Qualification Pack

Chemist - Production (Pharma, Cosmetics & Biologics)

Electives: Non-Sterile Product Manufacturing

Options: Regulated Business Operations

QP Code: LFS/Q1201 Instantiated QP Code: LFS/Q1201-SI006

Version: 4.0

NSQF Level: 5

Qualification Pack

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Qualification Pack

LFS/Q1201-SI006: Chemist - Production (Pharma, Cosmetics & Biologics)

Brief Job Description

Chemist - Production (Pharma, Cosmetics & Biologics) is responsible for monitoring the production processes and maintaining the compliance with regulatory standards. The job role holder carryout the reporting and documentation for regulatory compliance and responsible for maintaining the strict compliance to EHS and cGMP guidelines.

Personal Attributes

The individual should have good time management and analytical skills. The job holder must possess good communication and problem-solving skills. The person should be detail and result oriented.

Applicable National Occupational Standards (NOS)

Compulsory NOS:

1. LFS/N0274: Discuss about Life Sciences Industry and Basics of manufacturing Operations
2. LFS/N1219: Monitor the production process in compliance with cGMP and other regulatory guidelines
3. LFS/N0111: Ensure adherence to Environment, health and safety guidelines in production facility and cGMP controlled areas
4. LFS/N0117: Coordinate with Manager, team-members, cross-functional teams and auditors
5. LFS/N1220: Perform reporting and documentation for regulatory compliance
6. DGT/VSQ/N0102: Employability Skills (60 Hours)

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

Elective : Non-Sterile Product Manufacturing

This elective is for Production Chemist involved in the management of non-sterile formulation manufacturing process.

1. LFS/N1216: Manage non-sterile product manufacturing process in compliance with cGMP and other regulatory guidelines

Options*(Not mandatory):*

Option : Regulated Business Operations

This Option is about developing the entrepreneur skills.

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

Qualification Pack (QP) Parameters

Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Biotechnology
Occupation	Pharma Manufacturing
Country	India
NSQF Level	5
Credits	22
Aligned to NCO/ISCO/ISIC Code	NCO-2015/2262.0101
Minimum Educational Qualification & Experience	Completed 3 year diploma after 10th (Mechanical/ Mechatronics/ Electronics/ Chemical Engineering) with 1.5 years of experience in production of relevant product OR Completed 2nd year of UG (UG Diploma) (with Chemistry Subject)) OR Completed 2nd year of UG (UG Diploma) (B.E./ B.Tech. in Chemical Engineering / Biotechnology) OR Completed 2nd year of UG (UG Diploma) (B. Pharma) OR Certificate-NSQF (Level 4 Qualification for Production Machine Operator- Non Sterile Formulation) with 3 Years of experience in production of relevant product OR Certificate-NSQF (Level 4 Qualification for Production Equipment Operator- Active Pharmaceutical Ingredient (API)/ Bulk Drug) with 3 Years of experience in production of relevant product OR Certificate-NSQF (Level 4.5 Qualification for Production Equipment Operator- Sterile Formulation) with 1.5 years of experience in production of relevant product

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Minimum Level of Education for Training in School	
Pre-Requisite License or Training	NA
Minimum Job Entry Age	18 Years
Last Reviewed On	NA
Next Review Date	08/04/2028
NSQC Approval Date	08/04/2025
Version	4.0
Reference code on NQR	QG-05-LS-00255-2025-V2-LSSSDC
NQR Version	2.0

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

LFS/N1219: Monitor the production process in compliance with cGMP and other regulatory guidelines

Description

This NOS is about a Chemist - Production (Pharma, Cosmetics & Biologics) monitoring the production process while ensuring its compliance with cGMP and other regulatory guidelines

Scope

The scope covers the following :

- Pre-production process
- Production process
- Post-production process
- Environment sustainability

Elements and Performance Criteria

Pre-production process

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

PC1. ensure to wear PPE before entering in the production area and follow cleanroom behavior

