications/software
- KU8.** excellent knowledge of stored inventory tracker.
- KU9.** how to give customers clear, accurate and complete information about the terms of supply
- KU10.** legal and company procedures for checking the customers identify and credit status.

Generic Skills (GS)

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

- GS1.** use reading and comprehension skills to gauge the relevant information manuals, SOPs, health and safety instructions, memos, reports, job cards, and notes/comments
- GS2.** use written communication skills to maintain proper and concise records as per given format
- GS3.** use team-building skills during the interaction with teammates while managing the difficult/stressful or emotional situations at work
- GS4.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS5.** apply critical thinking skills to analyze and identify when to report an issue/concern to the higher authority and to deal with a colleague individually, depending on the type of concern

Qualification Pack

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Prepare daily plan and allocate resources</i>	5	10	-	5
PC1. Obtain receipt, storage and dispatch details	-	-	-	-
PC2. Develop daily work plan factoring in priority cases, and cases requiring exceptional handling.	-	-	-	-
PC3. Check for correct segregation of items.	-	-	-	-
PC4. Check for contamination or leakage of items.	-	-	-	-
PC5. Check and facilitate disposal of contaminated or leakage items as per policy.	-	-	-	-
PC6. Update tracker of stored inventory.	-	-	-	-
<i>Storage and dispensing</i>	10	20	5	5
PC7. Storage and dispensing	-	-	-	-
PC8. Maintain proper drugs storage, rack layout, cold chain, refrigeration, and upkeep of the pharmacy.	-	-	-	-
PC9. Maintain inventory of the stores, stock checking and inventory replenishment.	-	-	-	-
PC10. Perform visual inspection of inbound and outbound goods.	-	-	-	-
PC11. Check prescription of the patient and dispense medication to inpatient and outpatient pharmacy.	-	-	-	-
PC12. Check expiry of the medication while dispensing.	-	-	-	-
PC13. Follow First in and First Out protocols for dispensing medicines to the customer.	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC14. Check the mandatory documentation on receipt of stock and before unloading and ensure right quantity is received as per the documentation.	-	-	-	-
PC15. Supervise segregation of damaged goods and act as per SOP and in consultation with Manager.	-	-	-	-
<i>Sale of drug product</i>	10	20	5	5
PC16. Handle queries of the patient for medications.	-	-	-	-
PC17. Sale of Drug Products	-	-	-	-
PC18. Maintain records of purchase and sale of the drugs.	-	-	-	-
PC19. Ensure inventory status is updated in the ERP concurrently based on transactions and inventory counts.	-	-	-	-
PC20. Sell of the OTC Drugs/ Increase the OTC Sale.	-	-	-	-
PC21. Maintain records of Cash register.	-	-	-	-
PC22. Comply with regulatory laws of Pharmacy.	-	-	-	-
PC23. Build customer relationship to increase sale of the stores.	-	-	-	-
NOS Total	25	50	10	15



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0668
NOS Name	Supervise warehouse operations for storage, dispensing and sale of drug products
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Supply Chain Management
NSQF Level	5
Credits	3.00
Version	1.0
Last Reviewed Date	NA
Next Review Date	28/07/2025
NSQC Clearance Date	28/07/2022



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	08/05/2025
Next Review Date	31/10/2025
NSQC Clearance Date	08/05/2025



Qualification Pack

LFS/N0120: Establish own enterprise and perform various entrepreneurial activities to run the business operations in Life Sciences Sector

Description

This NOS is about an entrepreneur setting up his/her own enterprise and performing various entrepreneurial activities to run the business operations in Life Sciences Sector

Scope

The scope covers the following :

- Set up enterprise and perform entrepreneurial activities
- Maintenance of accounts and ledgers
- Comply with legal, regulatory and statutory standards

