

## Qualification Pack



# Chemist - Production (Pharma, Cosmetics & Biologics)

Electives: Sterile Product Manufacturing

QP Code: LFS/Q1201 Instantiated QP Code: LFS/Q1201-SI002

Version: 4.0

NSQF Level: 5

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## Qualification Pack

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### LFS/Q1201-SI002: 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 : Sterile Product Manufacturing

This elective is for production chemist involved in management of sterile formulation manufacturing process.

1. [LFS/N1222: Manage sterile product manufacturing process in compliance with cGMP and other regulatory guidelines](#)

#### Qualification Pack (QP) Parameters



## Qualification Pack

<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceutical, Bio Pharmaceutical, Biotechnology
<b>Occupation</b>	Pharma Manufacturing
<b>Country</b>	India
<b>NSQF Level</b>	5
<b>Credits</b>	20
<b>Aligned to NCO/ISCO/ISIC Code</b>	NCO-2015/2262.0101
<b>Minimum Educational Qualification &amp; Experience</b>	<p>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</p>
<b>Minimum Level of Education for Training in School</b>	
<b>Pre-Requisite License or Training</b>	NA
<b>Minimum Job Entry Age</b>	18 Years
<b>Last Reviewed On</b>	NA
<b>Next Review Date</b>	08/04/2028
<b>NSQC Approval Date</b>	08/04/2025



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Version	4.0
Reference code on NQR	QG-05-LS-00255-2025-V2-LSSSDC
NQR Version	2.0



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### 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



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- 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





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### Assessment Criteria

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





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### National Occupational Standards (NOS) Parameters

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



## Qualification Pack

# 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.** 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



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- 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



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### 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-to-day 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

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### Assessment Criteria

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

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<b>PC12.</b> 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.	-	-	-	-
<b>PC13.</b> monitor the production output of each shift operation for recording in the Batch Process Report (BPR) as per the approved guidelines	-	-	-	-
<b>PC14.</b> 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)	-	-	-	-
<b>PC15.</b> observe production incidents for any deviations from the standard production process	-	-	-	-
<b>PC16.</b> coordinate with QA for any change by originating change control request	-	-	-	-
<b>PC17.</b> verify various online documentation entries at each production step in a manufacturing process information system and lab management information system	-	-	-	-
<i>Post-production process</i>	<b>5</b>	<b>10</b>	<b>3</b>	<b>2</b>
<b>PC18.</b> observe to ensure waste disposal in compliance with WHO guidelines and ICH-cGMP rules	-	-	-	-
<b>PC19.</b> monitor the line clearance activities performed by junior staff on the shop floors for smooth work- flow	-	-	-	-
<b>PC20.</b> perform verification for the labels on finished good containers in compliance to labelling guidelines	-	-	-	-
<i>Environment Sustainability</i>	<b>5</b>	<b>10</b>	<b>3</b>	<b>2</b>
<b>PC21.</b> ensure energy conservation by switching off the machine and equipment post operations	-	-	-	-
<b>PC22.</b> identify ways to optimize the usage of electricity/energy in various tasks/activities/processes	-	-	-	-



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





## Qualification Pack

### National Occupational Standards (NOS) Parameters

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



## Qualification Pack

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

#### Description

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

#### Scope

The scope covers the following :

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

#### Elements and Performance Criteria

##### *Follow health and hygiene protocols*

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

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

##### *Adherence to safety and security procedures*

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

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

##### *Adherence to emergency procedures*

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



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

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

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

## Generic Skills (GS)

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

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



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



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### Assessment Criteria

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



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



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### National Occupational Standards (NOS) Parameters

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





## Qualification Pack

### 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



## Qualification Pack

### *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



## Qualification Pack

- 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

## Qualification Pack

### Assessment Criteria

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

## Qualification Pack

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



## Qualification Pack

### National Occupational Standards (NOS) Parameters

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



## Qualification Pack

### 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)





## Qualification Pack

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



## Qualification Pack

### Assessment Criteria

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



## Qualification Pack

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



## Qualification Pack

### National Occupational Standards (NOS) Parameters

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



## Qualification Pack

- 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.



