

Qualification Pack



Specialist- Quality Assurance (Pharma, Biological Products and Medical Devices)

Quality Management System

Regulated business Operations

QP Code: LFS/Q0313 Instantiated QP Code: LFS/Q0313-SI008

Version: 1.0

NSQF Level: 5.5



Qualification Pack

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LFS/Q0313-SI008: Specialist- Quality Assurance (Pharma, Biological Products and Medical Devices)

Brief Job Description

A Specialist- Quality Assurance (Pharma, Biological Products and Medical Devices) performs physical checks, conducts document verification exercise, ensures compliance to quality management systems and procedures, undertakes risk control assessment, conducts/participates in internal/external audits and also carries out process and equipment validation and in-process sampling, finished product sampling activities.

Personal Attributes

The individual should have good communication and interpersonal skills. The person should possess investigational abilities, analytical and reasoning skills. The role holder should have critical thinking skills along with excellent organizational skills.

Applicable National Occupational Standards (NOS)

Compulsory NOS:

1. [LFS/N0125: Ensure adherence to Environment, health and safety guidelines in a Manufacturing facility and GMP controlled areas](#)
2. [LFS/N0302: Coordinate with Manager, colleagues and auditors](#)
3. [LFS/N0348: Ensure GxP compliance, respond to issues and non-conformance to maintain regulatory standards and procedure](#)
4. [DGT/VSQ/N0103: Employability Skills \(90 Hours\)](#)

Electives(mandatory to select at least one):

Elective : Quality Management System

1. [LFS/N0327: Perform various QMS operations.](#)
2. [LFS/N0328: Ensure training related activities and suggesting Improvements to Quality Management System](#)

Options(Not mandatory):

Option : Regulated business Operations



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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
Occupation	Quality
Country	India
NSQF Level	5.5
Credits	20
Aligned to NCO/ISCO/ISIC Code	NCO-2015/2131.1300
Minimum Educational Qualification & Experience	<p>B.Tech ((in relevant field)) with 2 Years of experience Quality Assurance/Quality Control/production OR B.Pharm with 2 Years of experience Quality Assurance/Quality Control/production OR M.Sc (In relevant Subjects) with 2 Years of experience Quality Assurance/Quality Control/production OR M.Pharm (Final Year Student) OR M.Tech ((in relevant field) final year student) OR Previous relevant Qualification of NSQF Level (Level 5 Certificate of Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device)) with 1-2 Years of experience OR Previous relevant Qualification of NSQF Level (Level 5 Certificate of Analyst/ChemistQuality Contro) with 1-2 Years of experience OR Previous relevant Qualification of NSQF Level (Level 5 Certificate of Chemist- Production (Pharma, Cosmetics & Biologics)) with 1-2 Years of experience</p>



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Minimum Level of Education for Training in School	
Pre-Requisite License or Training	NA
Minimum Job Entry Age	21 Years
Last Reviewed On	NA
Next Review Date	29/09/2026
NSQC Approval Date	29/09/2023
Version	1.0
Reference code on NQR	QG-5.5-LS-00998-2023-V1-LSSSDC
NQR Version	1.0



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LFS/N0125: Ensure adherence to Environment, health and safety guidelines in a Manufacturing facility and GMP 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 manufacturing 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 and cGMP guidelines
- PC2.** wash hands and feet before entering in the manufacturing area with soap/alcohol based sanitizers
- PC3.** report any communicable or contagious diseases allergy, sickness or any other environment-related breach before 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 as per SoP while entering an environment controlled work area and ensure adherence to 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 deviations 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 highly hazardous, poisonous and explosive 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



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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.** health, safety and accident reporting procedures and the importance of reporting in GMP
- KU10.** different types of breaches in the environment, health, safety and security and how and when to report these
- KU11.** WHO guidelines for personal hygiene
- KU12.** type of safety gears and procedure to use them
- KU13.** the importance of material segregation and 5S system
- KU14.** 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>	10	15	-	5
PC1. comply with health and personal hygiene-related protocols as per WHO standards and cGMP guidelines	-	-	-	-
PC2. wash hands and feet before entering in the manufacturing area with soap/alcohol based sanitizers	-	-	-	-
PC3. report any communicable or contagious diseases allergy, sickness or any other environment-related breach before 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 as per SoP while entering an environment controlled work area and ensure adherence to the same by others	-	-	-	-
<i>Adherence to safety and security procedures</i>	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 deviations 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 highly hazardous,poisonous and explosive material	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
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	-	-	-	-
<i>Adherence to emergency procedures</i>	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



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0125
NOS Name	Ensure adherence to Environment, health and safety guidelines in a Manufacturing facility and GMP controlled areas
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Generic
NSQF Level	5.0
Credits	2.00
Version	1.0
Last Reviewed Date	29/09/2023
Next Review Date	29/09/2026
NSQC Clearance Date	29/09/2023