PC2. ensure that environmental conditions of the production area are maintained within the limits specified in the respective BMR

PC3. ensure that all the pre analysis checks are performed as per Standard Operating Procedure (SOP) and cGMP guidelines

PC4. identify out of order, non- calibrated, non- validated equipment and ensure they are segregated for maintenance

PC5. ensure the availability of sufficient stock of raw materials and chemicals for production process as per the production schedule

Production Process

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

PC6. maintain cGMP standards at shop floor and conditions suitable for production of quality products as per requirement

PC7. prepare standard operating procedures, equipment master list, and equipment qualification plan for production process

PC8. ensure the raw material is processed strictly as per BMR and SOP

PC9. check the production process is carried out as per the respective production schedules

PC10. monitor all the critical operations of the production process

PC11. check on production yields and reconciliation at various stages of production process

PC12. PC12. Implement and monitor automation systems and control technologies to optimize production efficiency, reduce manual errors, and ensure consistent product quality as per cGMP standards.

PC13. monitor the production output of each shift operation for recording in the Batch Process Report (BPR) as per the approved guidelines

PC14. ensure that all the in-process checks are carried out and quality of the product is ensured at each stage as per the Standard Operating Procedures (SOP)

PC15. observe production incidents for any deviations from the standard production process

PC16. coordinate with QA for any change by originating change control request

PC17. verify various online documentation entries at each production step in a manufacturing process information system and lab management information system

Post-production process

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

PC18. observe to ensure waste disposal in compliance with WHO guidelines and ICH-cGMP rules

PC19. monitor the line clearance activities performed by junior staff on the shop floors for smooth work- flow

PC20. perform verification for the labels on finished good containers in compliance to labelling guidelines

Environment Sustainability

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

PC21. ensure energy conservation by switching off the machine and equipment post operations

PC22. identify ways to optimize the usage of electricity/energy in various tasks/activities/processes

PC23. ensure energy conservation by optimizing the machine/ equipment performance

PC24. identify recyclable and non-recyclable, and hazardous waste generated

PC25. segregate waste into different categories to achieve minimum pollution of land and water

PC26. check for water leakage in plant/ work area and take corrective actions

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. the selection of safety gears and PPE to be used and their operating procedures

KU2. the cleanroom behaviour and guidelines to be followed

KU3. the standard environmental conditions of the production area

KU4. the different types of pre-analysis checks performed

KU5. the different types of production process

KU6. the production equipment and their operating procedures

KU7. the chemicals and reagents used in production process, their properties and storage conditions

KU8. the ideal working conditions of equipment

KU9. the change control procedures

KU10. the standard operating procedures of the entire production unit

KU11. the guidelines related to manufacturing operations and environmental sustainability

KU12. the WHO guidelines and ICH-cGMP rules for waste disposal and waste management

KU13. the standard labelling guidelines

KU14. the line clearance SOP

Generic Skills (GS)

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

GS1. use reading and comprehension skills to read and understand manuals, SOPs, health, and safety instructions

GS2. use written communication skills to draft reports or electronic mails to communicate the details of work done to appropriate people

GS3. use problem-solving skills in dealing with any deviation from SOPs and day-today problems

GS4. use critical thinking skills in analyzing any situation which needs an immediate escalation or emergency alarm

GS5. apply problem-solving skills to find solutions for workflow-related difficulties using concepts of basic sciences (chemistry), mathematics, statistics

GS6. use planning and organizing skills in every activity planned and performed in production operations and to achieve resource optimization

GS7. apply analytical skill to observe and identify OOS/ OOT/ deviations in the production process

