Qualification Pack

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

Equipment validation/ Process validation/ Internal audit/ Quality Management System/ Stability studies

Loan License Audit/ Regulated business Operations

QP Code: LFS/Q0313

Version: 1.0

Qualification Pack

NSQF Level: 5.5

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Contents

Qualification Pack

LFS/Q0313: 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 1: Equipment validation

1. LFS/N0329: Monitor Equipment Validation
2. LFS/N0349: Review documentation for equipment validation
3. LFS/N0350: Perform Equipment Validation for change control

Elective 2: Process validation

1. LFS/N0305: Perform Process validation
2. LFS/N0351: Documentation for process validation
3. LFS/N0352: Perform Process Validation for change control

Elective 3: Internal audit

1. LFS/N0318: Carry out Internal auditing activities
2. LFS/N0317: Carry out vendor audit related activities and perform other additional activities to track performance
3. LFS/N0315: Carry out audit related reporting and documentation to adhere to regulatory and Quality standards

Elective 4: Quality Management System

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

Elective 5: Stability studies

1. LFS/N0309: Perform stability studies
2. LFS/N0310: Carry out reporting and documentation for QC Stability Studies

Options*(Not mandatory):*

Option 1: Loan License Audit

1. LFS/N0353: Perform Loan License Audit and documentation activities

Option 2: Regulated business Operations

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

Qualification Pack

Qualification Pack (QP) Parameters

Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Quality
Country	India
NSQF Level	5.5
Credits	49
Aligned to NCO/ISCO/ISIC Code	NCO-2015/2131.1300
Minimum Educational Qualification & Experience	B.Tech ((in relevant field)) with 2 Years of experience Quality Assurance/Quality Control/production OR B.Pharma 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.Pharma (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
Minimum Level of Education for Training in School	
Pre-Requisite License or Training	NA
Minimum Job Entry Age	21 Years
Last Reviewed On	NA

Qualification Pack

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

Qualification Pack

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

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

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

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

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

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

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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Follow health and hygiene protocols	**10**	**15**	**-**	**5**
PC1. comply with health and personal hygiene-related protocols as per WHO standards 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	**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	-	-	-	-

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

National Occupational Standards (NOS) Parameters

NOS Code	LFS/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

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

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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Coordination with manager	**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	-	-	-	-
Coordination with colleagues and auditors	**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	-	-	-	-
Sensitivity towards all genders and people with disability	**10**	**10**	**-**	**-**
PC13. respect all genders, religions, and caste	-	-	-	-

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**

Qualification Pack

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

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.

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)

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.

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Regulatory Compliance and Non -Conformance	**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.	-	-	-	-
Risk Assessment and Quality Management	**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.	-	-	-	-

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.	-	-	-	-
Handle Corrective Action and Preventive Action (CAPA)	**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.	-	-	-	-

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

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

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

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

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

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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Introduction to Employability Skills	**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	-	-	-	-
Constitutional values – Citizenship	**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	-	-	-	-
Becoming a Professional in the 21st Century	**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	-	-	-	-
Basic English Skills	**3**	**4**	**-**	**-**
PC9. use basic English for everyday conversation in different contexts, in person and over the telephone	-	-	-	-

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	-	-	-	-
Career Development & Goal Setting	**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	-	-	-	-
Communication Skills	**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	-	-	-	-
Diversity & Inclusion	**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	-	-	-	-
Financial and Legal Literacy	**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	-	-	-	-

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	-	-	-	-
Essential Digital Skills	**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	-	-	-	-
Entrepreneurship	**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	-	-	-	-
Customer Service	**1**	**2**	**-**	**-**
PC33. identify different types of customers and ways to communicate with them	-	-	-	-

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	-	-	-	-
Getting ready for apprenticeship & Jobs	**2**	**3**	**-**	**-**
PC37. create a professional Curriculum vitae (Résumé)	-	-	-	-
PC38. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively	-	-	-	-
PC39. apply to identified job openings using offline /online methods as per requirement	-	-	-	-
PC40. answer questions politely, with clarity and confidence, during recruitment and selection	-	-	-	-
PC41. identify apprenticeship opportunities and register for it as per guidelines and requirements	-	-	-	-
NOS Total	**20**	**30**	**-**	**-**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	DGT/VSQ/N0103
NOS Name	Employability Skills (90 Hours)
Sector	Cross Sectoral
Sub-Sector	Professional Skills
Occupation	Employability
NSQF Level	5
Credits	3
Version	1.0
Last Reviewed Date	08/05/2025
Next Review Date	31/10/2025
NSQC Clearance Date	08/05/2025

LFS/N0329: Monitor Equipment Validation

Description

This NOS is about a Specialist QA - Equipment Validation performing the required activities to effectively supervise the quality and validation process

Scope

The scope covers the following :

- The Scope Covers the following:
- Monitoring equipment related activities
- Carrying out miscellaneous activities

Elements and Performance Criteria

Monitoring equipment related activities

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

PC1. Conduct all the equipment monitoring activities comply with regulatory requirements and internal quality standards and ensures that data is consistently collected within appropriate timeframes

PC2. Monitor and track equipment validation schedules to ensure timely completion of validation activities

PC3. Conduct the monitoring process with applicable regulatory requirements to ensure legal and ethical compliance

PC4. Maintains organized records of monitoring activities, including clear documentation of dates, times, and equipment settings.

PC5. Regularly reviews and monitors changes in regulations and standards that affect the monitoring process.

PC6. Identifies potential compliance risks related to monitoring equipment validation.

PC7. Implements risk mitigation strategies to prevent regulatory violations and minimize associated risks.

PC8. Implements corrective actions that prevent recurrence and improve the process.

Carrying out miscellaneous activities

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

PC9. Implements corrective actions to maintain compliance and performance.

PC10. Identifies opportunities for improving the monitoring process

PC11. participate in establishing standard quality and validation practice

PC12. monitor regulatory and inspection trends and report to the higher authorities

PC13. provide monitoring requirements, strategy, protocols, verification tests, execution and final reports for new equipment

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. Comprehensive knowledge of relevant regulations and internal quality standards applicable to the equipment monitoring process.

KU2. Knowledge of equipment validation processes, including qualification and calibration, and their significance in maintaining product quality and regulatory compliance.

KU3. Familiarity with data collection methods, tools, and the importance of consistent and accurate data recording.

KU4. Understanding the legal and ethical obligations related to equipment monitoring, including data privacy and confidentiality.

KU5. Proficiency in maintaining organized records of monitoring activities, including date, time, equipment settings, and any deviations.

KU6. Awareness of changes in regulations and standards, and the ability to monitor and adapt to new requirements affecting the monitoring process.

KU7. identify potential compliance risks related to equipment validation and monitoring.

KU8. Developing and implementing risk mitigation strategies to prevent regulatory violations and minimize associated risks.

KU9. Knowledge of implementing corrective actions to address non-compliance and improve the equipment monitoring process.

KU10. monitor and analyze regulatory and inspection trends and the ability to report findings to higher authorities for informed decision-making

KU11. expertise in providing the requirements, strategy, protocols, verification tests, execution plans, and final reports for the validation of new equipment, ensuring compliance with regulatory and quality standards.

Generic Skills (GS)

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

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

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

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

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

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

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

GS7. Use problem-solving skills to identify potential compliance risks during equipment monitoring

GS8. Apply project management skills when planning, executing, and overseeing equipment monitoring projects, especially those related to the validation of new equipment

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Monitoring equipment related activities	**15**	**25**	**5**	**5**
PC1. Conduct all the equipment monitoring activities comply with regulatory requirements and internal quality standards and ensures that data is consistently collected within appropriate timeframes	-	-	-	-
PC2. Monitor and track equipment validation schedules to ensure timely completion of validation activities	-	-	-	-
PC3. Conduct the monitoring process with applicable regulatory requirements to ensure legal and ethical compliance	-	-	-	-
PC4. Maintains organized records of monitoring activities, including clear documentation of dates, times, and equipment settings.	-	-	-	-
PC5. Regularly reviews and monitors changes in regulations and standards that affect the monitoring process.	-	-	-	-
PC6. Identifies potential compliance risks related to monitoring equipment validation.	-	-	-	-
PC7. Implements risk mitigation strategies to prevent regulatory violations and minimize associated risks.	-	-	-	-
PC8. Implements corrective actions that prevent recurrence and improve the process.	-	-	-	-
Carrying out miscellaneous activities	**15**	**25**	**5**	**5**
PC9. Implements corrective actions to maintain compliance and performance.	-	-	-	-
PC10. Identifies opportunities for improving the monitoring process	-	-	-	-
PC11. participate in establishing standard quality and validation practice	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. monitor regulatory and inspection trends and report to the higher authorities	-	-	-	-
PC13. provide monitoring requirements, strategy, protocols, verification tests, execution and final reports for new equipment	-	-	-	-
NOS Total	**30**	**50**	**10**	**10**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0329
NOS Name	Monitor Equipment Validation
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Quality
NSQF Level	5.5
Credits	2.0
Version	2.0
Last Reviewed Date	29/09/2023
Next Review Date	29/09/2026
NSQC Clearance Date	29/09/2023

LFS/N0349: Review documentation for equipment validation

Description

This job is about the job holder involved in the thorough review and validation of equipment documentation to ensure adherence to regulatory compliance and quality standards."