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LFS/N0302: Coordinate with Manager, colleagues and auditors

Description

This NOS unit is about the job holder coordinating with the manager, colleagues, and auditors

Scope

The scope covers the following :

- Coordination with manager
- Coordination with colleagues and auditors
- 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
- PC2.** communicate to reporting supervisor about process-flow improvements, production defects received from the previous process, repairs and maintenance of equipment as required
- PC3.** communicate deviations / abnormal incidents to the reporting manager
- PC4.** communicate any potential hazards or expected process disruptions to the manager

Coordination with colleagues and auditors

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

- PC5.** support team members and colleagues of other departments in work
- PC6.** train lab assistants and trainees
- PC7.** find solutions to workflow related difficulties with mutual agreement
- PC8.** coordinate with QA for audit related documentation for QC analysis
- PC9.** maintain sense of calm/equilibrium in self as well as team members
- PC10.** provide clear answers to the auditor's queries
- PC11.** produce the documented records of performed activities and operations to auditors
- PC12.** 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:

- PC13.** respect all genders, religions, and caste
- PC14.** empathize with the people with disability
- PC15.** offer support or help to a person with disability only when asked
- PC16.** ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act
- PC17.** report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee



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Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** company's policies on preferred language of communication, reporting and escalation policy, quality delivery standards, and personnel management
- KU2.** importance of team building skills
- KU3.** stress management strategies to be applied within teams
- KU4.** the types of possible disabilities among people with disability (PwD)
- KU5.** the challenges faced by PwD
- KU6.** the importance of displaying empathy towards PwD
- KU7.** the right way to use the laws acts, and provisions defined for PwD by the statutory bodies
- KU8.** the guidelines laid on Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act
- KU9.** importance of respecting all gender identities, religion, caste, and culture
- KU10.** how to develop a collaborative culture for cross-culture and gender-inclusive team

Generic Skills (GS)

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

- GS1.** use written communication skills to record information accurately in compliance with ALCOA principles as per SOP and GMP guidelines in the English language
- GS2.** use reading and comprehension skills to read the various coding systems, instructions, guidelines, procedures, rules, and signages
- GS3.** use listening skills to understand the instructions and procedures to be followed
- GS4.** use verbal communication skills to interact with colleagues effectively
- GS5.** use team-building skills while interacting with teammates and while managing the difficult/stressful or emotional situations at work
- GS6.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS7.** apply planning and organizing skills to plan and organize tools and material required to fulfil work requirements
- GS8.** apply critical thinking skills to analyze and identify when to report an issue/concern to the lab in charge and when to deal with a colleague individually, depending on the type of concern
- GS9.** apply customer-centricity to remain compliant with data integrity rules, GMP/GLP guidelines and to evaluate the impact of wrongdoings
- GS10.** apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations with clear choices and written instructions

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Coordination with manager</i>	10	20	-	5
PC1. coordinate with the reporting manager to obtain work instructions	-	-	-	-
PC2. communicate to reporting supervisor about process-flow improvements, production defects received from the previous process, repairs and maintenance of equipment as required	-	-	-	-
PC3. communicate deviations / abnormal incidents to the reporting manager	-	-	-	-
PC4. communicate any potential hazards or expected process disruptions to the manager	-	-	-	-
<i>Coordination with colleagues and auditors</i>	15	25	-	5
PC5. support team members and colleagues of other departments in work	-	-	-	-
PC6. train lab assistants and trainees	-	-	-	-
PC7. find solutions to workflow related difficulties with mutual agreement	-	-	-	-
PC8. coordinate with QA for audit related documentation for QC analysis	-	-	-	-
PC9. maintain sense of calm/equilibrium in self as well as team members	-	-	-	-
PC10. provide clear answers to the auditor's queries	-	-	-	-
PC11. produce the documented records of performed activities and operations to auditors	-	-	-	-
PC12. maintain data integrity while responding to auditors and regulatory inspectors	-	-	-	-
<i>Sensitivity towards all genders and people with disability</i>	10	10	-	-
PC13. respect all genders, religions, and caste	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC14. empathize with the people with disability	-	-	-	-
PC15. offer support or help to a person with disability only when asked	-	-	-	-
PC16. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act	-	-	-	-
PC17. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee	-	-	-	-
NOS Total	35	55	-	10



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0302
NOS Name	Coordinate with Manager, colleagues and auditors
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Quality
NSQF Level	5
Credits	2.00
Version	3.0
Last Reviewed Date	29/09/2023
Next Review Date	29/09/2026
NSQC Clearance Date	29/09/2023



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LFS/N0348: Ensure GxP compliance, respond to issues and non-conformance to maintain regulatory standards and procedure