Elements and Performance Criteria

Set up enterprise and perform entrepreneurial activities

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

- PC1.** perform a survey in the identified area for business activities to identify prospective customers and business opportunity
- PC2.** identify products and/ or services and it's sources, that match the business opportunity
- PC3.** develop business proposal with objective and identified business area for registering the proposed business as independent entity with competent authorities
- PC4.** submit business proposals and feasibility plans for securing the required funding from govt. schemes for MSMEs like MUDRA etc. as and when needed
- PC5.** present the business proposal to investors and stakeholders to gain their confidence and trust for possible funding
- PC6.** ensure setting up the infrastructure and resources for business as per approved plan and investors/ shareholders agreement
- PC7.** enrol into various government schemes and programs for MSME and avail the benefits
- PC8.** promote the product/ services through various means including digital promotions in line to regulations for promotion and sale as per land of law
- PC9.** develop the supply chain and distribution network
- PC10.** maintain updated information regarding new market trends to provide service to customers and constantly upskill self and employees for futuristic technologies, innovations and methodologies

Maintenance of accounts and ledgers

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

- PC11.** ensure to generate a final invoice for the services rendered/ or products sold
- PC12.** collect payment either in cash (as per RBI guidelines)/ cheque/ demand draft or through online transactions via RTGS/NEFT/UPI etc.



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- PC13.** ensure accounts and ledgers are maintained for the material supplied, payables and receivables, loan ledgers, taxes collected and paid into government treasury as well for wages paid and statutory benefits like PF, ESI contribution deposited with authorities
- PC14.** ensure maintenance and reconciliation of a monthly account as well as movable and immovable assets and stock to keep track of profit/ loss as well as periodic audit as per legal requirements

Comply with legal, regulatory and statutory standards

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

- PC15.** comply with workplace health and safety rules stipulated by local authorities
- PC16.** comply with rules related to taxes and licensing regulations
- PC17.** comply with prevalent labour laws and keep records for employee's qualifications, employment as well as trainings
- PC18.** comply with regulations and protocols related to maintenance of product/ service license including the pre conditions (if any)
- PC19.** comply with quality system like ISO/GMP/GLP etc and any other rule mandated by appropriate regulatory authorities
- PC20.** comply with pollution norms as per land of law and ensure near zero pollution for a sustainable environment and to earn carbon credits
- PC21.** ensure that business facility and employees are always prepared and ready for any surprise inspection/ audit from clients/ regulatory/ statutory authorities

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** business administration, financial and planning activities
- KU2.** data analysis techniques for continuous improvement and identifying new business opportunities
- KU3.** maintaining confidentiality for information about finances, business secrets and information shared by clients/ stakeholders
- KU4.** procedures for funding approvals, and presenting new business idea/ opportunity for license or stakeholder approvals
- KU5.** prevailing and possible environmental issues and expected quality standards
- KU6.** license, patent and copyright laws
- KU7.** applicable tax, duties and labour laws
- KU8.** fundamentals of costing, pricing and profit
- KU9.** accounting principles and use of accounting software and government software/ portals for taxes and returns
- KU10.** Good Practices (GxP), ISO and other quality systems
- KU11.** talent management and resource planning
- KU12.** Awareness of applicable engineering concepts
- KU13.** audits and regulations in Life Sciences sector applicable for chosen business area
- KU14.** market promotion, globally trending strategies and distribution network
- KU15.** concept of innovation and jugaad principle



Qualification Pack

Generic Skills (GS)

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

- GS1.** note the information to be communicated
- GS2.** fill relevant applications where required
- GS3.** write clear communications to government officials, funding partners, team members, etc
- GS4.** discuss task lists, schedules and activities with customers, peers, partners, vendors etc.
- GS5.** effectively communicate with teams
- GS6.** interact with successful local entrepreneurs, and enterprises in a similar field for best practices and expertise
- GS7.** ask questions in order to understand problems and clarify queries
- GS8.** multi-task and adapt to meet work timelines
- GS9.** apply emotional intelligence while dealing with other genders and people with disability

