Qualification Pack

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

Internal audit

Loan License Audit

QP Code: LFS/Q0313 Instantiated QP Code: LFS/Q0313-SI006

Version: 1.0

NSQF Level: 5.5

Qualification Pack

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Qualification Pack

LFS/Q0313-SI006: 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 : 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

Options*(Not mandatory):*

Option : Loan License Audit

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

Qualification Pack (QP) Parameters

Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Quality
Country	India
NSQF Level	5.5
Credits	23
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

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

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

National Occupational Standards (NOS) Parameters

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

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**

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

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**

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

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	10.71
LFS/N0302.Coordinate with Manager, colleagues and auditors	35	55	-	10	100	10.71
LFS/N0348.Ensure GxP compliance, respond to issues and non-conformance to maintain regulatory standards and procedure	30	50	10	10	100	14.29
DGT/VSQ/N0103.Employability Skills (90 Hours)	20	30	-	-	50	7.14
Total	**115**	**190**	**10**	**35**	**350**	**42.85**

Elective: 1 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	7.14
LFS/N0317.Carry out vendor audit related activities and perform other additional activities to track performance	30	50	10	10	100	7.14
LFS/N0315.Carry out audit related reporting and documentation to adhere to regulatory and Quality standards	30	50	10	10	100	14.29
Total	**90**	**150**	**30**	**30**	**300**	**28.57**

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	28.57
Total	**30**	**50**	**10**	**10**	**100**	**28.57**