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Pre-production process	**10**	**15**	**3**	**2**
PC1. ensure to wear PPE before entering in the production area and follow cleanroom behavior	-	-	-	-
PC2. ensure that environmental conditions of the production area are maintained within the limits specified in the respective BMR	-	-	-	-
PC3. ensure that all the pre analysis checks are performed as per Standard Operating Procedure (SOP) and cGMP guidelines	-	-	-	-
PC4. identify out of order, non- calibrated, non-validated equipment and ensure they are segregated for maintenance	-	-	-	-
PC5. ensure the availability of sufficient stock of raw materials and chemicals for production process as per the production schedule	-	-	-	-
Production Process	**10**	**15**	**3**	**2**
PC6. maintain cGMP standards at shop floor and conditions suitable for production of quality products as per requirement	-	-	-	-
PC7. prepare standard operating procedures, equipment master list, and equipment qualification plan for production process	-	-	-	-
PC8. ensure the raw material is processed strictly as per BMR and SOP	-	-	-	-
PC9. check the production process is carried out as per the respective production schedules	-	-	-	-
PC10. monitor all the critical operations of the production process	-	-	-	-
PC11. check on production yields and reconciliation at various stages of production process	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. PC12. Implement and monitor automation systems and control technologies to optimize production efficiency, reduce manual errors, and ensure consistent product quality as per cGMP standards.	-	-	-	-
PC13. monitor the production output of each shift operation for recording in the Batch Process Report (BPR) as per the approved guidelines	-	-	-	-
PC14. ensure that all the in-process checks are carried out and quality of the product is ensured at each stage as per the Standard Operating Procedures (SOP)	-	-	-	-
PC15. observe production incidents for any deviations from the standard production process	-	-	-	-
PC16. coordinate with QA for any change by originating change control request	-	-	-	-
PC17. verify various online documentation entries at each production step in a manufacturing process information system and lab management information system	-	-	-	-
Post-production process	**5**	**10**	**3**	**2**
PC18. observe to ensure waste disposal in compliance with WHO guidelines and ICH-cGMP rules	-	-	-	-
PC19. monitor the line clearance activities performed by junior staff on the shop floors for smooth work- flow	-	-	-	-
PC20. perform verification for the labels on finished good containers in compliance to labelling guidelines	-	-	-	-
Environment Sustainability	**5**	**10**	**3**	**2**
PC21. ensure energy conservation by switching off the machine and equipment post operations	-	-	-	-
PC22. identify ways to optimize the usage of electricity/energy in various tasks/activities/processes	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC23. ensure energy conservation by optimizing the machine/ equipment performance	-	-	-	-
PC24. identify recyclable and non-recyclable, and hazardous waste generated	-	-	-	-
PC25. segregate waste into different categories to achieve minimum pollution of land and water	-	-	-	-
PC26. check for water leakage in plant/ work area and take corrective actions	-	-	-	-
NOS Total	**30**	**50**	**12**	**8**

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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N1219
NOS Name	Monitor the production process in compliance with cGMP and other regulatory guidelines
Sector	Life Sciences
Sub-Sector	Pharmaceutical
Occupation	Pharma Manufacturing
NSQF Level	5
Credits	3.00
Version	3.0
Last Reviewed Date	08/04/2025
Next Review Date	08/04/2028
NSQC Clearance Date	08/04/2025

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

Description

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

Scope

The scope covers the following :

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

Elements and Performance Criteria

Follow health and hygiene protocols

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

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

PC2. wash hands before entering in the production area with soap/alcohol based sanitisers

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

PC4. take preventive actions on the report of any allergy, sickness or any other environment-related breach reported by subordinates

PC5. follow gowning procedures while entering an environment controlled work area and ensure the adherence of the same by others

Adherence to safety and security procedures

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

PC6. comply with safety and security policies and procedures

PC7. ensure the use of appropriate safety gears like headgear, masks, gloves and other accessories as mentioned in the guidelines, by self and subordinates while carrying out work

PC8. take preventive and corrective actions based on the report of any identified breaches in safety and security policies and procedures by subordinates

PC9. ensure that discipline for material segregation and 5S system is followed at the storage area

PC10. comply with material handling, segregation, and storage guidelines for hazardous material

PC11. take corrective actions for reported hazards in consultation with EHS personnel