Qualification Pack

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Set up enterprise and perform entrepreneurial activities</i>	20	30	6	3
PC1. perform a survey in the identified area for business activities to identify prospective customers and business opportunity	-	-	-	-
PC2. identify products and/ or services and it's sources, that match the business opportunity	-	-	-	-
PC3. develop business proposal with objective and identified business area for registering the proposed business as independent entity with competent authorities	-	-	-	-
PC4. submit business proposals and feasibility plans for securing the required funding from govt. schemes for MSMEs like MUDRA etc. as and when needed	-	-	-	-
PC5. present the business proposal to investors and stakeholders to gain their confidence and trust for possible funding	-	-	-	-
PC6. ensure setting up the infrastructure and resources for business as per approved plan and investors/ shareholders agreement	-	-	-	-
PC7. enrol into various government schemes and programs for MSME and avail the benefits	-	-	-	-
PC8. promote the product/ services through various means including digital promotions in line to regulations for promotion and sale as per land of law	-	-	-	-
PC9. develop the supply chain and distribution network	-	-	-	-
PC10. maintain updated information regarding new market trends to provide service to customers and constantly upskill self and employees for futuristic technologies, innovations and methodologies	-	-	-	-
<i>Maintenance of accounts and ledgers</i>	10	20	6	5

Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC11. ensure to generate a final invoice for the services rendered/ or products sold	-	-	-	-
PC12. collect payment either in cash (as per RBI guidelines)/ cheque/ demand draft or through online transactions via RTGS/NEFT/UPI etc.	-	-	-	-
PC13. ensure accounts and ledgers are maintained for the material supplied, payables and receivables, loan ledgers, taxes collected and paid into government treasury as well for wages paid and statutory benefits like PF, ESI contribution deposited with authorities	-	-	-	-
PC14. ensure maintenance and reconciliation of a monthly account as well as movable and immovable assets and stock to keep track of profit/ loss as well as periodic audit as per legal requirements	-	-	-	-
<i>Comply with legal, regulatory and statutory standards</i>	-	-	-	-
PC15. comply with workplace health and safety rules stipulated by local authorities	-	-	-	-
PC16. comply with rules related to taxes and licensing regulations	-	-	-	-
PC17. comply with prevalent labour laws and keep records for employee's qualifications, employment as well as trainings	-	-	-	-
PC18. comply with regulations and protocols related to maintenance of product/ service license including the pre conditions (if any)	-	-	-	-
PC19. comply with quality system like ISO/GMP/GLP etc and any other rule mandated by appropriate regulatory authorities	-	-	-	-
PC20. comply with pollution norms as per land of law and ensure near zero pollution for a sustainable environment and to earn carbon credits	-	-	-	-
PC21. ensure that business facility and employees are always prepared and ready for any surprise inspection/ audit from clients/ regulatory/ statutory authorities	-	-	-	-



Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
NOS Total	30	50	12	8



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0120
NOS Name	Establish own enterprise and perform various entrepreneurial activities to run the business operations in Life Sciences Sector
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Generic
NSQF Level	6
Credits	1.00
Version	2.0
Last Reviewed Date	29/09/2023
Next Review Date	29/09/2026
NSQC Clearance Date	29/09/2023



Qualification Pack

LFS/N0121: Maintain the critical business documents as Entrepreneur in Life Sciences Sector

Description

This NOS is about an entrepreneur maintaining the critical business documents for its business in life sciences sector.

Scope

The scope covers the following :

- Infrastructure related documentation
- Supply Chain related documentation
- Documentation for sales & marketing
- Quality audit and client/regulatory inspections related documentation

Elements and Performance Criteria

Infrastructure related documentation

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

- PC1.** ensure documentation and maintenance of records for architectural building layout like blueprint of plant/lab, electric circuit and plumbing layouts and safety equipment layout, infrastructure and asset insurance and lease/rent contracts/ sale deed (if owned facility)
- PC2.** ensure documentation and maintenance of records for all machineries, equipment and tools installed/used in the plant/ lab unit, with supplier/manufacturer details, manuals of all machineries / equipment, installation and qualification records and annual maintenance details etc
- PC3.** ensure documentation and maintenance of records for engineering and maintenance of each machinery/equipment, machine utilization, machine performance, breakdown details, corrective actions, spares changed, machine/equipment condition etc

