Qualification Pack

Production Equipment Operator- Active Pharmaceutical Ingredient (API) / Bulk Drug

Electives: Non Sterile Manufacturing/ Non Sterile Packaging/ Sterile Manufacturing and Packaging

QP Code: LFS/Q0207

Version: 4.0

NSQF Level: 4

Qualification Pack

Life Sciences Sector Skill Development Council || # 14, Rear 2nd Floor, Palam Marg, Vasant Vihar New Delhi-110057 || email:SHIVI.CHAUDHARY@LSSSDC.IN

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Qualification Pack

LFS/Q0207: Production Equipment Operator- Active Pharmaceutical Ingredient (API) / Bulk Drug

Brief Job Description

The Production Equipment Operator API program enables the learner to be able to meet the job responsibilities for operating the machines following Good Manufacturing Practices for the manufacturing/packaging of bulk drugs / active pharmaceutical ingredients (API). The program shall be able to develop learner to perform basic in-process quality checks to verify that the quality parameters are met for batch manufacturing/ continuous manufacturing and packaging. He/ she shall also be able to generate and maintain the critical records for every activity performed in compliance with data integrity rules. The Program shall also enable engineering skills in the learners to maintain the semi-automated and automated plant equipment and troubleshoot and resolve primary level simple engineering problems to ensure minimal breakdown of the production and packaging line.

Personal Attributes

The individual should have good communication skills in the regional language and be able to comprehend the instructions and process documents in the English language.He/She should have good analytical skills. The job holder should be able to give attention to detail and understand the criticality of the work.

Applicable National Occupational Standards (NOS)

Compulsory NOS:

1. LFS/N0274: Discuss about Life Sciences Industry and Basics of manufacturing Operations
2. LFS/N0213: Perform pre-production checks and prepare Equipment for bulk drug production
3. LFS/N0112: Adherence to Environment, health and safety guidelines in a production facility and GMP controlled area
4. LFS/N0265: Maintain compliance with current Good Manufacturing Practices (cGMP) and other regulations
5. LFS/N0113: Ensure a hygienic and clean work area to avoid contamination
6. LFS/N0104: Coordinate and communicate with Supervisor/ production chemist, teams and auditors
7. DGT/VSQ/N0102: Employability Skills (60 Hours)

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

Elective 1: Non Sterile Manufacturing

This elective is about a equipment Operator performing non-sterile bulk drug / API manufacturing

operations

1. LFS/N0214: Perform non- sterile bulk drug /API manufacturing operations

Elective 2: Non Sterile Packaging

This elective is about a equipment operator performing primary packaging operations of non-sterile bulk drug/ API

1. LFS/N0266: Perform primary packaging operations for Non-sterile Bulk Drug / API

Elective 3: Sterile Manufacturing and Packaging

This elective is about equipment operator performing Sterile Bulk Drug / API manufacturing and primary packaging operations

1. LFS/N0267: Perform sterile Bulk drug API/ manufacturing and primary packaging operations

Qualification Pack (QP) Parameters

Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Manufacturing
Country	India
NSQF Level	4
Credits	22
Aligned to NCO/ISCO/ISIC Code	NCO 2015/ 3133.99
Minimum Educational Qualification & Experience	12th Class (Science Subjects Preferred) with NA of experience OR Completed 1st year of diploma (after 12th) (Diploma in Pharmacy) OR 10th grade pass plus 2-year NTC (2 year NTC/NAC in Engg trade) OR Certificate-NSQF (Level 3 (Assistant- Manufacturing and Packaging (Pharma, Biologics and Medical device))) with 3 Years of experience relevant experience in Life Science Sector

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Minimum Level of Education for Training in School	10th Class
Pre-Requisite License or Training	NA
Minimum Job Entry Age	18 Years
Last Reviewed On	NA
Next Review Date	17/12/2027
NSQC Approval Date	17/12/2024
Version	4.0
Reference code on NQR	QG-04-LS-03402-2024-V2-LSSSDC
NQR Version	2.0

Remarks:

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

Qualification Pack

LFS/N0274: Discuss about Life Sciences Industry and Basics of manufacturing Operations

Description

This NOS unit is related to discussing about Life Sciences Industry and Basics of manufacturing Operations

Scope

The scope covers the following :

- Life Sciences industry and Manufacturing Occupation
- Basics of manufacturing Operations

Elements and Performance Criteria

Life Sciences industry and Manufacturing Occupation

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

PC1. discuss key insights in the life sciences sector through various market research reports

PC2. Identify the major segments within the life sciences industry (pharmaceuticals, biotechnology, medical devices, etc.).

PC3. Elaborate importance of a skilled individual in manufacturing Occupation

PC4. explain the role of government policies and initiatives in promoting the growth of the life sciences industry in India.

Basics of manufacturing Operations

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

PC5. Comply with key regulatory requirements for manufacturing facilities (e.g., cGMP, cGLP, cGDP).

PC6. Ensure ethical considerations in life sciences manufacturing, including data integrity and patient safety.

PC7. Analyze the impact of standard quantity effect on product quality and efficacy.

PC8. Analyze the role of each component in ensuring efficient and compliant manufacturing operations

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. Understand the Indian Life Sciences industry's key features and challenges.

KU2. major segments like pharmaceuticals, biotechnology, and medical devices.

KU3. critical role of skilled individuals in ensuring quality and safety in manufacturing.

KU4. various guidelines like current Good Manufacturing Practices, current Good Storage Practices, Good Documentation Practices

KU5. basics of ALCOA Principles, data integrity and information security rules

KU6. methods to conserve water and energy

KU7. methods to minimize the pollution

KU8. how government policies and initiatives drive industry growth.

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

GS2. use reading and comprehension skills to read the various coding systems, instructions, guidelines, procedures, rules, and signages

GS3. use listening skills to interpret the instructions, escalation matrix, procedures to be followed and to seek clarifications

GS4. use verbal communication skills to interact with teammates, supervisor, production chemist, and cross-functional teams

GS5. use team-building skills while dealing with teammates

GS6. apply problem-solving skills to find solutions for deviations found during process-related checks, non-conformities in standards and labeling

GS7. apply critical thinking skills to analyze and identify when to report an issue/concern to the supervisor and when to deal with a process error individually, depending on the type of concern

GS8. apply customer centricity to remain compliant with data integrity rules, GMP/GLP guidelines and to evaluate impact of wrongdoings