## Qualification Pack

**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





## Qualification Pack

- 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

## Qualification Pack

### Assessment Criteria

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

## Qualification Pack

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

## Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Entrepreneurship</i>	<b>2</b>	<b>3</b>	-	-
<b>PC23.</b> identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research	-	-	-	-
<b>PC24.</b> develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion	-	-	-	-
<b>PC25.</b> identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity	-	-	-	-
<i>Customer Service</i>	<b>1</b>	<b>2</b>	-	-
<b>PC26.</b> identify different types of customers	-	-	-	-
<b>PC27.</b> identify and respond to customer requests and needs in a professional manner.	-	-	-	-
<b>PC28.</b> follow appropriate hygiene and grooming standards	-	-	-	-
<i>Getting ready for apprenticeship &amp; Jobs</i>	<b>2</b>	<b>3</b>	-	-
<b>PC29.</b> create a professional Curriculum vitae (Résumé)	-	-	-	-
<b>PC30.</b> search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively	-	-	-	-
<b>PC31.</b> apply to identified job openings using offline /online methods as per requirement	-	-	-	-
<b>PC32.</b> answer questions politely, with clarity and confidence, during recruitment and selection	-	-	-	-
<b>PC33.</b> identify apprenticeship opportunities and register for it as per guidelines and requirements	-	-	-	-
<b>NOS Total</b>	<b>20</b>	<b>30</b>	-	-



## Qualification Pack

### National Occupational Standards (NOS) Parameters

<b>NOS Code</b>	DGT/VSQ/N0102
<b>NOS Name</b>	Employability Skills (60 Hours)
<b>Sector</b>	Cross Sectoral
<b>Sub-Sector</b>	Professional Skills
<b>Occupation</b>	Employability
<b>NSQF Level</b>	4
<b>Credits</b>	2
<b>Version</b>	1.0
<b>Last Reviewed Date</b>	18/02/2025
<b>Next Review Date</b>	18/02/2028
<b>NSQC Clearance Date</b>	18/02/2025



## Qualification Pack

# LFS/N1222: Manage 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 sterile manufacturing process and ensuring compliance with cGMP and other regulatory guideline

## Scope

The scope covers the following :

- Sterile manufacturing process
- cGMP compliant documentation

## Elements and Performance Criteria

### *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 sterile manufacturing process area is clean and is as per cleanroom guidelines
- PC3.** ensure raw materials, chemicals and reagents used in sterile manufacturing process are properly capped and stored according to specified conditions to avoid cross contamination
- PC4.** check the calibration and validation status of equipment used in sterile manufacturing facility
- PC5.** ensure sterile manufacturing process is carried out as per SOP
- PC6.** check finished sterile product containers are closed and properly labeled as per standard labeling guidelines
- PC7.** analyse the root cause for out-of-specification (OOS) and out-of-trend (OOT) products, deviations and incidents in production process
- PC8.** maintain all the records for sterile product manufacturing batches

### *cGMP compliant Documentation*

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

- PC9.** perform documentation of 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 related to production activities like BMRs, BPRs, log books , daily records and production SOP's as per cGMP and cGDP guidelines

## Knowledge and Understanding (KU)



## Qualification Pack

The individual on the job needs to know and understand:

- KU1.** the PPE used in sterile manufacturing and their work instructions
- KU2.** the basic process of sterile manufacturing
- KU3.** cleanroom behavior and guidelines for sterile manufacturing process
- KU4.** the ICH Q7 GMP guidelines for sterile production
- KU5.** sterile production equipment and their operating procedures
- KU6.** the chemicals and reagents used in 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
- GS4.** use critical thinking skills in analysing any situation which needs an 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