PC12. complete the records of safety drills and trainings undertaken by self and subordinates

Adherence to emergency procedures

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

PC13. report any hazards that he/she is not competent to deal with the relevant EHS personnel and warn other people who may be affected

PC14. raise the alarm and inform the concerned person immediately for action in the cases of spill, fall, injury, toxic inhale, fire or explosion

PC15. follow emergency protocols for any alarms and ensure the safety of subordinates in the area under supervision

PC16. follow emergency procedures efficiently

PC17. ensure injured employees are provided appropriate first aid and medical aid

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. company's procedures for the environment, health, and safety

KU2. implications that any non-compliance with health, safety and security may have on individuals and the organization

KU3. workplace hazards in the manufacturing facility in the life sciences sector, how and when to report hazards

KU4. limits of individual responsibility for dealing with hazards

KU5. chemical substances, their characteristics, and required precaution and safety measures

KU6. gowning procedure

KU7. the organization's emergency procedures for different emergencies and the importance of following these

KU8. evacuation procedures for employees, contract staff and visitors

KU9. how to summon medical assistance and the emergency services, where necessary

KU10. health, safety and accident reporting procedures and the importance of reporting in GMP

KU11. different types of breaches in the environment, health, safety and security and how and when to report these

KU12. WHO guidelines for personal hygiene

KU13. type of safety gears and procedure to use them

KU14. the importance of material segregation and 5S system

KU15. WHO guidelines for handling and storing hazardous material

Generic Skills (GS)

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

GS1. use reading and comprehension skills to understand the various coding systems and to read instructions, guidelines, procedures, rules, and signages to understand the procedure to be followed

GS2. use listening skills to follow the instructions and procedures during emergency alarms

GS3. use written communication skills to accurately record every information required to be reported as per SOP and GMP guidelines in the prescribed language

GS4. apply planning and organizing skills to plan and organize tools and material required for work to fulfil environment, health, safety and security requirements

GS5. use critical thinking skills to take relevant actions on the accidents and breach in compliance with EHS protocols

GS6. apply decision-making skills to make balanced judgments within the authority while dealing with hazards and breaches

GS7. apply problem-solving skills to find solutions for workflow-related difficulties

GS8. use verbal communication skills to communicate with supervisor/ manager/ EHS Incharge or any other concerned authority clearly for escalating any emergency or hazard

Assessment Criteria

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

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

National Occupational Standards (NOS) Parameters

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

LFS/N0117: Coordinate with Manager, team-members, cross-functional teams and auditors

Description

This NOS unit is about a person coordinating with cross-functional teams, Supervisor, team members and responding to auditors

Scope

The scope covers the following :

- Coordination with Manager
- Coordination within team and cross-functional teams
- Respond to audit queries
- Sensitivity towards all genders and people with disability

Elements and Performance Criteria

Coordination with Manager

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

PC1. coordinate with the reporting manager to obtain work instructions and develop the production plan

PC2. communicate to reporting manager about process-flow improvements and production defects received from previous process

PC3. inform concern authority for any potential hazards or expected process disruptions

PC4. provide maintenance, engineering related or process related change control request and its impact reports proactively to the manager

PC5. report periodically the status of planned batch/ continuous manufacturing schedule to manager within the timeline

Coordination within the team and cross-functional teams

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

PC6. work as a team with colleagues and share work as per their own workload

PC7. train junior chemists on procedures and provide assistance to them when needed

PC8. communicate and discuss workflow related difficulties to find solutions with mutual agreement

PC9. coordinate with maintenance team for any breakdowns and preventive and corrective maintenance of production equipment's

PC10. coordinate with Engineering department at the time of equipment qualification activities

PC11. coordinate with Stores manager to receive chemicals and materials in time

PC12. coordinate with quality control team for raw material availability / release of raw materials and, semi-finished and finished goods

PC13. coordinate with QA team for line clearance, change control approvals , calibration and validation activities

Respond to audit queries

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

PC14. provide clear answers to the auditor's queries

PC15. produce the documented records of performed activities and operations to auditors