GS9. apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Life Sciences industry and Manufacturing Occupation	**20**	**-**	**5**	**5**
PC1. discuss key insights in the life sciences sector through various market research reports	-	-	-	-
PC2. Identify the major segments within the life sciences industry (pharmaceuticals, biotechnology, medical devices, etc.).	-	-	-	-
PC3. Elaborate importance of a skilled individual in manufacturing Occupation	-	-	-	-
PC4. explain the role of government policies and initiatives in promoting the growth of the life sciences industry in India.	-	-	-	-
Basics of manufacturing Operations	**20**	**30**	**10**	**10**
PC5. Comply with key regulatory requirements for manufacturing facilities (e.g., cGMP, cGLP, cGDP).	-	-	-	-
PC6. Ensure ethical considerations in life sciences manufacturing, including data integrity and patient safety.	-	-	-	-
PC7. Analyze the impact of standard quantity effect on product quality and efficacy.	-	-	-	-
PC8. Analyze the role of each component in ensuring efficient and compliant manufacturing operations	-	-	-	-
NOS Total	**40**	**30**	**15**	**15**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0274
NOS Name	Discuss about Life Sciences Industry and Basics of manufacturing Operations
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Manufacturing
NSQF Level	4
Credits	1.00
Version	1.0
Last Reviewed Date	08/04/2025
Next Review Date	08/04/2028
NSQC Clearance Date	08/04/2025

Qualification Pack

LFS/N0112: Adherence to Environment, health and safety guidelines in a production facility and GMP controlled area

Description

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

Scope

The scope covers the following :

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

Elements and Performance Criteria

Follow health and personal hygiene protocols

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

PC1. comply with health and personal hygiene-related protocols as per WHO standards, , revised GMP and ICH GMP guidelines

PC2. wash hands before entering in the production area as per SOP

PC3. report any allergy, sickness or any other environment-related breach before or after entering the work premises to the designated person

PC4. follow gowning procedures while entering an environment controlled work area

Follow safety and security procedures

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

PC5. comply with safety and security policies and procedures

PC6. use appropriate safety gears like headgear, masks, gloves and other relevant safety accessories as mentioned in the guidelines, while carrying out work

PC7. use helmets, ropes, harness, and ladders while working at heights

PC8. use pulleys/ forklift (if available) to transport the material/ spares/ heavy assembly and tools

PC9. report any identified breaches in safety and security policies and procedures to the designated person

PC10. segregate material and follow the 5S system at the storage area

PC11. adhere to storage and handling guidelines for hazardous material

PC12. identify and correct any hazards that one can deal with safely, competently and within the limits of authority

PC13. record the details of completed safety drills and training

Follow emergency procedures

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

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/N0265: Maintain compliance with current Good Manufacturing Practices (cGMP) and other regulations

Description

This NOS unit is about maintaining compliance with current Good Manufacturing Practices (cGMP) and other regulations

Scope

The scope covers the following :

- GMP compliance in production process
- GMP compliance in waste management
- GMP compliance in machine maintenance
- GMP compliance in documentation
- Environment sustainability

Elements and Performance Criteria

GMP compliance in production process

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

PC1. perform the cleaning of machine in compliance with cGMP guidelines and SOP

PC2. monitor environmental conditions in production area as per SOP and cGMP guidelines

PC3. perform and record pre-production checks, job safety analysis

PC4. ensure adherence to Good Manufacturing Practices related to equipment operations

PC5. perform the specific in-process production checks as directed in SOPs

PC6. comply with the appropriate cGMP rules for the batch change over procedure

GMP Compliance in waste management

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

PC7. comply with the appropriate environmental rules and organizational SOP for the waste management and disposal

PC8. perform waste segregation and generate record for the same

PC9. perform waste disposal under supervision and ensure Effluent treatment and solvent recycling procedures under supervision

GMP compliance in equipment maintenance

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

PC10. perform the general routine maintenance of equipment and maintain semi-automated and automated plant equipment and troubleshoot of machine as per schedule

PC11. perform the calibration of equipment under supervision as per SOP

GMP compliance in documentation

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

PC12. adhere to ALCOA principles during documentation of the activities performed

PC13. secure authorization and approval in writing from competent authorities in quality assurance and production team before start of any production activity

PC14. ensure Audit trail of every document generated by oneself

PC15. ensure that only authorized user ID is used to enter the record entries in an automated system

PC16. file deviation in case of non adherence of Good Documentation Practices and SOPs and notify supervisor / manager

PC17. correct the wrong entries, using ALCOA principles

PC18. perform electronic record generation only after checking validation and calibration tag on the equipment panel/ computer

Environment Sustainability

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

PC19. ensure energy conservation by switching off the machine and equipment post operations

PC20. identify ways to optimize the usage of electricity/energy in various tasks/activities/processes

PC21. ensure energy conservation by optimizing the machine/ equipment performance

PC22. apply environment-friendly methods given in SOPs for waste disposal

PC23. ensure no leakage of water in the plant

PC24. follow organizational environment sustainability guidelines and procedures to achieve energy and water conservation as well as zero pollution.

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. organizational SOPs relevant to machine operations and production processes

KU2. SOP for entry and exit from GMP area

KU3. rules of WHO and ICH-GMP relevant to roles and responsibility of Machine Operator

KU4. Good Manufacturing Practices, Good Storage Practices, Good Documentation Practices

KU5. machine operation manual and troubleshooting of the machines available in assigned section

KU6. procedures for documentation, reporting and escalation

KU7. basics of ALCOA Principles, data integrity and information security rules

KU8. methods to conserve water and energy

KU9. methods to minimize the pollution

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

GS2. use reading and comprehension skills to read the various coding systems, instructions, guidelines, procedures, rules, and signages

GS3. use listening skills to interpret the instructions, escalation matrix, procedures to be followed and to seek clarifications

GS4. use verbal communication skills to interact with teammates, supervisor, production chemist, and cross-functional teams

GS5. use team-building skills while dealing with teammates

GS6. apply problem-solving skills to find solutions for deviations found during process-related checks, non-conformities in standards and labeling

GS7. apply critical thinking skills to analyze and identify when to report an issue/concern to the supervisor and when to deal with a process error individually, depending on the type of concern

GS8. apply customer centricity to remain compliant with data integrity rules, cGMP/GLP guidelines and to evaluate impact of wrongdoings