Supply Chain related documentation

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

- PC4.** ensure documentation and maintenance of records for all raw materials, ingredients and packaging materials handled, like name of the supplier, batch details, quantity supplied and quality of the materials supplies etc as well as
- PC5.** ensure documentation and maintenance of records for each supplier quality report on raw materials, ingredients, packaging materials, internal and external quality report on finished products, consumer and customer complaints , corrective actions, legal documents (if any)
- PC6.** ensure documentation and maintenance of records for storage facility, like condition of storage facility, storage parameters if any like temperature, humidity, pressure (as applicable), space utilised, stacking procedure etc
- PC7.** ensure documentation and maintenance of records for distribution details like transport details, quality, hygiene and cleanliness of vehicle, quantity loaded in the vehicle, distribution routes , outlet details, customer/ consumer details, distribution quantity, quantity returned etc.



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Documentation for sales & marketing

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

- PC8.** ensure documentation and maintenance of records for long term and short term business plans, feasibility reports, investor/shareholder agreements and disbursement and payment records for loan/grant/equity etc.
- PC9.** ensure documentation and maintenance of records for sale like customer details, customer type, location, quantity purchased by each stockist/consumer, frequency of purchase, sale details like quantity of products/brand sold in each territory

Quality audit and client/regulatory inspections related documentation

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

- PC10.** ensure documentation and maintenance of records for internal/ external audits with its observations, notices/ feedback, action reports and final submission of audit action reports
- PC11.** ensure documentation and maintenance of records for every communication sent to or received from regulatory/ licensing authorities

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** system of documentation as per ISO/ good documentation practices and method of implementation
- KU2.** scoring, grading and accreditation system of affiliating bodies and clients
- KU3.** guidelines for facing audits and best practices for making organization audit ready
- KU4.** software and latest information technology tools for documentation and record maintenance
- KU5.** statistical tools for analysis and monitoring
- KU6.** various recording and documentation formats applicable in sales, marketing, supply chain etc
- KU7.** basic awareness of engineering drawing and architectural layouts
- KU8.** best practices in engineering and maintenance in sector
- KU9.** accounting standards and regulations

Generic Skills (GS)

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

- GS1.** record and communicate details of work done to appropriate people using written/taped report
- GS2.** interact effectively with team members
- GS3.** communicate with team members for data/ information/support/ advice needed
- GS4.** communicate with people in a form and manner and using language that is open and respectful
- GS5.** apply balanced judgement to different situations
- GS6.** plan and organize assigned work in order to drive collaboration with team members
- GS7.** effectively interact with the various stakeholders to complete assigned tasks



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- GS8.** resolve any difficulties in relationships with colleagues , or get help from an appropriate person, in a way that preserves goodwill and trust
- GS9.** use team-building skills during the interaction with teammates while managing the difficult/stressful or emotional situations at work
- GS10.** apply emotional intelligence while dealing with other genders and people with disability