PC16. 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:

PC17. respect all genders, religions, and caste

PC18. empathize with people with disability

PC19. offer support or help to a person with disability only when asked

PC20. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act

PC21. 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 reporting structure of the organization

KU2. types of audits in the life sciences sector for the manufacturing plant

KU3. the required regulatory and statutory compliance related documentation

KU4. the guidelines for data integrity, ethics, and compliance in the life sciences industry

KU5. the guidelines laid on Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act

KU6. the methods of workplace communication

KU7. the methods of team coordination

KU8. the types of possible disabilities among people with disability (PWD)

KU9. the importance of awareness for gender sensitization and prevention of sexual harassment (POSH) act

KU10. the importance of respect for all the religions, caste, and cultures

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/typed report or computer-based record/electronic mail

GS3. use written communication skills to maintain proper and concise records as per given format

GS4. use verbal communication skills to communicate confidential and sensitive information discretely to the authorized person while interacting with teammates

GS5. use team-building skills during the interaction with teammates while managing the difficult/stressful or emotional situations at work

GS6. apply problem-solving skills to find solutions for workflow-related difficulties

GS7. 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

GS8. apply customer-centricity while responding to auditors, customer representatives and QA personnel

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Coordination with Manager	**10**	**15**	**3**	**2**
PC1. coordinate with the reporting manager to obtain work instructions and develop the production plan	-	-	-	-
PC2. communicate to reporting manager about process-flow improvements and production defects received from previous process	-	-	-	-
PC3. inform concern authority for any potential hazards or expected process disruptions	-	-	-	-
PC4. provide maintenance, engineering related or process related change control request and its impact reports proactively to the manager	-	-	-	-
PC5. report periodically the status of planned batch/ continuous manufacturing schedule to manager within the timeline	-	-	-	-
Coordination within the team and cross-functional teams	**10**	**15**	**3**	**2**
PC6. work as a team with colleagues and share work as per their own workload	-	-	-	-
PC7. train junior chemists on procedures and provide assistance to them when needed	-	-	-	-
PC8. communicate and discuss workflow related difficulties to find solutions with mutual agreement	-	-	-	-
PC9. coordinate with maintenance team for any breakdowns and preventive and corrective maintenance of production equipment's	-	-	-	-
PC10. coordinate with Engineering department at the time of equipment qualification activities	-	-	-	-
PC11. coordinate with Stores manager to receive chemicals and materials in time	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. coordinate with quality control team for raw material availability / release of raw materials and, semi-finished and finished goods	-	-	-	-
PC13. coordinate with QA team for line clearance, change control approvals , calibration and validation activities	-	-	-	-
Respond to audit queries	**5**	**10**	**3**	**2**
PC14. provide clear answers to the auditor's queries	-	-	-	-
PC15. produce the documented records of performed activities and operations to auditors	-	-	-	-
PC16. maintain data integrity while responding to auditors and regulatory inspectors	-	-	-	-
Sensitivity towards all genders and people with disability	**5**	**10**	**3**	**2**
PC17. respect all genders, religions, and caste	-	-	-	-
PC18. empathize with people with disability	-	-	-	-
PC19. offer support or help to a person with disability only when asked	-	-	-	-
PC20. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act	-	-	-	-
PC21. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee	-	-	-	-
NOS Total	**30**	**50**	**12**	**8**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0117
NOS Name	Coordinate with Manager, team-members, cross-functional teams and auditors
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Pharma Manufacturing
NSQF Level	5
Credits	1.00
Version	3.0
Last Reviewed Date	08/04/2025
Next Review Date	08/04/2028
NSQC Clearance Date	08/04/2025

LFS/N1220: Perform reporting and documentation for regulatory compliance

Description

This NOS is about a Chemist Production (Pharma, Cosmetics & Biologics) carrying out reporting and documentation and ensuring that the final documents meet regulatory and compliance requirements.