GS9. apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
GMP compliance in production process	**7**	**8**	**5**	**5**
PC1. perform the cleaning of machine in compliance with cGMP guidelines and SOP	-	-	-	-
PC2. monitor environmental conditions in production area as per SOP and cGMP guidelines	-	-	-	-
PC3. perform and record pre-production checks, job safety analysis	-	-	-	-
PC4. ensure adherence to Good Manufacturing Practices related to equipment operations	-	-	-	-
PC5. perform the specific in-process production checks as directed in SOPs	-	-	-	-
PC6. comply with the appropriate cGMP rules for the batch change over procedure	-	-	-	-
GMP Compliance in waste management	**5**	**7**	**5**	**3**
PC7. comply with the appropriate environmental rules and organizational SOP for the waste management and disposal	-	-	-	-
PC8. perform waste segregation and generate record for the same	-	-	-	-
PC9. perform waste disposal under supervision and ensure Effluent treatment and solvent recycling procedures under supervision	-	-	-	-
GMP compliance in equipment maintenance	**7**	**8**	**5**	**5**
PC10. perform the general routine maintenance of equipment and maintain semi-automated and automated plant equipment and troubleshoot of machine as per schedule	-	-	-	-
PC11. perform the calibration of equipment under supervision as per SOP	-	-	-	-
GMP compliance in documentation	**7**	**8**	**5**	**5**

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. adhere to ALCOA principles during documentation of the activities performed	-	-	-	-
PC13. secure authorization and approval in writing from competent authorities in quality assurance and production team before start of any production activity	-	-	-	-
PC14. ensure Audit trail of every document generated by oneself	-	-	-	-
PC15. ensure that only authorized user ID is used to enter the record entries in an automated system	-	-	-	-
PC16. file deviation in case of non adherence of Good Documentation Practices and SOPs and notify supervisor / manager	-	-	-	-
PC17. correct the wrong entries, using ALCOA principles	-	-	-	-
PC18. perform electronic record generation only after checking validation and calibration tag on the equipment panel/ computer	-	-	-	-
Environment Sustainability	**1**	**2**	**1**	**1**
PC19. ensure energy conservation by switching off the machine and equipment post operations	-	-	-	-
PC20. identify ways to optimize the usage of electricity/energy in various tasks/activities/processes	-	-	-	-
PC21. ensure energy conservation by optimizing the machine/ equipment performance	-	-	-	-
PC22. apply environment-friendly methods given in SOPs for waste disposal	-	-	-	-
PC23. ensure no leakage of water in the plant	-	-	-	-
PC24. follow organizational environment sustainability guidelines and procedures to achieve energy and water conservation as well as zero pollution.	-	-	-	-
NOS Total	**27**	**33**	**21**	**19**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0265
NOS Name	Maintain compliance with current Good Manufacturing Practices (cGMP) and other regulations
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Manufacturing
NSQF Level	4
Credits	4.00
Version	3.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024

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

PC16. ensure that, on completion of the work, the area is left clean and dry and meets WHO and cGMP requirements of sanitized premises

PC17. place the trolley, equipment, materials and personal protective equipment at the designated place after use, ensuring they are clean and securely stored

PC18. dispose of the waste garnered from the activity as per SOP

PC19. dispose of used and un-used solutions according to manufacturer's instructions, and clean the equipment thoroughly

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. levels of hygiene required by production area and the importance of maintaining the same

KU2. methodology for production area inspection with methods and materials required for cleaning a variety of surfaces and equipment

KU3. the method to check the treated surface and equipment on completion of cleaning

KU4. procedures for reporting any unidentified soiling or any deviation for cleaning validation

KU5. role of different materials, chemicals, and equipment in cleaning and sanitation of production area

KU6. current Good Manufacturing Practices (cGMP) and WHO guidelines for cleaning/ sanitation activity and maintaining hygiene

KU7. cleaning validation process

KU8. waste disposal guidelines as per WHO and cGMP and relevant organizational SOPs

Generic Skills (GS)

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

GS1. use written communication skills to record and communicate details of work done to appropriate people using written/typed report and electronic mail

GS2. use verbal communication skills to communicate with supervisor, cross-functional teams and auditors effectively

GS3. use critical thinking skills to interpret the various coding systems as per company norms and in identifying the non-compliance while performing the area inspection

GS4. apply customer centricity at work

GS5. apply problem-solving and decision making while dealing with any deviation

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
sanitation activities before starting the work	**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	-	-	-	-
Sanitation activities during work	**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	-	-	-	-
Sanitation activities after completion of work	**10**	**10**	**5**	**5**

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 cGMP requirements of sanitized premises	-	-	-	-
PC17. place the trolley, equipment, materials and personal protective equipment at the designated place after use, ensuring they are clean and securely stored	-	-	-	-
PC18. dispose of the waste garnered from the activity as per SOP	-	-	-	-
PC19. dispose of used and un-used solutions according to manufacturer’s instructions, and clean the equipment thoroughly	-	-	-	-
NOS Total	**30**	**40**	**15**	**15**

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	3.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024

LFS/N0104: Coordinate and communicate with Supervisor/ production chemist, teams and auditors

Description

This NOS unit is about coordinating with supervisor/ production chemist, teams, and auditors.

Scope

The scope covers the following :

- Coordination with supervisor/ production chemist
- Coordination with cross-functional teams
- Coordination with auditors
- Sensitivity towards all genders and people with disability

Elements and Performance Criteria

Coordination with Supervisor / production chemist

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

PC1. work as per instructions given by reporting supervisor

PC2. seek guidance/advice from supervisor on production plan for meeting the timelines

PC3. communicate process-flow improvements, production defects received from the previous process, repairs and maintenance of equipment to reporting supervisor/ production chemist

PC4. ensure timely intimation to supervisor/ production chemist about planned absence/ illness/ dizziness during work/ critical issues requiring his/her intervention

PC5. coordinate with supervisor on work-related and behavioral feedback

Coordination with cross-functional teams

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

PC6. support team members and colleagues of other departments in work

PC7. take handover from previous shift operator and give handover to next shift operator as per SOP

PC8. guide manufacturing and packaging assistants during production process

PC9. coordinate with warehouse team for material dispensing and issuance

PC10. coordinate with maintenance team for preventive and corrective maintenance, break down and calibration errors

PC11. coordinate with quality control team for sample collection and batch release

PC12. coordinate with QA for machine/ equipment validation at a routine interval as per SOP

PC13. provide inputs to the concerned stakeholders in periodic fence line review to detect non-compliance

PC14. coordinate with EHS team for any safety incident, accident and emergency

Coordination with auditors

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

PC15. provide clear answers to the auditor's queries

PC16. provide the required documents of performed activities and operations to auditors on time

PC17. maintain data integrity while responding to auditors and regulatory inspectors

Sensitivity towards all genders and people with disability

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

PC18. respect all genders, religions, and caste

PC19. empathize with people with disability

PC20. offer support or help to a person with disability only when asked

PC21. Adhere to the guidelines laid in POSH Act

PC22. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. the company's policies on the preferred language of communication, reporting and escalation policy

KU2. the reporting structure of the organization

KU3. types of audits in the life sciences sector for the manufacturing operations