Description

This Job function is about the job holder ensuring the GxP compliance, respond to issues and non-conformance to maintain regulatory standards and procedure

Scope

The scope covers the following :

- The Scope covers the following:
- Regulatory Compliance and Non -Conformance
- Risk Assessment and Quality Management
- Handle Corrective Action and Preventive Action (CAPA)

Elements and Performance Criteria

Regulatory Compliance and Non -Conformance

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

- PC1.** Identify key GxP (GMP ,GLP, GCP, GDP) regulations and their specific requirements in maintaining product quality, patient safety, and regulatory compliance.
- PC2.** Evaluate the potential consequences of non-conformance on product quality and regulatory compliance.
- PC3.** Collect information regarding the nature, context, and scope of the non-conformance incident.
- PC4.** maintain routine monitoring and auditing requirements as specified by SOPs and in accordance to GMP
- PC5.** ensure validation processes are in place and appropriately monitored and reviewed in line with SOPs and guidelines
- PC6.** plan and participate in self-inspections for various departments on the site as per predefined schedules and coordinate with cross functional teams
- PC7.** Apply root cause analysis techniques to investigate non-conformance incidents.
- PC8.** Analyse the potential consequences and risks associated with the non-conformance incident and determine the level of impact on product quality, patient safety, and regulatory compliance.

Risk Assessment and Quality Management

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

- PC9.** Perform risk assessments to evaluate potential impact and likelihood of non-conformance.
- PC10.** Design risk mitigation strategies to ensure product quality and patient safety.
- PC11.** Document non-conformance incidents accurately, including relevant evidence
- PC12.** Prepare comprehensive reports suitable for cross-functional communication and regulatory purposes.



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- PC13.** Communicate effectively to present issues, discuss solutions, and ensure coordinated actions.
- PC14.** Apply continuous improvement principles to suggest enhancements based on non-conformance insights.
- PC15.** Organize and maintain documentation for regulatory inspections related to non-conformance incidents.
- PC16.** Demonstrate readiness and competence during regulatory audits by explaining organizational processes.

Handle Corrective Action and Preventive Action (CAPA)

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

- PC17.** take appropriate corrective and or preventative action in response to compliance issues
- PC18.** Conduct root cause analyses to determine the underlying causes of compliance issues.
- PC19.** communicate appropriately to the organization for any corrective and preventative actions in response to compliance Issues
- PC20.** provide document support to regulatory departments for compilation of various regulatory documents, including verification of in-process quality check documentation
- PC21.** collaborate with the production/packaging teams for providing line clearance regular documentation (online/offline) of all the activities to remove compliance
- PC22.** Monitor and report compliance metrics to track performance and identify areas for improvement.

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** Understanding the key regulations such as Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Good Clinical Practices (GCP), and Good Distribution Practices (GDP) and their specific requirements.
- KU2.** Familiarity with Standard Operating Procedures (SOPs) and guidelines for routine monitoring, auditing, and validation processes.
- KU3.** Competence in root cause analysis techniques to investigate non-conformance incidents.
- KU4.** Ability to assess the potential consequences and risks associated with non-conformance incidents.
- KU5.** Understanding of continuous improvement principles and their application based on non-conformance insights.
- KU6.** Ability to organize and maintain documentation for regulatory inspections.
- KU7.** Effective communication within the organization regarding corrective and preventive actions.
- KU8.** Knowledge of appropriate corrective and preventive action procedures in response to compliance issues.
- KU9.** Understanding quality control and assurance principles, including the ability to ensure product quality meets established standards.
- KU10.** Proficiency in data analysis tools and techniques to assess compliance metrics and identify areas for improvement.

Generic Skills (GS)



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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.** apply decision-making skills to make balanced judgments within the authority while dealing with hazards and breaches
- GS6.** use critical thinking skills to take relevant actions on the accidents and breach in compliance with EHS protocols
- GS7.** use problem-solving skills to determine the root cause and devise a corrective action plan to address it effectively.