Scope

The scope covers the following :

- The Scope covers the folowing:
- To Provide Documentation review
- Documentation Compliance and Process Enhancement

Elements and Performance Criteria

To Provide Documentation review

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

PC1. Conduct review equipment validation documentation to ensure alignment with regulatory requirements and internal procedures.

PC2. Ensures that all validation documentation complies with both internal procedures and industry guidelines.

PC3. Review equipment validation protocols, reports, and records for accuracy, completeness, and consistency.

PC4. Validate that all required documentation is present and properly filled out.

PC5. Verify that validation procedures and tests were executed in accordance with defined parameters.

PC6. Evaluate the integrity and traceability of data recorded in the documentation.

PC7. Check that data entries are accurate, properly documented, and easily traceable.

PC8. Ensures data representation is clear and aligned with the validation process.

Documentation Compliance and Process Enhancement

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

PC9. Ensure that equipment validation documentation follows established SOPs

PC10. Review documentation to confirm that risk assessment activities were conducted appropriately.

PC11. Assess how deviations and non-conformances encountered during equipment validation were documented and addressed

PC12. Confirm that corrective actions and preventive measures were implemented effectively.

PC13. Collaborate with validation team members and other stakeholders to address documentation-related issues and concerns.

PC14. Provide guidance and support in resolving documentation challenges and ensuring alignment with requirements.

PC15. Identify opportunities to improve documentation processes and enhance the efficiency and effectiveness of equipment validation.

PC16. Implement improvements to streamline documentation review procedures and promote best practices.

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. Comprehensive knowledge of relevant regulatory requirements, standards, and industry guidelines pertaining to equipment validation documentation.

KU2. Understanding of internal standard operating procedures (SOPs) related to equipment validation and documentation review.

KU3. Familiarity with the various components of equipment validation documentation, including protocols, reports, and records.

KU4. ability to assess the completeness of validation documentation, ensuring that all required forms and records are present and correctly filled out.

KU5. Knowledge of validation procedures and tests, including the parameters and criteria against which they should be executed.

KU6. Proficiency in checking data accuracy, proper documentation, and clarity of data representation in the documentation.

KU7. Understanding of risk assessment methodologies and the ability to review documentation to confirm that risk assessment activities were conducted appropriately.

KU8. Knowledge of how deviations and non-conformances encountered during equipment validation should be documented and addressed.

KU9. Ability to provide guidance and support in resolving documentation challenges and ensuring alignment with requirements.

KU10. Knowledge and skills to implement improvements that streamline documentation review procedures and promote best practices in the organization.

Generic Skills (GS)

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

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

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

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

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

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

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

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

GS8. Strong analytical skills to assess the completeness and accuracy of validation documentation and to identify areas for improvement.

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
To Provide Documentation review	**15**	**25**	**5**	**5**
PC1. Conduct review equipment validation documentation to ensure alignment with regulatory requirements and internal procedures.	-	-	-	-
PC2. Ensures that all validation documentation complies with both internal procedures and industry guidelines.	-	-	-	-
PC3. Review equipment validation protocols, reports, and records for accuracy, completeness, and consistency.	-	-	-	-
PC4. Validate that all required documentation is present and properly filled out.	-	-	-	-
PC5. Verify that validation procedures and tests were executed in accordance with defined parameters.	-	-	-	-
PC6. Evaluate the integrity and traceability of data recorded in the documentation.	-	-	-	-
PC7. Check that data entries are accurate, properly documented, and easily traceable.	-	-	-	-
PC8. Ensures data representation is clear and aligned with the validation process.	-	-	-	-
Documentation Compliance and Process Enhancement	**15**	**25**	**5**	**5**
PC9. Ensure that equipment validation documentation follows established SOPs	-	-	-	-
PC10. Review documentation to confirm that risk assessment activities were conducted appropriately.	-	-	-	-
PC11. Assess how deviations and non-conformances encountered during equipment validation were documented and addressed	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. Confirm that corrective actions and preventive measures were implemented effectively.	-	-	-	-
PC13. Collaborate with validation team members and other stakeholders to address documentation-related issues and concerns.	-	-	-	-
PC14. Provide guidance and support in resolving documentation challenges and ensuring alignment with requirements.	-	-	-	-
PC15. Identify opportunities to improve documentation processes and enhance the efficiency and effectiveness of equipment validation.	-	-	-	-
PC16. Implement improvements to streamline documentation review procedures and promote best practices.	-	-	-	-
NOS Total	**30**	**50**	**10**	**10**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0349
NOS Name	Review documentation for equipment validation
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Quality
NSQF Level	5.5
Credits	2.0
Version	1.0
Last Reviewed Date	29/09/2023
Next Review Date	29/09/2026
NSQC Clearance Date	29/09/2023

LFS/N0350: Perform Equipment Validation for change control

Description

This Job is about the job holder Performing Equipment Validation for change control

Scope

The scope covers the following :

- The Scope Covers the following:
- Change Control and Validation Strategy Development
- Execution and Data Collection
- Documentation and Reporting

Elements and Performance Criteria

Change Control and Validation Strategy Development

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

PC1. Evaluate proposed changes to equipment and processes etc and assessing their impact on validation requirements

PC2. Analyze the scope and extent of the changes to determine the necessary validation activities.

PC3. Develop comprehensive validation protocols that cover all critical aspects of the equipment and process changes.

PC4. Ensure validation protocols align with regulatory guidelines, industry best practices, and internal quality standards.

PC5. Conduct a thorough risk assessment to identify potential risks associated with equipment changes.

PC6. Collaborate with relevant stakeholders, including engineering, production, and quality teams, to gather input and ensure alignment on validation plans.

PC7. Identifies areas for improving equipment validation processes within change control.

Execution and Data Collection

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

PC8. Conduct equipment testing, including all relevant parameters functional, performance, and qualification testing, as per the validation protocols.

PC9. Collect accurate and reliable data during validation activities, ensuring adherence to predefined data collection methods.

PC10. Analyze collected data to draw conclusions and make informed decisions regarding the validation outcomes.

PC11. Verify that validation documentation meets regulatory expectations and internal change control procedures.

Documentation and Reporting

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

PC12. Reviews change control documentation comprehensively to understand modifications.

PC13. Identifies potential impacts on equipment performance, reliability, and regulatory compliance.

PC14. Ensures proposed changes comply with relevant regulations and industry standards.

PC15. Validates that changes will maintain compliance throughout equipment validation

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. Comprehensive understanding of change control processes, including evaluating and assessing proposed changes to equipment and processes.

KU2. Proficiency in the principles and concepts of validation, encompassing equipment, processes, and associated regulatory requirements.

KU3. ability to assess the impact of proposed changes on validation requirements, including their scope and extent.

KU4. Knowledge of validation protocol development, ensuring comprehensive coverage of critical aspects related to equipment and process changes

KU5. Proficiency in collaborating with relevant stakeholders from engineering, production, and quality teams to gather input and align on validation plans.

KU6. Knowledge of equipment testing methods, including functional, performance, and qualification testing, as specified in validation protocols.

KU7. Proficiency in data collection methods, ensuring the accurate and reliable collection of data during validation activities.

KU8. analyze collected data, draw conclusions, and make informed decisions regarding the outcomes of validation activities.

KU9. Proficiency in reviewing change control documentation to understand modifications and their potential impact on equipment performance, reliability, and regulatory compliance.