KU4. the required regulatory and statutory compliance-related documentation

KU5. the guidelines for data integrity, ethics, and compliance in the life sciences industry

KU6. the guidelines laid on Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act

KU7. the methods of workplace communication

KU8. importance of team coordination

KU9. the types of possible disabilities among people with disability (PwD)

KU10. the challenges faced by PwD

KU11. the importance of displaying empathy towards PwD

KU12. the right way to use the laws, acts, and provisions defined for PwD by the statutory bodies

KU13. the importance of awareness for gender sensitization and prevention of sexual harassment (POSH) act

KU14. importance of respecting all gender identities, religion, caste, and culture

KU15. method to receive the performance feedback

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 record and communicate details of work done to appropriate stakeholders by using written or computer-based record/ electronic mail in a given format and compliant with ALCOA principle

GS3. use verbal communication skills to communicate confidential and sensitive information discretely to the authorized person while interacting with teammates

GS4. use team-building skills during the interaction with teammates while managing the difficult/stressful or emotional situations at work

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. apply customer-centricity skills while responding to auditors and QA personnel

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Coordination with Supervisor / production chemist	**10**	**10**	**5**	**5**
PC1. work as per instructions given by reporting supervisor	-	-	-	-
PC2. seek guidance/advice from supervisor on production plan for meeting the timelines	-	-	-	-
PC3. communicate process-flow improvements, production defects received from the previous process, repairs and maintenance of equipment to reporting supervisor/ production chemist	-	-	-	-
PC4. ensure timely intimation to supervisor/ production chemist about planned absence/ illness/ dizziness during work/ critical issues requiring his/her intervention	-	-	-	-
PC5. coordinate with supervisor on work-related and behavioral feedback	-	-	-	-
Coordination with cross-functional teams	**10**	**10**	**5**	**5**
PC6. support team members and colleagues of other departments in work	-	-	-	-
PC7. take handover from previous shift operator and give handover to next shift operator as per SOP	-	-	-	-
PC8. guide manufacturing and packaging assistants during production process	-	-	-	-
PC9. coordinate with warehouse team for material dispensing and issuance	-	-	-	-
PC10. coordinate with maintenance team for preventive and corrective maintenance, break down and calibration errors	-	-	-	-
PC11. coordinate with quality control team for sample collection and batch release	-	-	-	-
PC12. coordinate with QA for machine/ equipment validation at a routine interval as per SOP	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC13. provide inputs to the concerned stakeholders in periodic fence line review to detect non-compliance	-	-	-	-
PC14. coordinate with EHS team for any safety incident, accident and emergency	-	-	-	-
Coordination with auditors	**10**	**10**	**5**	**5**
PC15. provide clear answers to the auditor's queries	-	-	-	-
PC16. provide the required documents of performed activities and operations to auditors on time	-	-	-	-
PC17. maintain data integrity while responding to auditors and regulatory inspectors	-	-	-	-
Sensitivity towards all genders and people with disability	**3**	**3**	**2**	**2**
PC18. respect all genders, religions, and caste	-	-	-	-
PC19. empathize with people with disability	-	-	-	-
PC20. offer support or help to a person with disability only when asked	-	-	-	-
PC21. Adhere to the guidelines laid in POSH Act	-	-	-	-
PC22. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee	-	-	-	-
NOS Total	**33**	**33**	**17**	**17**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0104
NOS Name	Coordinate and communicate with Supervisor/ production chemist, teams and auditors
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

Qualification Pack

DGT/VSQ/N0102: Employability Skills (60 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. identify employability skills required for jobs in various industries

PC2. identify and explore learning and employability portals

Constitutional values – Citizenship

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

PC3. 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.

PC4. follow environmentally sustainable practices

Becoming a Professional in the 21st Century

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

PC5. recognize the significance of 21st Century Skills for employment

PC6. 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

Basic English Skills

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

PC7. use basic English for everyday conversation in different contexts, in person and over the telephone

PC8. read and understand routine information, notes, instructions, mails, letters etc. written in English

PC9. 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:

PC10. understand the difference between job and career

PC11. prepare a career development plan with short- and long-term goals, based on aptitude

Communication Skills

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

PC12. follow verbal and non-verbal communication etiquette and active listening techniques in various settings

PC13. work collaboratively with others in a team

Diversity & Inclusion

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

PC14. communicate and behave appropriately with all genders and PwD

PC15. 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:

PC16. select financial institutions, products and services as per requirement

PC17. carry out offline and online financial transactions, safely and securely

PC18. identify common components of salary and compute income, expenses, taxes, investments etc

PC19. 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:

PC20. operate digital devices and carry out basic internet operations securely and safely

PC21. use e- mail and social media platforms and virtual collaboration tools to work effectively

PC22. use basic features of word processor, spreadsheets, and presentations

Entrepreneurship

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

PC23. identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research

PC24. develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion

PC25. 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:

PC26. identify different types of customers

PC27. identify and respond to customer requests and needs in a professional manner.

PC28. follow appropriate hygiene and grooming standards

Getting ready for apprenticeship & Jobs

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

PC29. create a professional Curriculum vitae (Résumé)

PC30. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively

PC31. apply to identified job openings using offline /online methods as per requirement

PC32. answer questions politely, with clarity and confidence, during recruitment and selection

PC33. 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

KU11. 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 and use applications such as word processors, spreadsheets etc.

KU16. how to identify business opportunities

KU17. types and needs of customers

KU18. how to apply for a job and prepare for an interview

KU19. 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

GS2. communicate effectively using appropriate language in formal and informal settings

GS3. behave politely and appropriately with all
GS4. how to work in a virtual mode
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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Introduction to Employability Skills	**1**	**1**	**-**	**-**
PC1. identify employability skills required for jobs in various industries	-	-	-	-
PC2. identify and explore learning and employability portals	-	-	-	-
Constitutional values – Citizenship	**1**	**1**	**-**	**-**
PC3. 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.	-	-	-	-
PC4. follow environmentally sustainable practices	-	-	-	-
Becoming a Professional in the 21st Century	**2**	**4**	**-**	**-**
PC5. recognize the significance of 21st Century Skills for employment	-	-	-	-
PC6. 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	-	-	-	-
Basic English Skills	**2**	**3**	**-**	**-**
PC7. use basic English for everyday conversation in different contexts, in person and over the telephone	-	-	-	-
PC8. read and understand routine information, notes, instructions, mails, letters etc. written in English	-	-	-	-
PC9. write short messages, notes, letters, e-mails etc. in English	-	-	-	-
Career Development & Goal Setting	**1**	**2**	**-**	**-**