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Regulatory Compliance and Non -Conformance</i>	10	15	3	3
PC1. Identify key GxP (GMP ,GLP, GCP, GDP) regulations and their specific requirements in maintaining product quality, patient safety, and regulatory compliance.	-	-	-	-
PC2. Evaluate the potential consequences of non-conformance on product quality and regulatory compliance.	-	-	-	-
PC3. Collect information regarding the nature, context, and scope of the non-conformance incident.	-	-	-	-
PC4. maintain routine monitoring and auditing requirements as specified by SOPs and in accordance to GMP	-	-	-	-
PC5. ensure validation processes are in place and appropriately monitored and reviewed in line with SOPs and guidelines	-	-	-	-
PC6. plan and participate in self-inspections for various departments on the site as per predefined schedules and coordinate with cross functional teams	-	-	-	-
PC7. Apply root cause analysis techniques to investigate non-conformance incidents.	-	-	-	-
PC8. Analyse the potential consequences and risks associated with the non-conformance incident and determine the level of impact on product quality, patient safety, and regulatory compliance.	-	-	-	-
<i>Risk Assessment and Quality Management</i>	10	15	3	3
PC9. Perform risk assessments to evaluate potential impact and likelihood of non-conformance.	-	-	-	-
PC10. Design risk mitigation strategies to ensure product quality and patient safety.	-	-	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC11. Document non-conformance incidents accurately, including relevant evidence	-	-	-	-
PC12. Prepare comprehensive reports suitable for cross-functional communication and regulatory purposes.	-	-	-	-
PC13. Communicate effectively to present issues, discuss solutions, and ensure coordinated actions.	-	-	-	-
PC14. Apply continuous improvement principles to suggest enhancements based on non-conformance insights.	-	-	-	-
PC15. Organize and maintain documentation for regulatory inspections related to non-conformance incidents.	-	-	-	-
PC16. Demonstrate readiness and competence during regulatory audits by explaining organizational processes.	-	-	-	-
<i>Handle Corrective Action and Preventive Action (CAPA)</i>	10	20	4	4
PC17. take appropriate corrective and or preventative action in response to compliance issues	-	-	-	-
PC18. Conduct root cause analyses to determine the underlying causes of compliance issues.	-	-	-	-
PC19. communicate appropriately to the organization for any corrective and preventative actions in response to compliance Issues	-	-	-	-
PC20. provide document support to regulatory departments for compilation of various regulatory documents, including verification of in-process quality check documentation	-	-	-	-
PC21. collaborate with the production/packaging teams for providing line clearance regular documentation (online/offline) of all the activities to remove compliance	-	-	-	-
PC22. Monitor and report compliance metrics to track performance and identify areas for improvement.	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
NOS Total	30	50	10	10



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0348
NOS Name	Ensure GxP compliance, respond to issues and non-conformance to maintain regulatory standards and procedure
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Quality
NSQF Level	5.5
Credits	4.0
Version	1.0
Last Reviewed Date	29/09/2023
Next Review Date	29/09/2026
NSQC Clearance Date	29/09/2023



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DGT/VSQ/N0103: Employability Skills (90 Hours)

Description

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

Scope

The scope covers the following :

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

Elements and Performance Criteria

Introduction to Employability Skills

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

- PC1.** understand the significance of employability skills in meeting the current job market requirement and future of work
- PC2.** identify and explore learning and employability relevant portals
- PC3.** research about the different industries, job market trends, latest skills required and the available opportunities

Constitutional values – Citizenship

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

- PC4.** recognize the significance of constitutional values, including civic rights and duties, citizenship, responsibility towards society etc. and personal values and ethics such as honesty, integrity, caring and respecting others, etc.
- PC5.** follow environmentally sustainable practices

Becoming a Professional in the 21st Century

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

- PC6.** recognize the significance of 21st Century Skills for employment



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- PC7.** practice the 21st Century Skills such as Self-Awareness, Behaviour Skills, time management, critical and adaptive thinking, problem-solving, creative thinking, social and cultural awareness, emotional awareness, learning to learn for continuous learning etc. in personal and professional life
- PC8.** adopt a continuous learning mindset for personal and professional development

Basic English Skills

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

- PC9.** use basic English for everyday conversation in different contexts, in person and over the telephone
- PC10.** read and understand routine information, notes, instructions, mails, letters etc. written in English
- PC11.** write short messages, notes, letters, e-mails etc. in English

Career Development & Goal Setting

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

- PC12.** identify career goals based on the skills, interests, knowledge, and personal attributes
- PC13.** prepare a career development plan with short- and long-term goals

Communication Skills

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

- PC14.** follow verbal and non-verbal communication etiquette while communicating in professional and public settings
- PC15.** use active listening techniques for effective communication
- PC16.** communicate in writing using appropriate style and format based on formal or informal requirements
- PC17.** work collaboratively with others in a team

Diversity & Inclusion

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

- PC18.** communicate and behave appropriately with all genders and PwD
- PC19.** escalate any issues related to sexual harassment at workplace according to POSH Act

Financial and Legal Literacy

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

- PC20.** identify and select reliable institutions for various financial products and services such as bank account, debit and credit cards, loans, insurance etc.
- PC21.** carry out offline and online financial transactions, safely and securely, using various methods and check the entries in the passbook
- PC22.** identify common components of salary and compute income, expenses, taxes, investments etc
- PC23.** identify relevant rights and laws and use legal aids to fight against legal exploitation