Scope

The scope covers the following :

- Reporting
- Recording and documentation
- Data Integrity

Elements and Performance Criteria

Reporting

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

PC1. follow reporting and escalation matrix as prescribed by the company

PC2. report defects/problem/incidents/quality issues/as applicable in a timely manner to the appropriate authority as laid down by the company

PC3. provide reports of deviations and OOS and OOT incidents to quality assurance team

PC4. escalate any change control request to quality assurance and regulatory team for approval

Recording and documentation

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

PC5. identify documentation to be completed for assigned activity

PC6. review and approve the logbook entries made by operators for all the production batches

PC7. complete all documentation within stipulated time according to regulatory guidelines and SOP

PC8. prepare deviation reports with detailed findings and recommendations as per SOPs

PC9. ensure that the final document meets regulatory and compliance requirements as per cGDP and cGMP

Data integrity

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

PC10. maintain all original and controlled document files and manufacturing records in a timely and accurate manner following ALCOA PLUS principles

PC11. respond to requests for information in an appropriate manner whilst following organizational procedures

PC12. make sure documents are available to all appropriate authorities to inspect/ audit

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. the types of documentation in an organization and the importance of maintaining the same and different methods of recording information
KU2. the different methods of recording information
KU3. the reporting and recording formats
KU4. the importance of reporting incidents where standard operating procedures are not followed
KU5. the importance of complete and accurate documentation
KU6. the escalation matrix for reporting identified issues, hazards and breakage
KU7. the ALCOA PLUS Principles
KU8. the basic operating procedure for using a computer system and MS Office or any alternate software of MS Office
KU9. critical documentation steps for cGMP compliance in a regulated facility

Generic Skills (GS)

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

GS1. use written communication skills to record information accurately in compliance with ALCOA principles as per SOP and cGMP guidelines in the English language
GS2. use reading and comprehension skills to understand 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 understand the instructions and procedures to be followed
GS4. use verbal communication skills to interact with supervisor, teammates, cross-functional teams for coordination and to communicate confidential and sensitive information discretely to the authorized person
GS5. apply problem-solving skills to find solutions for workflow-related difficulties
GS6. apply customer-centricity while interacting with different stakeholders

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Reporting	**10**	**15**	**5**	**5**
PC1. follow reporting and escalation matrix as prescribed by the company	-	-	-	-
PC2. report defects/problem/incidents/quality issues/as applicable in a timely manner to the appropriate authority as laid down by the company	-	-	-	-
PC3. provide reports of deviations and OOS and OOT incidents to quality assurance team	-	-	-	-
PC4. escalate any change control request to quality assurance and regulatory team for approval	-	-	-	-
Recording and documentation	**10**	**15**	**5**	**5**
PC5. identify documentation to be completed for assigned activity	-	-	-	-
PC6. review and approve the logbook entries made by operators for all the production batches	-	-	-	-
PC7. complete all documentation within stipulated time according to regulatory guidelines and SOP	-	-	-	-
PC8. prepare deviation reports with detailed findings and recommendations as per SOPs	-	-	-	-
PC9. ensure that the final document meets regulatory and compliance requirements as per cGDP and cGMP	-	-	-	-
Data integrity	**10**	**15**	**3**	**2**
PC10. maintain all original and controlled document files and manufacturing records in a timely and accurate manner following ALCOA PLUS principles	-	-	-	-
PC11. respond to requests for information in an appropriate manner whilst following organizational procedures	-	-	-	-
PC12. make sure documents are available to all appropriate authorities to inspect/ audit	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
NOS Total	30	45	13	12

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N1220
NOS Name	Perform reporting and documentation for regulatory compliance
Sector	Life Sciences
Sub-Sector	Pharmaceutical
Occupation	Pharma Manufacturing
NSQF Level	5
Credits	1.00
Version	3.0
Last Reviewed Date	08/04/2025
Next Review Date	08/04/2028
NSQC Clearance Date	08/04/2025