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC10. understand the difference between job and career	-	-	-	-
PC11. prepare a career development plan with short- and long-term goals, based on aptitude	-	-	-	-
Communication Skills	**2**	**2**	**-**	**-**
PC12. follow verbal and non-verbal communication etiquette and active listening techniques in various settings	-	-	-	-
PC13. work collaboratively with others in a team	-	-	-	-
Diversity & Inclusion	**1**	**2**	**-**	**-**
PC14. communicate and behave appropriately with all genders and PwD	-	-	-	-
PC15. escalate any issues related to sexual harassment at workplace according to POSH Act	-	-	-	-
Financial and Legal Literacy	**2**	**3**	**-**	**-**
PC16. select financial institutions, products and services as per requirement	-	-	-	-
PC17. carry out offline and online financial transactions, safely and securely	-	-	-	-
PC18. identify common components of salary and compute income, expenses, taxes, investments etc	-	-	-	-
PC19. identify relevant rights and laws and use legal aids to fight against legal exploitation	-	-	-	-
Essential Digital Skills	**3**	**4**	**-**	**-**
PC20. operate digital devices and carry out basic internet operations securely and safely	-	-	-	-
PC21. use e- mail and social media platforms and virtual collaboration tools to work effectively	-	-	-	-
PC22. use basic features of word processor, spreadsheets, and presentations	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Entrepreneurship	**2**	**3**	**-**	**-**
PC23. identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research	-	-	-	-
PC24. develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion	-	-	-	-
PC25. identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity	-	-	-	-
Customer Service	**1**	**2**	**-**	**-**
PC26. identify different types of customers	-	-	-	-
PC27. identify and respond to customer requests and needs in a professional manner.	-	-	-	-
PC28. follow appropriate hygiene and grooming standards	-	-	-	-
Getting ready for apprenticeship & Jobs	**2**	**3**	**-**	**-**
PC29. create a professional Curriculum vitae (Résumé)	-	-	-	-
PC30. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively	-	-	-	-
PC31. apply to identified job openings using offline /online methods as per requirement	-	-	-	-
PC32. answer questions politely, with clarity and confidence, during recruitment and selection	-	-	-	-
PC33. 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/N0102
NOS Name	Employability Skills (60 Hours)
Sector	Cross Sectoral
Sub-Sector	Professional Skills
Occupation	Employability
NSQF Level	4
Credits	2
Version	1.0
Last Reviewed Date	07/10/2025
Next Review Date	07/10/2028
NSQC Clearance Date	07/10/2025

Qualification Pack

LFS/N0214: Perform non- sterile bulk drug /API manufacturing operations

Description

This NOS unit is about an equipment Operator performing non-sterile bulk drug / API manufacturing operations

Scope

The scope covers the following :

- Perform manufacturing operations
- In-process checks
- Reporting and escalation of deviations
- Documentation
- Post-production critical activities

Elements and Performance Criteria

Perform manufacturing operations

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

PC1. perform sanitization and gowning procedures as per cleanroom guidelines

PC2. wear personal protective equipment(PPE) before entering into the production area

PC3. ensure side equipment is in closed condition while charging/ loading material

PC4. charge the reactors with raw materials(RM) in the correct pattern as per the batch manufacturing record (BMR) to minimize material overflow/wastage/excess flash/spill

PC5. operate reactor and utilities (Steam/water for pharmaceutical use (WPU)/water for injections (WFI) /distilled water (DW)/ Gases) as per BMR and standard operating procedure (SOP)

PC6. maintain critical process parameters of reactor and utility systems as per BMR

PC7. monitor reactor and utility systems during every procedure to ensure optimum performance

In-process checks

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

PC8. perform a total range of in-process checks specified in BMR to ensure that the intermediate/final product coming out from the process manufacturing meets the specifications

PC9. use appropriate measuring instruments, equipment, tools, accessories, etc. as required for carrying out in-process checks

Reporting and escalation of deviations

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

PC10. identify non-conformities to quality assurance standards and product specifications

PC11. identify potential causes of non-conformities to quality assurance standards with the help of supervisor/ production chemist

PC12. report and escalate the deviations as per the escalation matrix and SOP

PC13. implement the corrective and preventive actions as guided by the production chemist and quality assurance team

Documentation

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

PC14. perform concurrent documentation as per SOP

PC15. ensure adherence to data integrity

PC16. maintain both electronic and manual records in the logbooks and other documentation required as per GMP and GDP like – breakdown time, daily manufacturing record, yield report, equipment log book, etc

Post-production critical activities

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

PC17. carry out status labelling and segregation of material/ intermediate / finished goods as per SOPs

PC18. label finished goods containers of non- sterile API in compliance to regulatory guidelines

PC19. segregate batchwise packaged and sealed non-sterile containers on pallets for storage and transportation in the warehouse

PC20. provide support for line clearance before the next batch of non-sterile API is produced and packaged

PC21. handover the work/ equipment to colleague in the next shift in adherence of the shift schedule

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. clean room behavior practices and gowning procedures

KU2. SOP for entry and exit from GMP area

KU3. PPE used in API manufacturing and their work instructions

KU4. material, segregation, handling, and storage guidelines for API production

KU5. type of reactors for non sterile API/ bulk drug manufacturing, their operating process, and critical parameters

KU6. manufacturing process of Water for Pharma Use (WPU)

KU7. in process checks for non sterile API/ bulk drug manufacturing

KU8. labelling guidelines as per cGMP

KU9. procedures for documentation, reporting, and escalation of incidents and deviations

KU10. procedure for generating electronic records

KU11. ALCOA Principles, data integrity, and information security rules

KU12. procedure for line clearance

KU13. procedure for handover and takeover

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 performed in manufacturing operations 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 in analyzing the impact of deviations, wastage, and rejects to the environment and efficiency, compliance and cost

GS8. apply decision making while making necessary adjustments in parameters to achieve quality specifications