Essential Digital Skills

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

- PC24.** operate digital devices and use their features and applications securely and safely
- PC25.** carry out basic internet operations by connecting to the internet safely and securely, using the mobile data or other available networks through Bluetooth, Wi-Fi, etc.
- PC26.** display responsible online behaviour while using various social media platforms



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- PC27.** create a personal email account, send and process received messages as per requirement
- PC28.** carry out basic procedures in documents, spreadsheets and presentations using respective and appropriate applications
- PC29.** utilize virtual collaboration tools to work effectively

Entrepreneurship

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

- PC30.** identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research
- PC31.** develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion
- PC32.** identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity

Customer Service

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

- PC33.** identify different types of customers and ways to communicate with them
- PC34.** identify and respond to customer requests and needs in a professional manner
- PC35.** use appropriate tools to collect customer feedback
- PC36.** follow appropriate hygiene and grooming standards

Getting ready for apprenticeship & Jobs

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

- PC37.** create a professional Curriculum vitae (Résumé)
- PC38.** search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively
- PC39.** apply to identified job openings using offline /online methods as per requirement
- PC40.** answer questions politely, with clarity and confidence, during recruitment and selection
- PC41.** identify apprenticeship opportunities and register for it as per guidelines and requirements

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** need for employability skills and different learning and employability related portals
- KU2.** various constitutional and personal values
- KU3.** different environmentally sustainable practices and their importance
- KU4.** Twenty first (21st) century skills and their importance
- KU5.** how to use English language for effective verbal (face to face and telephonic) and written communication in formal and informal set up
- KU6.** importance of career development and setting long- and short-term goals
- KU7.** about effective communication
- KU8.** POSH Act
- KU9.** Gender sensitivity and inclusivity
- KU10.** different types of financial institutes, products, and services



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- KU11.** components of salary and how to compute income and expenditure
- KU12.** importance of maintaining safety and security in offline and online financial transactions
- KU13.** different legal rights and laws
- KU14.** different types of digital devices and the procedure to operate them safely and securely
- KU15.** how to create and operate an e- mail account
- KU16.** use applications such as word processors, spreadsheets etc.
- KU17.** how to identify business opportunities
- KU18.** types and needs of customers
- KU19.** how to apply for a job and prepare for an interview
- KU20.** apprenticeship scheme and the process of registering on apprenticeship portal

Generic Skills (GS)

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

- GS1.** read and write different types of documents/instructions/correspondence in English and other languages
- GS2.** communicate effectively using appropriate language in formal and informal settings
- GS3.** behave politely and appropriately with all to maintain effective work relationship
- GS4.** how to work in a virtual mode, using various technological platforms
- GS5.** perform calculations efficiently
- GS6.** solve problems effectively
- GS7.** pay attention to details
- GS8.** manage time efficiently
- GS9.** maintain hygiene and sanitization to avoid infection