KU10. Comprehensive knowledge of relevant regulations and industry standards, ensuring proposed changes comply with these requirements.

Generic Skills (GS)

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

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

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

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

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

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

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

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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Change Control and Validation Strategy Development	**10**	**20**	**4**	**4**
PC1. Evaluate proposed changes to equipment and processes etc and assessing their impact on validation requirements	-	-	-	-
PC2. Analyze the scope and extent of the changes to determine the necessary validation activities.	-	-	-	-
PC3. Develop comprehensive validation protocols that cover all critical aspects of the equipment and process changes.	-	-	-	-
PC4. Ensure validation protocols align with regulatory guidelines, industry best practices, and internal quality standards.	-	-	-	-
PC5. Conduct a thorough risk assessment to identify potential risks associated with equipment changes.	-	-	-	-
PC6. Collaborate with relevant stakeholders, including engineering, production, and quality teams, to gather input and ensure alignment on validation plans.	-	-	-	-
PC7. Identifies areas for improving equipment validation processes within change control.	-	-	-	-
Execution and Data Collection	**10**	**10**	**3**	**3**
PC8. Conduct equipment testing, including all relevant parameters functional, performance, and qualification testing, as per the validation protocols.	-	-	-	-
PC9. Collect accurate and reliable data during validation activities, ensuring adherence to predefined data collection methods.	-	-	-	-
PC10. Analyze collected data to draw conclusions and make informed decisions regarding the validation outcomes.	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC11. Verify that validation documentation meets regulatory expectations and internal change control procedures.	-	-	-	-
Documentation and Reporting	**10**	**20**	**3**	**3**
PC12. Reviews change control documentation comprehensively to understand modifications.	-	-	-	-
PC13. Identifies potential impacts on equipment performance, reliability, and regulatory compliance.	-	-	-	-
PC14. Ensures proposed changes comply with relevant regulations and industry standards.	-	-	-	-
PC15. Validates that changes will maintain compliance throughout equipment validation	-	-	-	-
NOS Total	**30**	**50**	**10**	**10**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0350
NOS Name	Perform Equipment Validation for change control
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Quality
NSQF Level	5.5
Credits	2.0
Version	1.0
Last Reviewed Date	29/09/2023
Next Review Date	29/09/2026
NSQC Clearance Date	29/09/2023

LFS/N0305: Perform Process validation

Description

This NOS is about a Specialist QA - Process Validation performing the required activities to effectively carry out process validation .

Scope

The scope covers the following :

- The Scope covers the following:
- Carrying out various activities of process validation
- Preparing process validation documents
- Providing support in quality assurance activities applicable to process validation
- Maintaining processes and systems in compliance with current Good Manufacturing Practices (GMPs) and Good Laboratory Practices (GLPs)

Elements and Performance Criteria

Carrying out various activities of process validation.

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

PC1. coordination and performance of QC method qualifications, validations and transfers

PC2. responsible for the preparation and execution of process validation protocols for new products and for changes to existing products

PC3. support in making related changes to the process if the same have become obsolete.

PC4. organisation and execution of process development trials

PC5. develop testing strategies and rationale for equipment and systems.

PC6. manage the change requests and Corrective And Preventive Action Systems (CAPAS) that relate to process validation

PC7. develop and execute risk assessments.

Preparing process validation documents

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

PC8. maintain complete and accurate documentary evidence concerning Qualification and Validation exercises that the processes of the company (specific manufacturing process of the product) would consistently produce the desired quality of product meeting its predetermined specification

PC9. contribute towards company procedures (SOPs) regarding validations

PC10. create documents to ensure compliance with applicable quality objectives and regulatory requirements

PC11. maintain organization and archive of completed validation and qualification document packages

Providing support in quality assurance activities applicable to process validation

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

PC12. participate in establishing standard quality and validation practice.

PC13. ensure compliance with applicable quality objectives and regulatory requirements

PC14. liaise with QA, Production, technical services and NPI when necessary on process validation issues.

PC15. plan and coordinate all process validation testing with QC and review validation analytical data.

PC16. conduct reviews of previous qualifications and establish re-qualification programme where appropriate.

PC17. troubleshoot / investigate validation-related deviations.

Maintaining processes and systems in compliance with current Good Manufacturing Practices (GMPs) and Good Laboratory Practices (GLPs)

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

PC18. monitor regulatory and inspection trends and report to the higher authorities

PC19. responsible for ensuring conformance with current process validation regulations.

PC20. responsible person to liaise with auditors on process validation.

PC21. maintain routine programs and processes to ensure high quality products and compliance with current Good Manufacturing Practices (GMPs) and Good Laboratory Practices (GLPs)

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. In-depth knowledge of process validation methodologies and principles, including risk assessment, and validation protocols.

KU2. Understanding of industry-specific regulatory requirements and the ability to ensure compliance with these regulations.

KU3. Familiarity with change control procedures and the ability to manage changes to processes and equipment effectively.

KU4. Understanding of the importance of accurate documentation and maintaining complete records of validation exercises.

KU5. Knowledge of quality assurance principles and the ability to support quality assurance activities related to process validation.

KU6. Ability to investigate and troubleshoot validation-related deviations and implement corrective and preventive actions

KU7. Understanding of how to facilitate audits and address audit findings.

KU8. Understanding of how to contribute to the development and maintenance of Standard Operating Procedures (SOPs).

KU9. how to develop testing strategies for equipment and systems, including data analysis.

Generic Skills (GS)

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

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

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

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

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

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

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

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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Carrying out various activities of process validation.	**10**	**20**	**3**	**3**
PC1. coordination and performance of QC method qualifications, validations and transfers	-	-	-	-
PC2. responsible for the preparation and execution of process validation protocols for new products and for changes to existing products	-	-	-	-
PC3. support in making related changes to the process if the same have become obsolete.	-	-	-	-
PC4. organisation and execution of process development trials	-	-	-	-
PC5. develop testing strategies and rationale for equipment and systems.	-	-	-	-
PC6. manage the change requests and Corrective And Preventive Action Systems (CAPAS) that relate to process validation	-	-	-	-
PC7. develop and execute risk assessments.	-	-	-	-
Preparing process validation documents	**10**	**10**	**3**	**3**
PC8. maintain complete and accurate documentary evidence concerning Qualification and Validation exercises that the processes of the company (specific manufacturing process of the product) would consistently produce the desired quality of product meeting its predetermined specification	-	-	-	-
PC9. contribute towards company procedures (SOPs) regarding validations	-	-	-	-
PC10. create documents to ensure compliance with applicable quality objectives and regulatory requirements	-	-	-	-
PC11. maintain organization and archive of completed validation and qualification document packages	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Providing support in quality assurance activities applicable to process validation	**5**	**10**	**2**	**2**
PC12. participate in establishing standard quality and validation practice.	-	-	-	-
PC13. ensure compliance with applicable quality objectives and regulatory requirements	-	-	-	-
PC14. liaise with QA, Production, technical services and NPI when necessary on process validation issues.	-	-	-	-
PC15. plan and coordinate all process validation testing with QC and review validation analytical data.	-	-	-	-
PC16. conduct reviews of previous qualifications and establish re-qualification programme where appropriate.	-	-	-	-
PC17. troubleshoot / investigate validation-related deviations.	-	-	-	-
Maintaining processes and systems in compliance with current Good Manufacturing Practices (GMPs) and Good Laboratory Practices (GLPs)	**5**	**10**	**2**	**2**
PC18. monitor regulatory and inspection trends and report to the higher authorities	-	-	-	-
PC19. responsible for ensuring conformance with current process validation regulations.	-	-	-	-
PC20. responsible person to liaise with auditors on process validation.	-	-	-	-
PC21. maintain routine programs and processes to ensure high quality products and compliance with current Good Manufacturing Practices (GMPs) and Good Laboratory Practices (GLPs)	-	-	-	-
NOS Total	**30**	**50**	**10**	**10**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0305
NOS Name	Perform Process validation
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Quality
NSQF Level	5.5
Credits	2.0
Version	2.0
Last Reviewed Date	29/09/2023
Next Review Date	29/09/2026
NSQC Clearance Date	29/09/2023

LFS/N0351: Documentation for process validation

Description

This job function is about the job holder involves in creating and managing regulatory-compliant documentation, maintaining records, and facilitating change control processes to ensure process validation.