## Qualification Pack

### Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Sterile manufacturing process</i>	<b>15</b>	<b>30</b>	<b>10</b>	<b>5</b>
<b>PC1.</b> wear personal protective equipment before entering into the production area	-	-	-	-
<b>PC2.</b> ensure the sterile manufacturing process area is clean and is as per cleanroom guidelines	-	-	-	-
<b>PC3.</b> ensure raw materials, chemicals and reagents used in sterile manufacturing process are properly capped and stored according to specified conditions to avoid cross contamination	-	-	-	-
<b>PC4.</b> check the calibration and validation status of equipment used in sterile manufacturing facility	-	-	-	-
<b>PC5.</b> ensure sterile manufacturing process is carried out as per SOP	-	-	-	-
<b>PC6.</b> check finished sterile product containers are closed and properly labeled as per standard labeling guidelines	-	-	-	-
<b>PC7.</b> analyse the root cause for out-of-specification (OOS) and out-of-trend (OOT) products, deviations and incidents in production process	-	-	-	-
<b>PC8.</b> maintain all the records for sterile product manufacturing batches	-	-	-	-
<i>cGMP compliant Documentation</i>	<b>10</b>	<b>15</b>	<b>10</b>	<b>5</b>
<b>PC9.</b> perform documentation of the activities as per ALCOA principles	-	-	-	-
<b>PC10.</b> record the required information of all significant activities, incidents, and deviations as per recording formats in compliance with SOP and ICH-GMP guidelines	-	-	-	-
<b>PC11.</b> identify corrective and preventive action (CAPA) for every incident and deviations in compliance with cGMP and other regulatory guidelines	-	-	-	-





## Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<b>PC12.</b> review and approve the change control request in case of deviations in consultation with QA and regulatory team	-	-	-	-
<b>PC13.</b> review and approve the logbook entries and trial run records	-	-	-	-
<b>PC14.</b> maintain online documentation related to production activities like BMRs, BPRs, log books , daily records and production SOP's as per cGMP and cGDP guidelines	-	-	-	-
<b>NOS Total</b>	<b>25</b>	<b>45</b>	<b>20</b>	<b>10</b>



## Qualification Pack

### National Occupational Standards (NOS) Parameters

<b>NOS Code</b>	LFS/N1222
<b>NOS Name</b>	Manage sterile product manufacturing process in compliance with cGMP and other regulatory guidelines
<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceutical
<b>Occupation</b>	Pharma Manufacturing
<b>NSQF Level</b>	5
<b>Credits</b>	11
<b>Version</b>	3.0
<b>Last Reviewed Date</b>	08/04/2025
<b>Next Review Date</b>	08/04/2028
<b>NSQC Clearance Date</b>	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 viva for every student at each examination/training center based on this criterion.
6. Wherever any assessment component is not applicable/ feasible, the balance assessment components will be used to assess the candidate and accordingly the total marks will be calculated only for the applied



## Qualification Pack

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	10
LFS/N1219.Monitor the production process in compliance with cGMP and other regulatory guidelines	30	50	12	8	100	15
LFS/N0111.Ensure adherence to Environment, health and safety guidelines in production facility and cGMP controlled areas	30	55	-	15	100	10
LFS/N0117.Coordinate with Manager, team-members, cross-functional teams and auditors	30	50	12	8	100	10
LFS/N1220.Perform reporting and documentation for regulatory compliance	30	45	13	12	100	15



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National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
DGT/VSQ/N0102.Employability Skills (60 Hours)	20	30	-	-	50	10
<b>Total</b>	<b>180</b>	<b>260</b>	<b>52</b>	<b>58</b>	<b>550</b>	<b>70</b>

Elective: 1 Sterile Product Manufacturing

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N1222.Manage sterile product manufacturing process in compliance with cGMP and other regulatory guidelines	25	45	20	10	100	30
<b>Total</b>	<b>25</b>	<b>45</b>	<b>20</b>	<b>10</b>	<b>100</b>	<b>30</b>