GS9. apply customer-centricity while responding to auditors and QA personnel

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Perform manufacturing operations	**8**	**12**	**8**	**12**
PC1. perform sanitization and gowning procedures as per cleanroom guidelines	-	-	-	-
PC2. wear personal protective equipment(PPE) before entering into the production area	-	-	-	-
PC3. ensure side equipment is in closed condition while charging/ loading material	-	-	-	-
PC4. charge the reactors with raw materials(RM) in the correct pattern as per the batch manufacturing record (BMR) to minimize material overflow/wastage/excess flash/spill	-	-	-	-
PC5. operate reactor and utilities (Steam/water for pharmaceutical use (WPU)/water for injections (WFI) /distilled water (DW)/ Gases) as per BMR and standard operating procedure (SOP)	-	-	-	-
PC6. maintain critical process parameters of reactor and utility systems as per BMR	-	-	-	-
PC7. monitor reactor and utility systems during every procedure to ensure optimum performance	-	-	-	-
In-process checks	**2**	**3**	**2**	**3**
PC8. perform a total range of in-process checks specified in BMR to ensure that the intermediate/final product coming out from the process manufacturing meets the specifications	-	-	-	-
PC9. use appropriate measuring instruments, equipment, tools, accessories, etc. as required for carrying out in-process checks	-	-	-	-
Reporting and escalation of deviations	**2**	**3**	**2**	**3**
PC10. identify non-conformities to quality assurance standards and product specifications	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC11. identify potential causes of non-conformities to quality assurance standards with the help of supervisor/ production chemist	-	-	-	-
PC12. report and escalate the deviations as per the escalation matrix and SOP	-	-	-	-
PC13. implement the corrective and preventive actions as guided by the production chemist and quality assurance team	-	-	-	-
Documentation	**4**	**6**	**4**	**6**
PC14. perform concurrent documentation as per SOP	-	-	-	-
PC15. ensure adherence to data integrity	-	-	-	-
PC16. maintain both electronic and manual records in the logbooks and other documentation required as per GMP and GDP like – breakdown time, daily manufacturing record, yield report, equipment log book, etc	-	-	-	-
Post-production critical activities	**4**	**6**	**4**	**6**
PC17. carry out status labelling and segregation of material/ intermediate / finished goods as per SOPs	-	-	-	-
PC18. label finished goods containers of non- sterile API in compliance to regulatory guidelines	-	-	-	-
PC19. segregate batchwise packaged and sealed non-sterile containers on pallets for storage and transportation in the warehouse	-	-	-	-
PC20. provide support for line clearance before the next batch of non-sterile API is produced and packaged	-	-	-	-
PC21. handover the work/ equipment to colleague in the next shift in adherence of the shift schedule	-	-	-	-
NOS Total	**20**	**30**	**20**	**30**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0214
NOS Name	Perform non- sterile bulk drug /API manufacturing operations
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Manufacturing
NSQF Level	4
Credits	3.00
Version	5.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024

LFS/N0266: Perform primary packaging operations for Non-sterile Bulk Drug / API

Description

This NOS unit is about an operator performing primary packaging operations of non-sterile Bulk Drug/ API

Scope

The scope covers the following :

- Perform primary packaging
- In process checks
- Reporting and escalation of deviation
- Documentation
- Post-packaging activities

Elements and Performance Criteria

Perform Primary Packaging

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

PC1. perform sanitization and gowning procedures as per clean room guidelines

PC2. wear personal protective equipment (PPE)before entering into the production area

PC3. ensure availability of QA approved bulk drug containers and closures

PC4. charge the finished goods in the filling line with care to minimize material overflow/ wastage/ excess flash/ spill

PC5. operate filling and packaging line in the correct pattern as per the SOP

PC6. maintain critical process parameters of packaging line and automatic 2D printing and labelling machines as per the SOP

PC7. monitor filling, packaging, printing and labeling machines during every procedure to ensure optimum performance

PC8. minimize waste/ rejections during entire packaging operation

In-process checks

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

PC9. perform total range of in-process checks specified for bulk drug/ API packaging

PC10. use appropriate measuring instruments, equipment, tools for carrying out in-process checks

PC11. confirm that packaged containers meet the specifications for packaging, storage conditions and labelling

Reporting and escalation of deviations

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

PC12. identify non-conformities to quality assurance standards for packaging specifications

PC13. identify potential causes of non-conformities to quality assurance standards with the help of supervisor/ production chemist

PC14. report and escalate the deviations as per escalation matrix

PC15. implement the corrective and preventive actions as guided by the production chemist and quality assurance team

Documentation

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

PC16. identify documentation to be completed as per SOP and cGMP rules

PC17. record the required information of all significant activities, incidents and deviations as per recording formats in compliance with SOP and cGMP guidelines

PC18. perform concurrent documentation

PC19. maintain both electronic and manual records in the log books and other documentation required as per cGMP and GDP like – breakdown time, daily manufacturing record, yield report, etc.

PC20. update the equipment log books , status boards and ensure they are in line with the process

Post-packaging activities

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

PC21. segregate batch wise packaged and sealed non-sterile API containers on pallets for storage and transportation in warehouse

PC22. segregate packaging waste and perform disposal under supervision

PC23. provide support for line clearance before the next batch of non-sterile API is processed for packaging

PC24. handover the work/ equipment to colleague in next shift in adherence to the shift schedule

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. the organizational coding system for packaging material

KU2. the basic principle of the packaging process and its functions

KU3. types of packaging process

KU4. different types of machine used in the packaging process and their applications

KU5. quality requirements of materials and the effect of variation on process performance

KU6. different types of labels

KU7. GMP guidelines

KU8. batch packaging records (BPR)

KU9. in-process checks during packaging

KU10. the common causes of variation and corrective action required

KU11. the safety measures taken during waste disposal

KU12. principles of ALCOA

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 performed in packaging operations 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 in analyzing the impact of deviations, wastage, and rejects to the environment and efficiency, compliance and cost

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Perform Primary Packaging	**8**	**12**	**8**	**12**
PC1. perform sanitization and gowning procedures as per clean room guidelines	-	-	-	-
PC2. wear personal protective equipment (PPE)before entering into the production area	-	-	-	-
PC3. ensure availability of QA approved bulk drug containers and closures	-	-	-	-
PC4. charge the finished goods in the filling line with care to minimize material overflow/ wastage/ excess flash/ spill	-	-	-	-
PC5. operate filling and packaging line in the correct pattern as per the SOP	-	-	-	-
PC6. maintain critical process parameters of packaging line and automatic 2D printing and labelling machines as per the SOP	-	-	-	-
PC7. monitor filling, packaging, printing and labeling machines during every procedure to ensure optimum performance	-	-	-	-
PC8. minimize waste/ rejections during entire packaging operation	-	-	-	-
In-process checks	**2**	**3**	**2**	**3**
PC9. perform total range of in-process checks specified for bulk drug/ API packaging	-	-	-	-
PC10. use appropriate measuring instruments, equipment, tools for carrying out in-process checks	-	-	-	-
PC11. confirm that packaged containers meet the specifications for packaging, storage conditions and labelling	-	-	-	-
Reporting and escalation of deviations	**2**	**3**	**2**	**3**