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Infrastructure related documentation</i>	5	20	5	2
PC1. ensure documentation and maintenance of records for architectural building layout like blueprint of plant/lab, electric circuit and plumbing layouts and safety equipment layout, infrastructure and asset insurance and lease/rent contracts/ sale deed (if owned facility)	-	-	-	-
PC2. ensure documentation and maintenance of records for all machineries, equipment and tools installed/used in the plant/ lab unit, with supplier/manufacturer details, manuals of all machineries / equipment, installation and qualification records and annual maintenance details etc	-	-	-	-
PC3. ensure documentation and maintenance of records for engineering and maintenance of each machinery/equipment, machine utilization, machine performance, breakdown details, corrective actions, spares changed, machine/equipment condition etc	-	-	-	-
<i>Supply Chain related documentation</i>	5	20	5	3
PC4. ensure documentation and maintenance of records for all raw materials, ingredients and packaging materials handled, like name of the supplier, batch details, quantity supplied and quality of the materials supplies etc as well as	-	-	-	-
PC5. ensure documentation and maintenance of records for each supplier quality report on raw materials, ingredients, packaging materials, internal and external quality report on finished products, consumer and customer complaints , corrective actions, legal documents (if any)	-	-	-	-
PC6. ensure documentation and maintenance of records for storage facility, like condition of storage facility, storage parameters if any like temperature, humidity, pressure (as applicable), space utilised, stacking procedure etc	-	-	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC7. ensure documentation and maintenance of records for distribution details like transport details, quality, hygiene and cleanliness of vehicle, quantity loaded in the vehicle, distribution routes , outlet details, customer/ consumer details, distribution quantity, quantity returned etc.	-	-	-	-
<i>Documentation for sales & marketing</i>	5	10	3	3
PC8. ensure documentation and maintenance of records for long term and short term business plans, feasibility reports, investor/shareholder agreements and disbursement and payment records for loan/grant/equity etc.	-	-	-	-
PC9. ensure documentation and maintenance of records for sale like customer details, customer type, location, quantity purchased by each stockist/consumer, frequency of purchase, sale details like quantity of products/brand sold in each territory	-	-	-	-
<i>Quality audit and client/regulatory inspections related documentation</i>	5	5	2	2
PC10. ensure documentation and maintenance of records for internal/ external audits with its observations, notices/ feedback, action reports and final submission of audit action reports	-	-	-	-
PC11. ensure documentation and maintenance of records for every communication sent to or received from regulatory/ licensing authorities	-	-	-	-
NOS Total	20	55	15	10



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0121
NOS Name	Maintain the critical business documents as Entrepreneur in Life Sciences Sector
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Generic
NSQF Level	6
Credits	1.00
Version	2.0
Last Reviewed Date	29/09/2023
Next Review Date	29/09/2026
NSQC Clearance Date	29/09/2023

Assessment Guidelines and Assessment Weightage

Assessment Guidelines

1. Criteria for assessment for each Qualification Pack will be created by Life Sciences Sector Skill Development Council (LSSSDC)
2. Each Element will be assigned marks proportional to its importance in NOS. LSSSDC will also lay down the proportion of marks for Theory, Practical, Project, and Viva for each Element.
3. The assessment for the theory part will be based on the knowledge bank of questions created by the LSSSDC.
4. Assessment will be conducted for all compulsory NOS, and where applicable, on the selected elective/option NOS/set of NOS.
5. LSSSDC as an assessment and awarding body will create unique evaluations for each assessment component i.e. theory, practical, project, and viva for every student at each examination/training center based on this criterion.
6. Wherever any assessment component is not applicable/ feasible, the balance assessment components will be used to assess the candidate, and accordingly the total marks will be calculated only for the applied



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assessment component.

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

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

Minimum Aggregate Passing % at QP Level : 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/N0602.Carry out reporting and documentation for appropriate storage of material/products	25	45	15	15	100	20
LFS/N0118.Coordinate with supervisor, teammates, and cross-functional teams	20	45	18	17	100	10
LFS/N0113.Ensure a hygienic and clean work area to avoid contamination	30	40	15	15	100	10
LFS/N0101.Follow Environment ,health and safety guidelines in GMP/GLP controlled areas and laboratory	30	55	-	15	100	10
LFS/N0656.Supervise waste disposal as per environment sustainable practices	30	50	10	10	100	20



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National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0668.Supervise warehouse operations for storage, dispensing and sale of drug products	25	50	10	15	100	20
DGT/VSQ/N0103.Employability Skills (90 Hours)	20	30	-	-	50	10
Total	180	315	68	87	650	100