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Introduction to Employability Skills</i>	1	1	-	-
PC1. understand the significance of employability skills in meeting the current job market requirement and future of work	-	-	-	-
PC2. identify and explore learning and employability relevant portals	-	-	-	-
PC3. research about the different industries, job market trends, latest skills required and the available opportunities	-	-	-	-
<i>Constitutional values – Citizenship</i>	1	1	-	-
PC4. recognize the significance of constitutional values, including civic rights and duties, citizenship, responsibility towards society etc. and personal values and ethics such as honesty, integrity, caring and respecting others, etc.	-	-	-	-
PC5. follow environmentally sustainable practices	-	-	-	-
<i>Becoming a Professional in the 21st Century</i>	1	3	-	-
PC6. recognize the significance of 21st Century Skills for employment	-	-	-	-
PC7. practice the 21st Century Skills such as Self-Awareness, Behaviour Skills, time management, critical and adaptive thinking, problem-solving, creative thinking, social and cultural awareness, emotional awareness, learning to learn for continuous learning etc. in personal and professional life	-	-	-	-
PC8. adopt a continuous learning mindset for personal and professional development	-	-	-	-
<i>Basic English Skills</i>	3	4	-	-
PC9. use basic English for everyday conversation in different contexts, in person and over the telephone	-	-	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC10. read and understand routine information, notes, instructions, mails, letters etc. written in English	-	-	-	-
PC11. write short messages, notes, letters, e-mails etc. in English	-	-	-	-
<i>Career Development & Goal Setting</i>	1	2	-	-
PC12. identify career goals based on the skills, interests, knowledge, and personal attributes	-	-	-	-
PC13. prepare a career development plan with short- and long-term goals	-	-	-	-
<i>Communication Skills</i>	2	2	-	-
PC14. follow verbal and non-verbal communication etiquette while communicating in professional and public settings	-	-	-	-
PC15. use active listening techniques for effective communication	-	-	-	-
PC16. communicate in writing using appropriate style and format based on formal or informal requirements	-	-	-	-
PC17. work collaboratively with others in a team	-	-	-	-
<i>Diversity & Inclusion</i>	1	1	-	-
PC18. communicate and behave appropriately with all genders and PwD	-	-	-	-
PC19. escalate any issues related to sexual harassment at workplace according to POSH Act	-	-	-	-
<i>Financial and Legal Literacy</i>	2	3	-	-
PC20. identify and select reliable institutions for various financial products and services such as bank account, debit and credit cards, loans, insurance etc.	-	-	-	-
PC21. carry out offline and online financial transactions, safely and securely, using various methods and check the entries in the passbook	-	-	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC22. identify common components of salary and compute income, expenses, taxes, investments etc	-	-	-	-
PC23. identify relevant rights and laws and use legal aids to fight against legal exploitation	-	-	-	-
<i>Essential Digital Skills</i>	3	5	-	-
PC24. operate digital devices and use their features and applications securely and safely	-	-	-	-
PC25. carry out basic internet operations by connecting to the internet safely and securely, using the mobile data or other available networks through Bluetooth, Wi-Fi, etc.	-	-	-	-
PC26. display responsible online behaviour while using various social media platforms	-	-	-	-
PC27. create a personal email account, send and process received messages as per requirement	-	-	-	-
PC28. carry out basic procedures in documents, spreadsheets and presentations using respective and appropriate applications	-	-	-	-
PC29. utilize virtual collaboration tools to work effectively	-	-	-	-
<i>Entrepreneurship</i>	2	3	-	-
PC30. identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research	-	-	-	-
PC31. develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion	-	-	-	-
PC32. identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity	-	-	-	-
<i>Customer Service</i>	1	2	-	-
PC33. identify different types of customers and ways to communicate with them	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC34. identify and respond to customer requests and needs in a professional manner	-	-	-	-
PC35. use appropriate tools to collect customer feedback	-	-	-	-
PC36. follow appropriate hygiene and grooming standards	-	-	-	-
<i>Getting ready for apprenticeship & Jobs</i>	2	3	-	-
PC37. create a professional Curriculum vitae (Résumé)	-	-	-	-
PC38. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively	-	-	-	-
PC39. apply to identified job openings using offline /online methods as per requirement	-	-	-	-
PC40. answer questions politely, with clarity and confidence, during recruitment and selection	-	-	-	-
PC41. identify apprenticeship opportunities and register for it as per guidelines and requirements	-	-	-	-
NOS Total	20	30	-	-



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	DGT/VSQ/N0103
NOS Name	Employability Skills (90 Hours)
Sector	Cross Sectoral
Sub-Sector	Professional Skills
Occupation	Employability
NSQF Level	5
Credits	3
Version	1.0
Last Reviewed Date	30/05/2024
Next Review Date	30/05/2027
NSQC Clearance Date	30/05/2024



Qualification Pack

LFS/N0327: Perform various QMS operations.

Description

This OS is about a Quality Management System In charge performing various QMS operations

Scope

The scope covers the following :

- The Scope for this NOS is-
- Implementing operations in compliance with Global Quality Standards CGMPs
- Change Control and CAPA Implementation with QMS
- Undertake product quality reviews and investigations

Elements and Performance Criteria

Implementing operations in compliance with Global Quality Standards cGMP

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

- PC1.** implement, operate and maintain efficient operations on site in compliance with Global Quality Standards and CGMPs
- PC2.** ensures that all the processes, procedures, and practices align with established quality norms.
- PC3.** Timely completes investigations and generates comprehensive reports for market complaints, product recalls, deviations, and Out of Specifications (OOS) etc.
- PC4.** ensures that change controls are maintained and aligned with compliance requirements.
- PC5.** implement error-free spec. / STP documents and maintain their conformance with approved LPs / pharmacopoeias etc
- PC6.** maintains strict conformance to regulatory and quality standards

Change Control and CAPA Implementation with QMS

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

- PC7.** implement and / or close all change control and ensure compliance to Corrective and Preventive Actions (CAPA)
- PC8.** validates compliance with Corrective and Preventive Actions (CAPA) requirements.
- PC9.** initiate, monitor and conclude the product quality review and communicate the findings with the quality management review members and regulatory bodies
- PC10.** implement the quality management system such that it is aligned with the departmental/organizational quality policies/procedures
- PC11.** ensures that the quality framework supports overarching quality goals

Undertake product quality reviews and investigations

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

- PC12.** assist in scheduling and preparation of management review meetings
- PC13.** collaborates with cross-functional teams to drive quality enhancements



Qualification Pack

PC14. assist in design and execution of continuous improvement initiatives to enhance product quality, compliance, drive efficiencies and cost effectiveness in QMS function

PC15. provides support to QA teams in the process and equipment validation process.