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. identify non-conformities to quality assurance standards for packaging specifications	-	-	-	-
PC13. identify potential causes of non-conformities to quality assurance standards with the help of supervisor/ production chemist	-	-	-	-
PC14. report and escalate the deviations as per escalation matrix	-	-	-	-
PC15. implement the corrective and preventive actions as guided by the production chemist and quality assurance team	-	-	-	-
Documentation	**4**	**6**	**4**	**6**
PC16. identify documentation to be completed as per SOP and cGMP rules	-	-	-	-
PC17. record the required information of all significant activities, incidents and deviations as per recording formats in compliance with SOP and cGMP guidelines	-	-	-	-
PC18. perform concurrent documentation	-	-	-	-
PC19. maintain both electronic and manual records in the log books and other documentation required as per cGMP and GDP like – breakdown time, daily manufacturing record, yield report, etc.	-	-	-	-
PC20. update the equipment log books , status boards and ensure they are in line with the process	-	-	-	-
Post-packaging activities	**4**	**6**	**4**	**6**
PC21. segregate batch wise packaged and sealed non-sterile API containers on pallets for storage and transportation in warehouse	-	-	-	-
PC22. segregate packaging waste and perform disposal under supervision	-	-	-	-
PC23. provide support for line clearance before the next batch of non-sterile API is processed for packaging	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC24. handover the work/ equipment to colleague in next shift in adherence to the shift schedule	-	-	-	-
NOS Total	**20**	**30**	**20**	**30**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0266
NOS Name	Perform primary packaging operations for Non-sterile Bulk Drug / API
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Manufacturing
NSQF Level	4
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/N0267: Perform sterile Bulk drug API/ manufacturing and primary packaging operations

Description

This NOS unit is about machine operator performing Sterile Bulk Drug / API manufacturing and primary packaging operations

Scope

The scope covers the following :

- Maintain aseptic conditions
- Perform aseptic manufacturing and primary packaging
- Reporting and escalation of deviations
- Documentation
- Post-production critical activities

Elements and Performance Criteria

Maintain aseptic conditions

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

PC1. wear personal protective equipment (PPE) before entering into the production area as per SOP

PC2. perform sanitization and sterilization as per clean room guidelines

PC3. inspect in-line equipment/ balance as per the SOP

PC4. start the equipment safely and ensure cleaning-in-place (CIP) and sterilization-in-place (SIP) are done

PC5. perform cleaning validation under supervision

PC6. maintain aseptic conditions and clean room parameters in the classified area to avoid cross contamination

Perform aseptic manufacturing and primary packaging

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

PC7. identify approved labeled Raw Materials(RM) and handle appropriately to avoid contamination

PC8. charge the reactors with RM in the correct pattern as per the Batch Manufacturing Record (BMR) to minimize material overflow/wastage/excess flash/spill

PC9. operate reactor and utilities (Steam/Water for Pharmaceutical Use (WPU)/Water for Injections (WFI) /Distilled Water (DW)/ Gases) as per BMR and Standard Operating Procedure (SOP)

PC10. maintain critical process parameters of reactor and utility systems as per BMR

PC11. perform a total range of in-process checks specified in BMR to ensure that the intermediate/final product coming out from the process manufacturing meets the specifications

PC12. perform sterilization process of final product

PC13. perform filling and containerization process using QA approved sterilized containers and closures

Reporting and escalation of deviations

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

PC14. identify non-conformities to quality assurance standards and product specifications

PC15. identify potential causes of non-conformities to quality assurance standards with the help of supervisor/ production chemist/ biologist

PC16. report and escalate the deviations as per the escalation matrix and SOP

PC17. implement the corrective and preventive actions as guided by the production chemist/ biologist and quality assurance team

Documentation

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

PC18. perform concurrent documentation as per BMR and SOP

PC19. ensure adherence to data integrity

PC20. maintain both electronic and manual records in the log books and other documentation required as per GMP and GDP like – breakdown time, daily manufacturing record, yield report, equipment log book etc.

Post-production critical activities

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

PC21. carry out status labelling and segregation of material/ intermediate/ finished goods of sterile API as per SOPs

PC22. label finished goods containers of sterile API in compliance with regulatory guidelines

PC23. segggregate batchwise packaged and sealed sterile API containers on pallets for storage and transportation in warehouse

PC24. segggregate waste and perform disposal under supervison

PC25. provide support for line clearance before the next batch of sterile API is produced and packaged

PC26. handover the work/ equipment to colleague in next shift in adherence of the shift schedule

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. clean room behavior practices and gowning procedures for aseptic manufacturing

KU2. SOP for entry and exit from GMP area

KU3. PPE used in sterile API manufacturing and their work instructions

KU4. material segregation, handling, and storage guidelines for sterile drugs

KU5. types of reactors for sterile API/ Bulk drug manufacturing, their operating process and critical parameters

KU6. manufacturing process of Water for Pharma Use (WPU)/ Water for injections (WFI) / Distilled Water (DW)

KU7. utilities in Sterile API/ Bulk drug manufacturing plant

KU8. in-process checks for Sterile API/ Bulk drug manufacturing

KU9. labelling guidelines as per cGMP
KU10. procedures for documentation, reporting and escalation of incidents and deviations
KU11. procedure for generating electronic records
KU12. basics of ALCOA principles, data integrity and information security rules
KU13. procedure for line clearance
KU14. procedure for handover and takeover
KU15. procedure of CIP and SIP
KU16. procedure for sterilization of material, drug products and equiment
KU17. primary packaging guidelines for sterile bulk drug products

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 performed in manufacturing operations 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 in analyzing impact of deviations, wastage and rejects to the environment and efficiency, complianc and cost
GS8. apply decision making while making necessary adjustments in parameters to achieve quality specifications
GS9. apply customer-centricity while responding to auditors and QA personnel