Scope

The scope covers the following :

- The Scope Covers the following:
- To Provide Process Documentation review
- Documentation Compliance and Process Enhancement

Elements and Performance Criteria

To Provide Process Documentation review

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

PC1. Conduct review of process validation documentation to ensure alignment with regulatory requirements and internal procedures.

PC2. Ensures that all process validation documentation complies with both internal procedures and industry guidelines.

PC3. Review process validation protocols, reports, and records for accuracy, completeness, and consistency.

PC4. Validate that all required documentation is present and properly filled out.

PC5. Verify that validation procedures and tests were executed in accordance with defined parameters.

PC6. Evaluate the integrity and traceability of data recorded in the documentation.

Documentation Compliance and Process Enhancement

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

PC7. Ensure that process validation documentation as per follows established SOPs.

PC8. Review documentation to confirm that risk assessment activities were conducted appropriately.

PC9. Assess how deviations and non-conformances encountered during process validation were documented and addressed.

PC10. Confirm that corrective actions and preventive measures were implemented effectively.

PC11. Collaborate with validation team members and other stakeholders to address documentation-related issues and concerns.

PC12. Provide guidance and support in resolving documentation challenges and ensuring alignment with requirements.

PC13. Identify opportunities to improve documentation processes and enhance the efficiency and effectiveness of equipment validation.

PC14. Implement improvements to streamline documentation review procedures and promote best practices.

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. Knowledge of relevant industry-specific regulations and standards governing process validation documentation.

KU2. Understanding of document review procedures, including accuracy, completeness, and consistency checks.

KU3. Knowledge of maintaining data integrity and traceability within documentation.

KU4. Familiarity with quality control and assurance processes in documentation review.

KU5. Knowledge of risk assessment methodologies and how they apply to documentation review

KU6. Understanding of how deviations and non-conformances are documented and addressed during process validation.

KU7. Ability to identify opportunities for process enhancement, streamline review procedures, and promote best practices in documentation.

KU8. Proficiency in assessing and confirming the effectiveness of CAPAs in addressing issues.

Generic Skills (GS)

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

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

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

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

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

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

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

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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
To Provide Process Documentation review	**15**	**25**	**5**	**5**
PC1. Conduct review of process validation documentation to ensure alignment with regulatory requirements and internal procedures.	-	-	-	-
PC2. Ensures that all process validation documentation complies with both internal procedures and industry guidelines.	-	-	-	-
PC3. Review process validation protocols, reports, and records for accuracy, completeness, and consistency.	-	-	-	-
PC4. Validate that all required documentation is present and properly filled out.	-	-	-	-
PC5. Verify that validation procedures and tests were executed in accordance with defined parameters.	-	-	-	-
PC6. Evaluate the integrity and traceability of data recorded in the documentation.	-	-	-	-
Documentation Compliance and Process Enhancement	**15**	**25**	**5**	**5**
PC7. Ensure that process validation documentation as per follows established SOPs.	-	-	-	-
PC8. Review documentation to confirm that risk assessment activities were conducted appropriately.	-	-	-	-
PC9. Assess how deviations and non-conformances encountered during process validation were documented and addressed.	-	-	-	-
PC10. Confirm that corrective actions and preventive measures were implemented effectively.	-	-	-	-
PC11. Collaborate with validation team members and other stakeholders to address documentation-related issues and concerns.	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. Provide guidance and support in resolving documentation challenges and ensuring alignment with requirements.	-	-	-	-
PC13. Identify opportunities to improve documentation processes and enhance the efficiency and effectiveness of equipment validation.	-	-	-	-
PC14. Implement improvements to streamline documentation review procedures and promote best practices.	-	-	-	-
NOS Total	**30**	**50**	**10**	**10**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0351
NOS Name	Documentation for process validation
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Quality
NSQF Level	5.5
Credits	2.0
Version	1.0
Last Reviewed Date	29/09/2023
Next Review Date	29/09/2026
NSQC Clearance Date	29/09/2023

LFS/N0352: Perform Process Validation for change control

Description

This Job function is about the job holder responsible for performing Process Validation for change control

Scope

The scope covers the following :

- The Scope Covers the following:
- Change Control and Validation Strategy Development
- Execution and Data Collection
- Documentation and Reporting

Elements and Performance Criteria

Change Control and Validation Strategy Development

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

PC1. Evaluate proposed changes to equipment and processes, assessing their impact on validation requirements.

PC2. Analyze the scope and extent of the changes to determine the necessary validation activities

PC3. Develop comprehensive validation protocols that cover all critical aspects of the process changes.

PC4. Ensure validation protocols align with regulatory guidelines, industry best practices, and internal quality standards.

PC5. Conduct a thorough risk assessment to identify potential risks associated with process changes.

PC6. Collaborate with relevant stakeholders, including engineering, production, and quality teams, to gather input and ensure alignment on validation plans.

PC7. Identifies areas for improving process validation processes within change control.

Execution and Data Collection

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

PC8. Conduct equipment testing, including all relevant parameters functional, performance, and qualification testing, as per the validation protocols.

PC9. Collect accurate and reliable data during validation activities, ensuring adherence to predefined data collection methods.

PC10. Analyze collected data to draw conclusions and make informed decisions regarding the validation outcomes.

PC11. Verify that validation documentation meets regulatory expectations and internal change control procedures

Documentation and Reporting

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

PC12. Reviews change control documentation comprehensively to understand modifications.

PC13. Identifies potential impacts on process performance, reliability, and regulatory compliance.

PC14. Ensures proposed changes comply with relevant regulations and industry standards.

PC15. Validates that changes will maintain compliance throughout process validation

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. Understanding of relevant regulatory requirements and guidelines governing change control and validation processes.

KU2. Knowledge of how to assess the impact of proposed changes on equipment and processes in terms of validation requirements.

KU3. Ability to conduct in-depth risk assessments to identify and mitigate potential risks associated with process changes.

KU4. Knowledge of process improvement methodologies

KU5. Ability to identify areas for enhancing the process validation process within change control.

KU6. Proficiency in collecting accurate and reliable data during validation activities and analyzing it to make informed decisions

KU7. Understanding of how to ensure that proposed changes comply with relevant regulations and industry standards throughout the process validation.

Generic Skills (GS)

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

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

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

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

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

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

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

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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Change Control and Validation Strategy Development	**10**	**20**	**4**	**4**
PC1. Evaluate proposed changes to equipment and processes, assessing their impact on validation requirements.	-	-	-	-
PC2. Analyze the scope and extent of the changes to determine the necessary validation activities	-	-	-	-
PC3. Develop comprehensive validation protocols that cover all critical aspects of the process changes.	-	-	-	-
PC4. Ensure validation protocols align with regulatory guidelines, industry best practices, and internal quality standards.	-	-	-	-
PC5. Conduct a thorough risk assessment to identify potential risks associated with process changes.	-	-	-	-
PC6. Collaborate with relevant stakeholders, including engineering, production, and quality teams, to gather input and ensure alignment on validation plans.	-	-	-	-
PC7. Identifies areas for improving process validation processes within change control.	-	-	-	-
Execution and Data Collection	**10**	**10**	**3**	**3**
PC8. Conduct equipment testing, including all relevant parameters functional, performance, and qualification testing, as per the validation protocols.	-	-	-	-
PC9. Collect accurate and reliable data during validation activities, ensuring adherence to predefined data collection methods.	-	-	-	-
PC10. Analyze collected data to draw conclusions and make informed decisions regarding the validation outcomes.	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC11. Verify that validation documentation meets regulatory expectations and internal change control procedures	-	-	-	-
Documentation and Reporting	**10**	**20**	**3**	**3**
PC12. Reviews change control documentation comprehensively to understand modifications.	-	-	-	-
PC13. Identifies potential impacts on process performance, reliability, and regulatory compliance.	-	-	-	-
PC14. Ensures proposed changes comply with relevant regulations and industry standards.	-	-	-	-
PC15. Validates that changes will maintain compliance throughout process validation	-	-	-	-
NOS Total	**30**	**50**	**10**	**10**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0352
NOS Name	Perform Process Validation for change control
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Quality
NSQF Level	5.5
Credits	2.0
Version	1.0
Last Reviewed Date	29/09/2023
Next Review Date	29/09/2026
NSQC Clearance Date	29/09/2023

LFS/N0318: Carry out Internal auditing activities

Description

This NOS is about a performing the required activities to effectively carry out internal auditing activities.