Qualification Pack

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**	**-**	**-**

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	08/05/2025
Next Review Date	06/05/2028
NSQC Clearance Date	08/05/2025

LFS/N1216: Manage non-sterile product manufacturing process in compliance with cGMP and other regulatory guidelines

Description

This NOS is about a Chemist Production (Pharma, Cosmetics & Biologics) managing the non-sterile product manufacturing process and ensuring compliance with cGMP and other regulatory guidelines

Scope

The scope covers the following :

- Non-sterile manufacturing process
- cGMP compliant documentation

Elements and Performance Criteria

Non-sterile manufacturing process

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

PC1. wear personal protective equipment before entering into the production area

PC2. ensure the non-sterile manufacturing process area is clean and is as per cleanroom guidelines

PC3. conduct regular checks on equipment and instrument used in non-sterile manufacturing process for calibration and validation state

PC4. ensure all chemicals, reagents and raw materials are clearly identified by labels and remain permanently attached to the sample containers under all storage conditions

PC5. ensure non-sterile manufacturing process is carried out as per SOP

PC6. analyse the root cause for out-of-specification (OOS) and out-of-trend (OOT) products, deviations and incidents in production process

PC7. ensure finished products are stored under proper storage conditions and are labeled as per standard labeling guidelines

PC8. maintain the records for non- sterile product manufacturing batches

cGMP compliant documentation

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

PC9. document the activities as per ALCOA principles

PC10. record the required information of all significant activities, incidents, and deviations as per recording formats in compliance with SOP and ICH-GMP guidelines

PC11. identify corrective and preventive action (CAPA) for every incident and deviations in compliance with cGMP and other regulatory guidelines

PC12. review and approve the change control request in case of deviations in consultation with QA and regulatory team

PC13. review and approve the logbook entries and trial run records

PC14. maintain online documentation like BMRs, BPRs, log books, daily records etc related to production activities as per SOP`s, cGMP and cGDP guidelines

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. the PPE used in non-sterile manufacturing and their work instructions
KU2. the basic process of non-sterile manufacturing
KU3. cleanroom behavior and guidelines for non-sterile manufacturing process
KU4. the ICH Q7 GMP guidelines for non-sterile production
KU5. the equipment used in non-sterile production and their operating procedures
KU6. the chemicals and reagents used in non-sterile production process, their properties and storage conditions
KU7. the procedures for reporting non-conformance, deviations, OOS/OOT
KU8. procedures for documentation, reporting and escalation
KU9. the concepts of data integrity and ALCOA PLUS

Generic Skills (GS)

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

GS1. use reading and comprehension skills to read and understand manuals, SOPs, health, and safety instructions
GS2. use written communication skills to record information accurately in compliance with ALCOA principles as per SOP and cGMP guidelines in the English language
GS3. apply problem-solving skills to find solutions for workflow-related difficulties and for dealing with any deviation from SOPs
GS4. use critical thinking skills in analyzing any situation that requires immediate escalation or emergency alarm
GS5. use planning and organizing skills in every activity planned and performed in production operations and to achieve resource optimization
GS6. apply analytical skill to observe and identify OOS/ OOT/ deviations in the production process
GS7. 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
Non-sterile manufacturing process	**15**	**30**	**10**	**5**
PC1. wear personal protective equipment before entering into the production area	-	-	-	-
PC2. ensure the non-sterile manufacturing process area is clean and is as per cleanroom guidelines	-	-	-	-
PC3. conduct regular checks on equipment and instrument used in non-sterile manufacturing process for calibration and validation state	-	-	-	-
PC4. ensure all chemicals, reagents and raw materials are clearly identified by labels and remain permanently attached to the sample containers under all storage conditions	-	-	-	-
PC5. ensure non-sterile manufacturing process is carried out as per SOP	-	-	-	-
PC6. analyse the root cause for out-of-specification (OOS) and out-of-trend (OOT) products, deviations and incidents in production process	-	-	-	-
PC7. ensure finished products are stored under proper storage conditions and are labeled as per standard labeling guidelines	-	-	-	-
PC8. maintain the records for non- sterile product manufacturing batches	-	-	-	-
cGMP compliant documentation	**10**	**20**	**5**	**5**
PC9. document the activities as per ALCOA principles	-	-	-	-
PC10. record the required information of all significant activities, incidents, and deviations as per recording formats in compliance with SOP and ICH-GMP guidelines	-	-	-	-
PC11. identify corrective and preventive action (CAPA) for every incident and deviations in compliance with cGMP and other regulatory guidelines	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. review and approve the change control request in case of deviations in consultation with QA and regulatory team	-	-	-	-
PC13. review and approve the logbook entries and trial run records	-	-	-	-
PC14. maintain online documentation like BMRs, BPRs, log books, daily records etc related to production activities as per SOP`s, cGMP and cGDP guidelines	-	-	-	-
NOS Total	**25**	**50**	**15**	**10**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N1216
NOS Name	Manage non-sterile product manufacturing process in compliance with cGMP and other regulatory guidelines
Sector	Life Sciences
Sub-Sector	Pharmaceutical
Occupation	Pharma Manufacturing
NSQF Level	5
Credits	11.0
Version	3.0
Last Reviewed Date	08/04/2025
Next Review Date	08/04/2028
NSQC Clearance Date	08/04/2025