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Maintain aseptic conditions	**2**	**3**	**2**	**3**
PC1. wear personal protective equipment (PPE) before entering into the production area as per SOP	-	-	-	-
PC2. perform sanitization and sterilization as per clean room guidelines	-	-	-	-
PC3. inspect in-line equipment/ balance as per the SOP	-	-	-	-
PC4. start the equipment safely and ensure cleaning-in-place (CIP) and sterilization-in-place (SIP) are done	-	-	-	-
PC5. perform cleaning validation under supervision	-	-	-	-
PC6. maintain aseptic conditions and clean room parameters in the classified area to avoid cross contamination	-	-	-	-
Perform aseptic manufacturing and primary packaging	**8**	**12**	**8**	**12**
PC7. identify approved labeled Raw Materials(RM) and handle appropriately to avoid contamination	-	-	-	-
PC8. charge the reactors with RM in the correct pattern as per the Batch Manufacturing Record (BMR) to minimize material overflow/wastage/excess flash/spill	-	-	-	-
PC9. operate reactor and utilities (Steam/Water for Pharmaceutical Use (WPU)/Water for Injections (WFI) /Distilled Water (DW)/ Gases) as per BMR and Standard Operating Procedure (SOP)	-	-	-	-
PC10. maintain critical process parameters of reactor and utility systems as per BMR	-	-	-	-
PC11. perform a total range of in-process checks specified in BMR to ensure that the intermediate/final product coming out from the process manufacturing meets the specifications	-	-	-	-
PC12. perform sterilization process of final product	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC13. perform filling and containerization process using QA approved sterilized containers and closures	-	-	-	-
Reporting and escalation of deviations	**2**	**3**	**2**	**3**
PC14. identify non-conformities to quality assurance standards and product specifications	-	-	-	-
PC15. identify potential causes of non-conformities to quality assurance standards with the help of supervisor/ production chemist/ biologist	-	-	-	-
PC16. report and escalate the deviations as per the escalation matrix and SOP	-	-	-	-
PC17. implement the corrective and preventive actions as guided by the production chemist/ biologist and quality assurance team	-	-	-	-
Documentation	**4**	**6**	**4**	**6**
PC18. perform concurrent documentation as per BMR and SOP	-	-	-	-
PC19. ensure adherence to data integrity	-	-	-	-
PC20. maintain both electronic and manual records in the log books and other documentation required as per GMP and GDP like – breakdown time, daily manufacturing record, yield report, equipment log book etc.	-	-	-	-
Post-production critical activities	**4**	**6**	**4**	**6**
PC21. carry out status labelling and segregation of material/ intermediate/ finished goods of sterile API as per SOPs	-	-	-	-
PC22. label finished goods containers of sterile API in compliance with regulatory guidelines	-	-	-	-
PC23. segggregate batchwise packaged and sealed sterile API containers on pallets for storage and transportation in warehouse	-	-	-	-
PC24. segggregate waste and perform disposal under supervison	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC25. provide support for line clearance before the next batch of sterile API is produced and packaged	-	-	-	-
PC26. handover the work/ equipment to colleague in next shift in adherence of the shift schedule	-	-	-	-
NOS Total	**20**	**30**	**20**	**30**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0267
NOS Name	Perform sterile Bulk drug API/ manufacturing and primary packaging operations
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Manufacturing
NSQF Level	4
Credits	3.00
Version	3.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024

Assessment Guidelines and Assessment Weightage

Assessment Guidelines

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

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

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

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

5. LSSSDC as 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.

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/N0274.Discuss about Life Sciences Industry and Basics of manufacturing Operations	40	30	15	15	100	5
LFS/N0213.Perform pre-production checks and prepare Equipment for bulk drug production	21	32	17	30	100	10
LFS/N0112.Adherence to Environment, health and safety guidelines in a production facility and GMP controlled area	30	40	15	15	100	20
LFS/N0265.Maintain compliance with current Good Manufacturing Practices (cGMP) and other regulations	27	33	21	19	100	10
LFS/N0113.Ensure a hygienic and clean work area to avoid contamination	30	40	15	15	100	10

Qualification Pack

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0104.Coordinate and communicate with Supervisor/ production chemist, teams and auditors	33	33	17	17	100	10
DGT/VSQ/N0102.Employability Skills (60 Hours)	20	30	-	-	50	5
Total	**201**	**238**	**100**	**111**	**650**	**70**

Elective: 1 Non Sterile Manufacturing

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0214.Perform non-sterile bulk drug /API manufacturing operations	20	30	20	30	100	30
Total	**20**	**30**	**20**	**30**	**100**	**30**

Elective: 2 Non Sterile Packaging

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0266.Perform primary packaging operations for Non-sterile Bulk Drug / API	20	30	20	30	100	30
Total	**20**	**30**	**20**	**30**	**100**	**30**

Elective: 3 Sterile Manufacturing and Packaging

Qualification Pack

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0267.Perform sterile Bulk drug API/ manufacturing and primary packaging operations	20	30	20	30	100	30
Total	**20**	**30**	**20**	**30**	**100**	**30**

Acronyms

NOS	National Occupational Standard(s)
NSQF	National Skills Qualifications Framework
QP	Qualifications Pack
TVET	Technical and Vocational Education and Training
NOS	National Occupational Standard
NSQF	National Skills Qualifications Framework
NCVET	National Council of Vocational Education and Training
BMR	Batch Manufacturing Record
PPE	Personal Protective Equipment
SOP	Standard Operating Procedure
BPR	Batch Packaging Record
ALCOA	Attributable, Legible, Contemporaneous, Original and Accurate
API	Active Pharmaceutical Ingredient
CIP	Cleaning-in-Place
SIP	Sterilization-in-Place
WPU	Water for Pharma Use
WFI	Water for Injection
DW	Distilled Water
QA	Quality Assurance
GMP	Good Manufacturing Practice
ICH	International Council for Harmonisation
GDP	Good Documentation Practice
WHO	World Health Organization
EHS	Environment, Health and Safety
MSDS	Material Safety Data Sheet

POSH	Prevention of Sexual Harassment
PwD	People With Disability
AA	Assessment Agency
AB	Awarding Body
ISCO	International Standard Classification of Occupations
NCO	National Classification of Occupations
NCrF	National Credit Framework
NOS	National Occupational Standard(s)
NQR	National Qualification Register
NSQF	National Skills Qualification Framework
OJT	On the Job Training
SOP	Standard operating procedure
AA	Assessment Agency
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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.
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.
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.
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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

Knowledge and Understanding	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.
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National Occupational Standard	NOS define the measurable performance outcomes required from an individual engaged in a particular task. They list down what an individual performing that task should know and also do.
Qualification	A formal outcome of an assessment and validation process which is obtained when a competent body determines that an individual has achieved learning outcomes to given standards
Qualification File	A Qualification File is a template designed to capture necessary information of a Qualification from the perspective of NSQF compliance. The Qualification File will be normally submitted by the awarding body for the qualification.
Sector	A grouping of professional activities on the basis of their main economic function, product, service or technology.
BMR	Batch manufacturing record
MSDS	Material safety data sheet
QA	Quality Assurance
National Occupational Standard	NOS defines the measurable performance outcomes required from an individual engaged in a particular task. They list down what an individual performing that task should know and also do.
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Qualification	A formal outcome of an assessment and validation process which is obtained when a competent body determines that an individual has achieved learning outcomes to given standards
Qualification File	A Qualification File is a template designed to capture necessary information of a Qualification from the perspective of NSQF compliance. The Qualification File will be normally submitted by the awarding body for the qualification.
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BMR	Batch manufacturing record
MSDS	Material safety data sheet
QA	Quality Assurance
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