Scope

The scope covers the following :

- the scope of this NOS is:
- Participating in internal process reviews
- Conducting various GMP and GLP Audits
- Preparing the sites for regulatory and audit inspections

Elements and Performance Criteria

Participating in internal process reviews

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

PC1. participate in internal process reviews and operational excellence initiatives, both within the department and company-wide

PC2. participates in internal inspections, ensuring compliance with quality standards and norms

PC3. plan and verify the implementation status of Corrective and Preventive Actions (CAPA) following inspections.

PC4. analyzes audit, inspection, and assessment outcomes to ensure alignment with regulatory standards

Conducting various GMP and GLP Audits

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

PC5. plans and executes GMP and GLP audits, ensuring comprehensive coverage of critical areas.

PC6. monitor batch and continuous manufacturing records for any incident/deviations in manufacturing, equipment, System, Utilities

PC7. perform the audits using knowledge of regulatory requirements and knowledge of biopharmaceutical operations in areas including but not limited to QC, QA, manufacturing, materials management, supply chain and validation

PC8. Ensures audits are conducted with a deep understanding of regulatory expectations.

Preparing the sites for regulatory and audit inspections

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

PC9. maintains audit status in real-time within the designated tracking system or tool

PC10. prepare and review external and internal reports and other documentation required by regulatory agencies, or customers, to support the quality assurance function

PC11. establish and maintain quality systems to support good clinical practice

PC12. design and implement tracking mechanisms and process improvement for training compliance

PC13. prepare the site for regulatory agency inspections

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. organizational coding system of finished materials, compounds and company manual
KU2. different quality management systems (ISO-9000, ISO-14001,OHSAS18000) and good laboratory and manufacturing practices
KU3. quality systems and procedures
KU4. audit methodology and internal controls
KU5. pharmaceutical regulations and guidelines
KU6. types of documentation in organization, importance of maintaining the same and different methods of recording information
KU7. method of preparing audit plans, audit reports, audit responses
KU8. method of reporting incidents where standard operating procedures are not followed
KU9. the appropriate authority for reporting any imbalances
KU10. key quality systems (market complaints, deviations management, internal audit, training, handling of recalls, etc.)
KU11. all concepts that are taught as part of the professional certification in audit
KU12. different standard reference materials
KU13. global quality and compliance principles
KU14. pharmaceutical manufacturing, packaging, quality assurance, and quality control operations
KU15. importance of quality checks along with quality and production targets
KU16. methods and techniques involved in evaluating information

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.

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Participating in internal process reviews	**10**	**15**	**3**	**3**
PC1. participate in internal process reviews and operational excellence initiatives, both within the department and company-wide	-	-	-	-
PC2. participates in internal inspections, ensuring compliance with quality standards and norms	-	-	-	-
PC3. plan and verify the implementation status of Corrective and Preventive Actions (CAPA) following inspections.	-	-	-	-
PC4. analyzes audit, inspection, and assessment outcomes to ensure alignment with regulatory standards	-	-	-	-
Conducting various GMP and GLP Audits	**10**	**20**	**4**	**4**
PC5. plans and executes GMP and GLP audits, ensuring comprehensive coverage of critical areas.	-	-	-	-
PC6. monitor batch and continuous manufacturing records for any incident/deviations in manufacturing, equipment, System, Utilities	-	-	-	-
PC7. perform the audits using knowledge of regulatory requirements and knowledge of biopharmaceutical operations in areas including but not limited to QC, QA, manufacturing, materials management, supply chain and validation	-	-	-	-
PC8. Ensures audits are conducted with a deep understanding of regulatory expectations.	-	-	-	-
Preparing the sites for regulatory and audit inspections	**10**	**15**	**3**	**3**
PC9. maintains audit status in real-time within the designated tracking system or tool	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC10. prepare and review external and internal reports and other documentation required by regulatory agencies, or customers, to support the quality assurance function	-	-	-	-
PC11. establish and maintain quality systems to support good clinical practice	-	-	-	-
PC12. design and implement tracking mechanisms and process improvement for training compliance	-	-	-	-
PC13. prepare the site for regulatory agency inspections	-	-	-	-
NOS Total	**30**	**50**	**10**	**10**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0318
NOS Name	Carry out Internal auditing activities
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Quality
NSQF Level	5.5
Credits	2.0
Version	2.0
Last Reviewed Date	29/09/2023
Next Review Date	29/09/2026
NSQC Clearance Date	29/09/2023

LFS/N0317: Carry out vendor audit related activities and perform other additional activities to track performance

Description

This NOS unit is about to carry out vendor audit related activities and perform other additional activities to track performance

Scope

The scope covers the following :

- The scope of this NOS is
- Providing support for on-site vendor regulatory audit
- Managing and reviewing vendor related documents
- Preparing metrics to track performance of each department and vendor

Elements and Performance Criteria

Providing support for on-site vendor regulatory audit

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

PC1. identifies potential areas for improvement and regulatory alignment

PC2. perform on-site audits of vendors to ensure satisfactory regulatory compliance and quality standards

PC3. facilitate and provide support for on-site customer and regulatory audit/inspections

PC4. ensure adherence to quality agreements with vendors and business partners by providing inputs on opportunities for quality standards improvements

Managing and reviewing vendor related documents

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

PC5. review and manage GMP related documents and activities in order to support GMP manufacturing at vendor sites

PC6. ensures that documentation reflects adherence to established standards

PC7. review and manage the vendor documents the In-house Checklist or Questionnarie

PC8. validates that records are accurate and aligned with regulatory expectations

Preparing metrics to track performance of each department and vendor

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

PC9. • defines a robust framework for identifying, analyzing, and handling vendor
• issues.

PC10. develops an online system for efficient issue detection, tracking, and closure

PC11. maintain routine programs and processes to ensure high quality products and compliance with current Good Manufacturing Practices(GMPs) and Good Laboratory Practices(GLPs)

PC12. conducts thorough follow-up procedures to verify the implementation and effectiveness of action plans resulting from audits.

PC13. prepare metrics to track performance of each department and vendor

PC14. provides a data-driven approach to monitoring and improving vendor relationships

PC15. release or hold the manufacturing for further inspection according to findings

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. pharmaceutical regulations and guidelines

KU2. risk and impact of not following defined procedures/work instructions

KU3. types of documentation used in the organization, importance of maintaining the same and different methods of recording information

KU4. impact of various practices on cost, quality, productivity, delivery and safety

KU5. the importance of complete and accurate documentation

KU6. implications (impact on internal/external customers) of defective products, materials or components

KU7. the reason and impact of the occurrence of problems

KU8. measures, steps and possible solutions that have been taken/identified to address the previous problems

KU9. the correct method for carrying out corrective actions outlined for each problem

KU10. key quality systems (market complaints, deviations management, internal audit, training, handling of recalls, etc.)

KU11. steps and requirements for vendor on boarding

KU12. vendor compliances and awareness of common scientific and technical journals

KU13. method of interpreting financial reports (as needed) and legal documents and translating operational limits in to protocol acceptance criteria

KU14. application of statistical ,risk assessment, experimental design and process improvement tools

KU15. stability guidance documents, GMP documentation and pharmaceutical quality systems

KU16. pharmaceutical GMPs and regulatory requirements

KU17. inspection or test points (control points) in the process and the related procedures and recording requirements

KU18. common causes of variation and corrective action required

KU19. procedures and responsibility for reporting production and performance information

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.