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** In-depth knowledge of global quality standards and Current Good Manufacturing Practices (CGMPs)
- KU2.** Ability to align processes, procedures, and practices with established quality norms.
- KU3.** Ability to generate comprehensive reports for market complaints, product recalls, deviations, and Out of Specifications (OOS).
- KU4.** Understanding and implementation of change controls in compliance with regulatory requirements.
- KU5.** Proficiency in creating error-free specifications (spec.) and Standard Test Procedures (STP) documents.
- KU6.** Ability to validate compliance with CAPA requirements, ensuring that corrective and preventive actions are effective in addressing identified issues.
- KU7.** Expertise in implementing the quality management system, aligning it with departmental and organizational quality policies and procedures.
- KU8.** Providing support to QA teams in the process and equipment validation process to ensure compliance and reliability.

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.** apply decision-making skills to make balanced judgments within the authority while dealing with hazards and breaches
- GS6.** use critical thinking skills to take relevant actions on the accidents and breach in compliance with EHS protocols
- GS7.** use problem-solving skills to determine the root cause and devise a corrective action plan to address it effectively.

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Implementing operations in compliance with Global Quality Standards cGMP</i>	10	20	4	4
PC1. implement, operate and maintain efficient operations on site in compliance with Global Quality Standards and CGMPs	-	-	-	-
PC2. ensures that all the processes, procedures, and practices align with established quality norms.	-	-	-	-
PC3. Timely completes investigations and generates comprehensive reports for market complaints, product recalls, deviations, and Out of Specifications (OOS) etc.	-	-	-	-
PC4. ensures that change controls are maintained and aligned with compliance requirements.	-	-	-	-
PC5. implement error-free spec. / STP documents and maintain their conformance with approved LPs / pharmacopoeias etc	-	-	-	-
PC6. maintains strict conformance to regulatory and quality standards	-	-	-	-
<i>Change Control and CAPA Implementation with QMS</i>	10	20	3	3
PC7. implement and / or close all change control and ensure compliance to Corrective and Preventive Actions (CAPA)	-	-	-	-
PC8. validates compliance with Corrective and Preventive Actions (CAPA) requirements.	-	-	-	-
PC9. initiate, monitor and conclude the product quality review and communicate the findings with the quality management review members and regulatory bodies	-	-	-	-
PC10. implement the quality management system such that it is aligned with the departmental/organizational quality policies/procedures	-	-	-	-
PC11. ensures that the quality framework supports overarching quality goals	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Undertake product quality reviews and investigations</i>	10	10	3	3
PC12. assist in scheduling and preparation of management review meetings	-	-	-	-
PC13. collaborates with cross-functional teams to drive quality enhancements	-	-	-	-
PC14. assist in design and execution of continuous improvement initiatives to enhance product quality, compliance, drive efficiencies and cost effectiveness in QMS function	-	-	-	-
PC15. provides support to QA teams in the process and equipment validation process.	-	-	-	-
NOS Total	30	50	10	10



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0327
NOS Name	Perform various QMS operations.
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Quality
NSQF Level	5.5
Credits	3.0
Version	2.0
Last Reviewed Date	29/09/2023
Next Review Date	29/09/2026
NSQC Clearance Date	29/09/2023



Qualification Pack

LFS/N0328: Ensure training related activities and suggesting Improvements to Quality Management System

Description

This OS unit is about a Quality management system in charge ensuring training related activities and suggesting improvements to Quality Management System.

Scope

The scope covers the following :

- Training and Quality Improvement Activities

Elements and Performance Criteria

Training and Quality Improvement related Activities

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

- PC1.** create comprehensive training plans that encompass all relevant roles and responsibilities within the organization.
- PC2.** ensures that training programs align with regulatory requirements and organizational needs.
- PC3.** reviews training materials and content to ensure accuracy, clarity, and relevance.
- PC4.** support in updating the standard operating procedures by identifying improvements
- PC5.** participate in and support quality audits (internal and external), troubleshooting efforts, and other quality system processes
- PC6.** follow-up on action items from quality notifications and management review
- PC7.** provide cross functional support for quality management systems and quality department functions
- PC8.** provide training, technical assistance and share ideas with peers
- PC9.** participate in the implementation and monitoring of the training program
- PC10.** deliver comprehensive training sessions to cross-functional groups on the usage of the electronic document management system (EDMS).
- PC11.** ensure users understand EDMS functionalities, promoting efficient document control practices

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** Expertise in reviewing training materials and content for accuracy, clarity, and relevance to guarantee that information is up-to-date and effectively communicated.
- KU2.** Knowledge of standard operating procedures (SOPs) and the ability to identify areas for improvement, supporting the update and enhancement of procedures.