Optional: 1 Regulated Business Operations

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0120.Establish own enterprise and perform various entrepreneurial activities to run the business operations in Life Sciences Sector	30	50	12	8	100	30
LFS/N0121.Maintain the critical business documents as Entrepreneur in Life Sciences Sector	20	55	15	10	100	30
Total	50	105	27	18	200	60



Qualification Pack

Acronyms

NOS	National Occupational Standard(s)
NSQF	National Skills Qualifications Framework
QP	Qualifications Pack
TVET	Technical and Vocational Education and Training
SOP	Standard Operating Procedure
GMP	Good Manufacturing Practices
SOP	Standard Operating Procedures
GMP	Good Manufacturing Practices
NOS	National Occupational standards
SOP	Standard Operating Procedure
QA	Quality Assurance
EHS	Environment, Health and Safety
GMP	Good Manufacturing Practice
WHO	World Health Organisation
WHO	World Health Organization
ICH	Council for Harmonisation
GMP	Good Manufacturing Practice
GLP	Good Laboratory Practice
MSDS	Material Safety Data Sheet
EHS	Environment Health and Safety
ALCOA	Attributable, Legible, Contemporaneous, Original and Accurate
SOP	Standard Operating Procedure
SOP	Standard Operating Procedure
GMP	Good Manufacturing Practices
SOP	Standard Operating Procedure

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SOP	Standard Operating Procedure
GMP	Good Manufacturing Practices
SOP	Standard Operating Procedures
GMP	Good Manufacturing Practices
NOS	National Occupational standards
SOP	Standard Operating Procedure
QA	Quality Assurance
EHS	Environment, Health and Safety
GMP	Good Manufacturing Practice
WHO	World Health Organisation
WHO	World Health Organization
ICH	Council for Harmonisation
GMP	Good Manufacturing Practice
GLP	Good Laboratory Practice
MSDS	Material Safety Data Sheet
EHS	Environment Health and Safety
ALCOA	Attributable, Legible, Contemporaneous, Original and Accurate
SOP	Standard Operating Procedure
SOP	Standard Operating Procedure
GMP	Good Manufacturing Practices
SOP	Standard Operating Procedure
SOP	Standard Operating Procedure
GMP	Good Manufacturing Practices
SOP	Standard Operating Procedures
GMP	Good Manufacturing Practices
NOS	National Occupational standards



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SOP	Standard Operating Procedure
QA	Quality Assurance
EHS	Environment, Health and Safety
GMP	Good Manufacturing Practice
WHO	World Health Organisation
WHO	World Health Organization
ICH	Council for Harmonisation
GMP	Good Manufacturing Practice
GLP	Good Laboratory Practice
MSDS	Material Safety Data Sheet
EHS	Environment Health and Safety
ALCOA	Attributable, Legible, Contemporaneous, Original and Accurate
SOP	Standard Operating Procedure
SOP	Standard Operating Procedure
GMP	Good Manufacturing Practices
SOP	Standard Operating Procedure

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Glossary

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



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Knowledge and Understanding (KU)	Knowledge and Understanding (KU) are statements which together specify the technical, generic, professional and organisational specific knowledge that an individual needs in order to perform to the required standard.
Organisational Context	Organisational context includes the way the organisation is structured and how it operates, including the extent of operative knowledge managers have of their relevant areas of responsibility.
Technical Knowledge	Technical knowledge is the specific knowledge needed to accomplish specific designated responsibilities.
Core Skills/ Generic Skills (GS)	Core skills or Generic Skills (GS) are a group of skills that are the key to learning and working in today's world. These skills are typically needed in any work environment in today's world. These skills are typically needed in any work environment. In the context of the OS, these include communication related skills that are applicable to most job roles.
Electives	Electives are NOS/set of NOS that are identified by the sector as contributive to specialization in a job role. There may be multiple electives within a QP for each specialized job role. Trainees must select at least one elective for the successful completion of a QP with Electives.
Options	Options are NOS/set of NOS that are identified by the sector as additional skills. There may be multiple options within a QP. It is not mandatory to select any of the options to complete a QP with Options.