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Providing support for on-site vendor regulatory audit	**10**	**20**	**4**	**4**
PC1. identifies potential areas for improvement and regulatory alignment	-	-	-	-
PC2. perform on-site audits of vendors to ensure satisfactory regulatory compliance and quality standards	-	-	-	-
PC3. facilitate and provide support for on-site customer and regulatory audit/inspections	-	-	-	-
PC4. ensure adherence to quality agreements with vendors and business partners by providing inputs on opportunities for quality standards improvements	-	-	-	-
Managing and reviewing vendor related documents	**10**	**10**	**3**	**3**
PC5. review and manage GMP related documents and activities in order to support GMP manufacturing at vendor sites	-	-	-	-
PC6. ensures that documentation reflects adherence to established standards	-	-	-	-
PC7. review and manage the vendor documents the In-house Checklist or Questionnarie	-	-	-	-
PC8. validates that records are accurate and aligned with regulatory expectations	-	-	-	-
Preparing metrics to track performance of each department and vendor	**10**	**20**	**3**	**3**
PC9. • defines a robust framework for identifying, analyzing, and handling vendor • issues.	-	-	-	-
PC10. develops an online system for efficient issue detection, tracking, and closure	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC11. maintain routine programs and processes to ensure high quality products and compliance with current Good Manufacturing Practices(GMPs) and Good Laboratory Practices(GLPs)	-	-	-	-
PC12. conducts thorough follow-up procedures to verify the implementation and effectiveness of action plans resulting from audits.	-	-	-	-
PC13. prepare metrics to track performance of each department and vendor	-	-	-	-
PC14. provides a data-driven approach to monitoring and improving vendor relationships	-	-	-	-
PC15. release or hold the manufacturing for further inspection according to findings	-	-	-	-
NOS Total	**30**	**50**	**10**	**10**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0317
NOS Name	Carry out vendor audit related activities and perform other additional activities to track performance
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Biotechnology
Occupation	Quality
NSQF Level	5.5
Credits	2.00
Version	2.0
Last Reviewed Date	29/09/2023
Next Review Date	29/09/2026
NSQC Clearance Date	29/09/2023

LFS/N0315: Carry out audit related reporting and documentation to adhere to regulatory and Quality standards

Description

This NOS is about a carrying out audit related reporting and documentation to adhere to regulatory and Quality standards

Scope

The scope covers the following :

- Reporting of discrepancies
- Recording and Documentation
- Information Security

Elements and Performance Criteria

Reporting of discrepancies

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

PC1. report data/problems/incidents as applicable in a timely manner

PC2. report to the appropriate authority as laid down by the company

PC3. follow reporting procedures as prescribed by the company

Recording and Documentation

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

PC4. identify documentation to be completed relating to ones role

PC5. record details accurately in an appropriate format

PC6. complete all documentation within stipulated time according to company procedure

PC7. ensure that the final document meets regulatory and compliance requirements

PC8. make sure documents are available to all appropriate authorities to inspect

Information Security

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

PC9. respond to requests for information in an appropriate manner whilst following organizational procedures

PC10. inform the appropriate authority of requests for information received

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. method of reporting incidents where standard operating procedures are not followed

KU2. the importance of complete and accurate documentation

KU3. Knowledge of the appropriate authority to whom reports should be submitted

KU4. Familiarity with company-prescribed reporting procedures.

KU5. Understanding the accurate recording of details in an appropriate format.

KU6. Awareness of the stipulated timeframes for completing all documentation in accordance with company procedures.

KU7. Knowledge of regulatory and compliance requirements for the final document.

KU8. Understanding the process to ensure availability of documents for inspection by relevant authorities.

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.

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Reporting of discrepancies	**15**	**20**	**4**	**4**
PC1. report data/problems/incidents as applicable in a timely manner	-	-	-	-
PC2. report to the appropriate authority as laid down by the company	-	-	-	-
PC3. follow reporting procedures as prescribed by the company	-	-	-	-
Recording and Documentation	**10**	**15**	**3**	**3**
PC4. identify documentation to be completed relating to ones role	-	-	-	-
PC5. record details accurately in an appropriate format	-	-	-	-
PC6. complete all documentation within stipulated time according to company procedure	-	-	-	-
PC7. ensure that the final document meets regulatory and compliance requirements	-	-	-	-
PC8. make sure documents are available to all appropriate authorities to inspect	-	-	-	-
Information Security	**5**	**15**	**3**	**3**
PC9. respond to requests for information in an appropriate manner whilst following organizational procedures	-	-	-	-
PC10. inform the appropriate authority of requests for information received	-	-	-	-
NOS Total	**30**	**50**	**10**	**10**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0315
NOS Name	Carry out audit related reporting and documentation to adhere to regulatory and Quality standards
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Biotechnology
Occupation	Quality
NSQF Level	5.5
Credits	2.00
Version	2.0
Last Reviewed Date	29/09/2023
Next Review Date	29/09/2026
NSQC Clearance Date	29/09/2023

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

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.

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Implementing operations in compliance with Global Quality Standards cGMP	**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	-	-	-	-
Change Control and CAPA Implementation with QMS	**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	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Undertake product quality reviews and investigations	**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

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.

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.

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Training and Quality Improvement related Activities	**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

LFS/N0309: Perform stability studies

Description

This NOS is about a stability specialist performing the required activities related to stability activities and effectively supporting in quality checks of the drug products.

Scope

The scope covers the following :

- Conducting Effective Stability Studies
- Stability Studies Management and Execution

Elements and Performance Criteria

Conducting Effective Stability Studies

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

PC1. Develop robust stability study protocols aligned with guidelines and best practices.
PC2. Design an effective strategy for accurate sample collection over time
PC3. Maintain accurate and organized records of stability study activities.
PC4. Ensure studies comply with relevant regulatory requirements
PC5. Generate comprehensive stability study reports with insightful analysis.
PC6. Analyze stability data to identify trends and provide meaningful insights.
PC7. Collaborate effectively with different teams for coordinated execution
PC8. Address stability-related inquiries promptly and accurately.

Stability Studies Management and Execution

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

PC9. Identify and resolve deviations from stability protocols effectively.
PC10. Regularly review stability test results for compliance and data integrity.
PC11. implement process improvements for optimized execution.
PC12. Utilize knowledge to guide and assist team members effectively.
PC13. Ensure stability storage areas are well-maintained.
PC14. Ensure availability of backup power systems for stability equipment.
PC15. Provide expert guidance in resolving stability-related challenges.
PC16. Apply technical skills to assist in investigations
PC17. Conduct long-term stability studies to support ongoing trials.
PC18. Carry out short-term stability studies for formulation evaluation.

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. In-depth knowledge of regulatory guidelines and best practices related to stability studies to ensure the development of robust protocols aligned with industry standards.

KU2. Expertise in designing an effective strategy for accurate sample collection over time, considering variables that may impact stability results.

KU3. Understanding the importance of maintaining accurate and organized records of stability study activities to ensure traceability and data integrity.

KU4. Proficiency in generating comprehensive stability study reports with insightful analysis, providing a clear understanding of the study outcomes.

KU5. Ability to analyze stability data, identify trends, and provide meaningful insights to support decision-making processes.

KU6. Ability to address stability-related inquiries promptly and accurately, fostering clear communication within and outside the team.

KU7. Knowledge and skills to identify and resolve deviations from stability protocols effectively, ensuring data accuracy and protocol adherence.

KU8. Knowledge of maintaining stability storage areas to ensure proper conditions for the storage of stability samples.

KU9. Providing expert guidance in resolving stability-related challenges, drawing on experience and technical knowledge.

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.

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Conducting Effective Stability Studies	**15**	**25**	**5**	**5**
PC1. Develop robust stability study protocols aligned with guidelines and best practices.	-	-	-	-
PC2. Design an effective strategy for accurate sample collection over time	-	-	-	-
PC3. Maintain accurate and organized records of stability study activities.	-	-	-	-
PC4. Ensure studies comply with relevant regulatory requirements	-	-	-	-
PC5. Generate comprehensive stability study reports with insightful analysis.	-	-	-	-
PC6. Analyze stability data to identify trends and provide meaningful insights.	-	-	-	-
PC7. Collaborate effectively with different teams for coordinated execution	-	-	-	-
PC8. Address stability-related inquiries promptly and accurately.	-	-	-	-
Stability Studies Management and Execution	**15**	**25**	**5**	**5**
PC9. Identify and resolve deviations from stability protocols effectively.	-	-	-	-
PC10. Regularly review stability test results for compliance and data integrity.	-	-	-	-
PC11. implement process improvements for optimized execution.	-	-	-	-
PC12. Utilize knowledge to guide and assist team members effectively.	-	-	-	-
PC13. Ensure stability storage areas are well-maintained.	-	-	-	-
PC14. Ensure availability of backup power systems for stability equipment.	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC15. Provide expert guidance in resolving stability-related challenges.	-	-	-	-
PC16. Apply technical skills to assist in investigations	-	-	-	-
PC17. Conduct long-term stability studies to support ongoing trials.	-	-	-	-
PC18. Carry out short-term stability studies for formulation evaluation.	-	-	-	-
NOS Total	**30**	**50**	**10**	**10**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0309
NOS Name	Perform stability studies
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