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.

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/cGMP/cGLP 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. current 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

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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Set up enterprise and perform entrepreneurial activities	**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	-	-	-	-
Maintenance of accounts and ledgers	**10**	**20**	**6**	**5**

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	-	-	-	-
Comply with legal, regulatory and statutory standards	-	-	-	-
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/cGMP/cGLP 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	-	-	-	-

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	3.0
Last Reviewed Date	08/04/2025
Next Review Date	08/04/2028
NSQC Clearance Date	08/04/2025

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.

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/typed 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

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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Infrastructure related documentation	**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	-	-	-	-
Supply Chain related documentation	**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	-	-	-	-

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.	-	-	-	-
Documentation for sales & marketing	**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	-	-	-	-
Quality audit and client/regulatory inspections related documentation	**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**

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	3.0
Last Reviewed Date	08/04/2025
Next Review Date	08/04/2028
NSQC Clearance Date	08/04/2025

Assessment Guidelines and Assessment Weightage

Assessment Guidelines

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

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

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

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

5. LSSSDC as assessment and awarding body will create unique evaluations for each assessment component i.e. theory, practical, project and via for every student at each examination/training center based on this criterion.

6. Wherever any assessment component is not applicable/ feasible, the balance assessment components will be used to assess the candidate and accordingly the total marks will be calculated only for the applied

assessment component.

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

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

Minimum Aggregate Passing % at QP Level : 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	7.69
LFS/N1219.Monitor the production process in compliance with cGMP and other regulatory guidelines	30	50	12	8	100	11.54
LFS/N0111.Ensure adherence to Environment, health and safety guidelines in production facility and cGMP controlled areas	30	55	-	15	100	7.69
LFS/N0117.Coordinate with Manager, team-members, cross-functional teams and auditors	30	50	12	8	100	7.69
LFS/N1220.Perform reporting and documentation for regulatory compliance	30	45	13	12	100	11.54

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
DGT/VSQ/N0102.Employability Skills (60 Hours)	20	30	-	-	50	7.69
Total	**180**	**260**	**52**	**58**	**550**	**53.839999999999996**

Elective: 1 Non-Sterile Product Manufacturing

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N1216.Manage non-sterile product manufacturing process in compliance with cGMP and other regulatory guidelines	25	50	15	10	100	23.08
Total	**25**	**50**	**15**	**10**	**100**	**23.08**

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	11.54
LFS/N0121.Maintain the critical business documents as Entrepreneur in Life Sciences Sector	20	55	15	10	100	11.54
Total	**50**	**105**	**27**	**18**	**200**	**23.08**