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- KU3.** Familiarity with quality audit processes, both internal and external, and the ability to actively participate and support these audits, contributing to troubleshooting efforts and other quality system processes.
- KU4.** Understanding the importance of following up on action items from quality notifications and management reviews to ensure timely closure of identified issues.
- KU5.** Ability to provide cross-functional support for quality management systems and various functions within the quality department, fostering collaboration across departments.
- KU6.** Proficiency in delivering comprehensive training sessions to cross-functional groups on the usage of the electronic document management system
- KU7.** Ability to ensure users understand the functionalities of the EDMS, promoting efficient document control practices and adherence to document management procedures.

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.** apply decision-making skills to make balanced judgments within the authority while dealing with hazards and breaches
- GS6.** use critical thinking skills to take relevant actions on the accidents and breach in compliance with EHS protocols
- GS7.** use problem-solving skills to determine the root cause and devise a corrective action plan to address it effectively.

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Training and Quality Improvement related Activities</i>	30	50	10	10
PC1. create comprehensive training plans that encompass all relevant roles and responsibilities within the organization.	-	-	-	-
PC2. ensures that training programs align with regulatory requirements and organizational needs.	-	-	-	-
PC3. reviews training materials and content to ensure accuracy, clarity, and relevance.	-	-	-	-
PC4. support in updating the standard operating procedures by identifying improvements	-	-	-	-
PC5. participate in and support quality audits (internal and external), troubleshooting efforts, and other quality system processes	-	-	-	-
PC6. follow-up on action items from quality notifications and management review	-	-	-	-
PC7. provide cross functional support for quality management systems and quality department functions	-	-	-	-
PC8. provide training, technical assistance and share ideas with peers	-	-	-	-
PC9. participate in the implementation and monitoring of the training program	-	-	-	-
PC10. deliver comprehensive training sessions to cross-functional groups on the usage of the electronic document management system (EDMS).	-	-	-	-
PC11. ensure users understand EDMS functionalities, promoting efficient document control practices	-	-	-	-
NOS Total	30	50	10	10



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0328
NOS Name	Ensure training related activities and suggesting Improvements to Quality Management System
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Quality
NSQF Level	5.5
Credits	3.0
Version	2.0
Last Reviewed Date	29/09/2023
Next Review Date	29/09/2026
NSQC Clearance Date	29/09/2023



Qualification Pack

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

Description

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

Scope

The scope covers the following :

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

Elements and Performance Criteria

Set up enterprise and perform entrepreneurial activities

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

- PC1.** perform a survey in the identified area for business activities to identify prospective customers and business opportunity
- PC2.** identify products and/ or services and its 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 law of law
- PC9.** develop the supply chain and distribution network
- PC10.** maintain updated information regarding new market trends to provide service to customers and constantly upskill self and employees for futuristic technologies, innovations and methodologies

Maintenance of accounts and ledgers

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

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

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

Comply with legal, regulatory and statutory standards

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

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

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

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



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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

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Assessment Criteria

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

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



Qualification Pack

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



Qualification Pack

National Occupational Standards (NOS) Parameters

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



Qualification Pack

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

Description

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

Scope

The scope covers the following :

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

Elements and Performance Criteria

Infrastructure related documentation

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

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

Supply Chain related documentation

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

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



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Documentation for sales & marketing

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

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

Quality audit and client/regulatory inspections related documentation

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

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

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

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

Generic Skills (GS)

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

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



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

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Assessment Criteria

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

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



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National Occupational Standards (NOS) Parameters

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

Assessment Guidelines and Assessment Weightage

Assessment Guidelines

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



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assessment component.

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

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

Minimum Aggregate Passing % at QP Level : 70

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

Minimum Passing % at NOS Level: 70

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

Assessment Weightage

Compulsory NOS

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0125.Ensure adherence to Environment, health and safety guidelines in a Manufacturing facility and GMP controlled areas	30	55	0	15	100	10
LFS/N0302.Coordinate with Manager, colleagues and auditors	35	55	-	10	100	10
LFS/N0348.Ensure GxP compliance, respond to issues and non-conformance to maintain regulatory standards and procedure	30	50	10	10	100	13.33
DGT/VSQ/N0103.Employability Skills (90 Hours)	20	30	-	-	50	6.67
Total	115	190	10	35	350	40

Elective: 1 Quality Management System



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National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0327.Perform various QMS operations.	30	50	10	10	100	13.33
LFS/N0328.Ensure training related activities and suggesting Improvements to Quality Management System	30	50	10	10	100	13.33
Total	60	100	20	20	200	26.66

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	16.67
LFS/N0121.Maintain the critical business documents as Entrepreneur in Life Sciences Sector	20	55	15	10	100	16.67
Total	50	105	27	18	200	33.34