LFS/N0310: Carry out reporting and documentation for QC Stability Studies

Description

This NOS is about a stability specialist reporting, recording the incidents, and maintaining information security

Scope

The scope covers the following :

- Reporting
- Recording and documentation
- Information security

Elements and Performance Criteria

Reporting

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

PC1. • report problems/incidents/quality issues/test results to the appropriate authority
• as applicable in a timely manner

PC2. follow reporting procedures as prescribed by the company

PC3. meet change control and SOP approver teams

PC4. help other R&D lab staff with any other testing required during the developmental work

PC5. provide expertise to ensure all issues related to continued product stability, and sample investigation are adequately addressed, tracked, and resolved

PC6. liaison with regulatory agencies for quality accreditation renewals and registrations at regular intervals

Recording and documentation

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

PC7. identify documentation to be completed relating to one’s role

PC8. record details accurately in appropriate format and timely review of master document

PC9. prepare matrices of SOP v/s standards and process maps

PC10. collect data for metrics collection/preparation, write/revise SOPs

PC11. write protocols and final study report

PC12. ensure that the final document meets regulatory and compliance requirements

PC13. distribute data, collect, and compile all analytical data associated with analytical testing/stability samples

PC14. assist in designing stability studies, author protocols, track and monitor completion of test results, and trend data

PC15. perform review of records and other documentation for compliance with established procedures and good documentation practices

PC16. program and administrate release specifications, stability studies, data, etc. into the site Lab Information Management System (LIMS)

PC17. prepare inspection reports as per the inspection activity performed

PC18. document the results of the inspections and testing

PC19. assist in preparation of the stability section of the annual report and annual product review

PC20. review on-going stability data

PC21. perform data review and statistical analyses to establish, extend and/or support expiration date

Information security

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

PC22. respond to requests for information in an appropriate manner whilst following organizational procedures

PC23. inform the appropriate authority of requests for information received

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. importance of complete and accurate documentation

KU2. importance of identifying non-conforming materials

KU3. importance of quality control procedures

KU4. risk and impact of not following defined procedures/work instructions

KU5. escalation matrix for reporting identified issues

KU6. records to be maintained and implications of non-maintenance of the same

KU7. importance of stability of drugs

KU8. relevance of stability studies

KU9. factors that adversely affect integrity of the sample

KU10. use of basic computer applications/software

KU11. standard operating procedures for products non-conforming with quality standards

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.

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Reporting	**10**	**20**	**4**	**4**
PC1. • report problems/incidents/quality issues/test results to the appropriate authority • as applicable in a timely manner	-	-	-	-
PC2. follow reporting procedures as prescribed by the company	-	-	-	-
PC3. meet change control and SOP approver teams	-	-	-	-
PC4. help other R&D lab staff with any other testing required during the developmental work	-	-	-	-
PC5. provide expertise to ensure all issues related to continued product stability, and sample investigation are adequately addressed, tracked, and resolved	-	-	-	-
PC6. liaison with regulatory agencies for quality accreditation renewals and registrations at regular intervals	-	-	-	-
Recording and documentation	**15**	**20**	**3**	**3**
PC7. identify documentation to be completed relating to one’s role	-	-	-	-
PC8. record details accurately in appropriate format and timely review of master document	-	-	-	-
PC9. prepare matrices of SOP v/s standards and process maps	-	-	-	-
PC10. collect data for metrics collection/preparation, write/revise SOPs	-	-	-	-
PC11. write protocols and final study report	-	-	-	-
PC12. ensure that the final document meets regulatory and compliance requirements	-	-	-	-
PC13. distribute data, collect, and compile all analytical data associated with analytical testing/stability samples	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC14. assist in designing stability studies, author protocols, track and monitor completion of test results, and trend data	-	-	-	-
PC15. perform review of records and other documentation for compliance with established procedures and good documentation practices	-	-	-	-
PC16. program and administrate release specifications, stability studies, data, etc. into the site Lab Information Management System (LIMS)	-	-	-	-
PC17. prepare inspection reports as per the inspection activity performed	-	-	-	-
PC18. document the results of the inspections and testing	-	-	-	-
PC19. assist in preparation of the stability section of the annual report and annual product review	-	-	-	-
PC20. review on-going stability data	-	-	-	-
PC21. perform data review and statistical analyses to establish, extend and/or support expiration date	-	-	-	-
Information security	**5**	**10**	**3**	**3**
PC22. respond to requests for information in an appropriate manner whilst following organizational procedures	-	-	-	-
PC23. inform the appropriate authority of requests for information received	-	-	-	-
NOS Total	**30**	**50**	**10**	**10**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0310
NOS Name	Carry out reporting and documentation for QC Stability Studies
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/N0353: Perform Loan License Audit and documentation activities

Description

This Job function is about the job holder responsible for performing Loan License Audit and documentation activities

Scope

The scope covers the following :

- The NOS covers the following :
- Audit Planning and Compliance assessment
- Reporting, Communication, and Continuous Improvement

Elements and Performance Criteria

Audit Planning and Compliance assessment

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

PC1. develop a comprehensive audit plan outlining objectives, scope, and methodologies for the loan license audit.

PC2. Collect necessary documentation and information required for the audit process

PC3. ensure alignment of the audit plan with regulatory requirements and quality assurance standards.

PC4. review loan license agreements, contracts, and associated documents for alignment with regulatory and quality standards

PC5. evaluate adherence to quality assurance processes and protocols specified in the agreement.

PC6. review documentation related to loan license activities, quality controls, and manufacturing practices.

PC7. verify that documentation accurately reflects processes and adherence to agreed terms.

PC8. Conduct on-site inspections to assess manufacturing processes, quality control practices, and compliance with loan license terms.

PC9. collect relevant data, records, and evidence during the audit.

PC10. identify and document any deviations, non-conformances, or discrepancies observed during the audit

PC11. evaluate potential risks associated with loan license activities and assess their impact on product quality and compliance.

Reporting, Communication, and Continuous Improvement

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

PC12. prepare comprehensive audit reports detailing findings, observations, and recommendations for improvement.

PC13. effectively communicate audit results to relevant stakeholders, including management and regulatory authorities.

PC14. collaborate with cross-functional teams, including legal, regulatory, and manufacturing, to address audit findings.

PC15. ensure coordinated efforts in implementing corrective actions and process improvements.

PC16. collaborate with teams to develop and implement corrective and preventive actions based on audit findings

PC17. maintain organized records of audit activities, findings, corrective actions, and follow-up actions.

PC18. ensure proper documentation control and accessibility.

PC19. identify areas for process enhancement and suggest improvements to loan license practices and quality assurance processes.

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. Understanding of relevant regulatory requirements and industry standards.

KU2. Knowledge of how to develop a comprehensive audit plan, including objectives, scope, and methodologies.

KU3. Understanding of the types of documentation required for audits and the ability to collect them efficiently.

KU4. Familiarity with reviewing loan license agreements, contracts, and associated documents to ensure compliance with regulatory and quality standards.

KU5. Knowledge of collecting relevant data, records, and evidence during the audit process.

KU6. Understanding of conducting on-site inspections to assess manufacturing processes, quality control practices, and compliance with loan license terms.

KU7. Proficiency in identifying and documenting deviations, non-conformances, or discrepancies observed during the audit.

KU8. Proficiency in reviewing documentation related to loan license activities, quality controls, and manufacturing practices.

KU9. how to prepare comprehensive audit reports and effective communication to stakeholders.

Generic Skills (GS)

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

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

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

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

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

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

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

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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Audit Planning and Compliance assessment	**15**	**25**	**5**	**5**
PC1. develop a comprehensive audit plan outlining objectives, scope, and methodologies for the loan license audit.	-	-	-	-
PC2. Collect necessary documentation and information required for the audit process	-	-	-	-
PC3. ensure alignment of the audit plan with regulatory requirements and quality assurance standards.	-	-	-	-
PC4. review loan license agreements, contracts, and associated documents for alignment with regulatory and quality standards	-	-	-	-
PC5. evaluate adherence to quality assurance processes and protocols specified in the agreement.	-	-	-	-
PC6. review documentation related to loan license activities, quality controls, and manufacturing practices.	-	-	-	-
PC7. verify that documentation accurately reflects processes and adherence to agreed terms.	-	-	-	-
PC8. Conduct on-site inspections to assess manufacturing processes, quality control practices, and compliance with loan license terms.	-	-	-	-
PC9. collect relevant data, records, and evidence during the audit.	-	-	-	-
PC10. identify and document any deviations, non-conformances, or discrepancies observed during the audit	-	-	-	-
PC11. evaluate potential risks associated with loan license activities and assess their impact on product quality and compliance.	-	-	-	-
Reporting, Communication, and Continuous Improvement	**15**	**25**	**5**	**5**

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. prepare comprehensive audit reports detailing findings, observations, and recommendations for improvement.	-	-	-	-
PC13. effectively communicate audit results to relevant stakeholders, including management and regulatory authorities.	-	-	-	-
PC14. collaborate with cross-functional teams, including legal, regulatory, and manufacturing, to address audit findings.	-	-	-	-
PC15. ensure coordinated efforts in implementing corrective actions and process improvements.	-	-	-	-
PC16. collaborate with teams to develop and implement corrective and preventive actions based on audit findings	-	-	-	-
PC17. maintain organized records of audit activities, findings, corrective actions, and follow-up actions.	-	-	-	-
PC18. ensure proper documentation control and accessibility.	-	-	-	-
PC19. identify areas for process enhancement and suggest improvements to loan license practices and quality assurance processes.	-	-	-	-
NOS Total	**30**	**50**	**10**	**10**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0353
NOS Name	Perform Loan License Audit and documentation activities
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Quality
NSQF Level	5.5
Credits	5.0
Version	1.0
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 it's sources, that match the business opportunity

PC3. develop business proposal with objective and identified business area for registering the proposed business as independent entity with competent authorities

PC4. submit business proposals and feasibility plans for securing the required funding from govt. schemes for MSMEs like MUDRA etc. as and when needed

PC5. present the business proposal to investors and stakeholders to gain their confidence and trust for possible funding

PC6. ensure setting up the infrastructure and resources for business as per approved plan and investors/ shareholders agreement

PC7. enrol into various government schemes and programs for MSME and avail the benefits

PC8. promote the product/ services through various means including digital promotions in line to regulations for promotion and sale as per land of law

PC9. develop the supply chain and distribution network

PC10. maintain updated information regarding new market trends to provide service to customers and constantly upskill self and employees for futuristic technologies, innovations and methodologies

Maintenance of accounts and ledgers

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

PC11. ensure to generate a final invoice for the services rendered/ or products sold

PC12. collect payment either in cash (as per RBI guidelines)/ cheque/ demand draft or through online transactions via RTGS/NEFT/UPI etc.

PC13. ensure accounts and ledgers are maintained for the material supplied, payables and receivables, loan ledgers, taxes collected and paid into government treasury as well for wages paid and statutory benefits like PF, ESI contribution deposited with authorities

PC14. ensure maintenance and reconciliation of a monthly account as well as movable and immovable assets and stock to keep track of profit/ loss as well as periodic audit as per legal requirements

Comply with legal, regulatory and statutory standards

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

PC15. comply with workplace health and safety rules stipulated by local authorities

PC16. comply with rules related to taxes and licensing regulations

PC17. comply with prevalent labour laws and keep records for employee's qualifications, employment as well as trainings

PC18. comply with regulations and protocols related to maintenance of product/ service license including the pre conditions (if any)

PC19. comply with quality system like ISO/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

Generic Skills (GS)

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

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

Assessment Criteria

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

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

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.

Documentation for sales & marketing

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

PC8. ensure documentation and maintenance of records for long term and short term business plans, feasibility reports, investor/shareholder agreements and disbursement and payment records for loan/grant/equity etc.

PC9. ensure documentation and maintenance of records for sale like customer details, customer type, location, quantity purchased by each stockist/consumer, frequency of purchase, sale details like quantity of products/brand sold in each territory

Quality audit and client/regulatory inspections related documentation

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

PC10. ensure documentation and maintenance of records for internal/ external audits with its observations, notices/ feedback, action reports and final submission of audit action reports

PC11. ensure documentation and maintenance of records for every communication sent to or received from regulatory/ licensing authorities

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. system of documentation as per ISO/ good documentation practices and method of implementation

KU2. scoring, grading and accreditation system of affiliating bodies and clients

KU3. guidelines for facing audits and best practices for making organization audit ready

KU4. software and latest information technology tools for documentation and record maintenance

KU5. statistical tools for analysis and monitoring

KU6. various recording and documentation formats applicable in sales, marketing, supply chain etc

KU7. basic awareness of engineering drawing and architectural layouts

KU8. best practices in engineering and maintenance in sector

KU9. accounting standards and regulations

Generic Skills (GS)

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

GS1. record and communicate details of work done to appropriate people using written/typed report

GS2. interact effectively with team members

GS3. communicate with team members for data/ information/support/ advice needed

GS4. communicate with people in a form and manner and using language that is open and respectful

GS5. apply balanced judgement to different situations

GS6. plan and organize assigned work in order to drive collaboration with team members

GS7. effectively interact with the various stakeholders to complete assigned tasks

GS8. resolve any difficulties in relationships with colleagues , or get help from an appropriate person, in a way that preserves goodwill and trust

GS9. use team-building skills during the interaction with teammates while managing the difficult/stressful or emotional situations at work

GS10. apply emotional intelligence while dealing with other genders and people with disability

Assessment Criteria

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

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

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0121
NOS Name	Maintain the critical business documents as Entrepreneur in Life Sciences Sector
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Generic
NSQF Level	6
Credits	1.00
Version	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 via for every student at each examination/training center based on this criterion.

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

assessment component.

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

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

Minimum Aggregate Passing % at QP Level : 70

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

Minimum Passing % at NOS Level: 70

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

Assessment Weightage

Compulsory NOS

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0125.Ensure adherence to Environment, health and safety guidelines in a Manufacturing facility and GMP controlled areas	30	55	0	15	100	15
LFS/N0302.Coordinate with Manager, colleagues and auditors	35	55	-	10	100	15
LFS/N0348.Ensure GxP compliance, respond to issues and non-conformance to maintain regulatory standards and procedure	30	50	10	10	100	20
DGT/VSQ/N0103.Employability Skills (90 Hours)	20	30	-	-	50	10
Total	**115**	**190**	**10**	**35**	**350**	**60**

Elective: 1 Equipment validation

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0329.Monitor Equipment Validation	30	50	10	10	100	20
LFS/N0349.Review documentation for equipment validation	30	50	10	10	100	10
LFS/N0350.Perform Equipment Validation for change control	30	50	10	10	100	10
Total	**90**	**150**	**30**	**30**	**300**	**40**

Elective: 2 Process validation

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0305.Perform Process validation	30	50	10	10	100	20
LFS/N0351.Documentation for process validation	30	50	10	10	100	10
LFS/N0352.Perform Process Validation for change control	30	50	10	10	100	10
Total	**90**	**150**	**30**	**30**	**300**	**40**

Elective: 3 Internal audit

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0318.Carry out Internal auditing activities	30	50	10	10	100	10

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0317.Carry out vendor audit related activities and perform other additional activities to track performance	30	50	10	10	100	10
LFS/N0315.Carry out audit related reporting and documentation to adhere to regulatory and Quality standards	30	50	10	10	100	20
Total	**90**	**150**	**30**	**30**	**300**	**40**

Elective: 4 Quality Management System

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	20
LFS/N0328.Ensure training related activities and suggesting Improvements to Quality Management System	30	50	10	10	100	20
Total	**60**	**100**	**20**	**20**	**200**	**40**

Elective: 5 Stability studies

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0309.Perform stability studies	30	50	10	10	100	20

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0310.Carry out reporting and documentation for QC Stability Studies	30	50	10	10	100	20
Total	**60**	**100**	**20**	**20**	**200**	**40**

Optional: 1 Loan License Audit

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0353.Perform Loan License Audit and documentation activities	30	50	10	10	100	40
Total	**30**	**50**	**10**	**10**	**100**	**40**

Optional: 2 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	25
LFS/N0121.Maintain the critical business documents as Entrepreneur in Life Sciences Sector	20	55	15	10	100	25
Total	**50**	**105**	**27**	**18**	**200**	**50**

Acronyms

NOS	National Occupational Standard(s)
NSQF	National Skills Qualifications Framework
QP	Qualifications Pack
TVET	Technical and Vocational Education and Training

Glossary

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

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