Qualification Pack

Chemist-Quality Control

Electives: Gas Chromatography (GC)/ Ultraviolet-visible Spectroscopy (UV)

QP Code: LFS/Q1301 Instantiated QP Code: LFS/Q1301-SI003

Version: 4.0

NSQF Level: 5

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LFS/Q1301-SI003: Chemist-Quality Control

Brief Job Description

Chemist-Quality Control tests samples, reagents from all phases of the manufacturing process to ensure the product quality meets the standards. The individual is responsible for the testing of in-process/input raw materials, packaging materials, product stability of samples, in-process intermediate samples, finished products, preliminary investigation in case of out of specification results, laboratory incidents and handling/preparation of standards. The person is responsible for preparing the documents for reporting the test results and ensures compliance with cGMP, GLP and workplace safety while handling hazardous materials. The role holder also carries out testing of process validation samples and cleaning validation samples.

Personal Attributes

The individual should have good communication and interpersonal skills. The person should possess excellent analytical and reasoning skills. The role holder should pay attention to details. The individual should have the critical thinking approach along with excellent organizational skills.

Applicable National Occupational Standards (NOS)

Compulsory NOS:

1. LFS/N0362: Discuss about Life Sciences industry and Basics of Quality Control
2. LFS/N1306: Perform laboratory investigations and analysis in compliance with current Good Manufacturing Practices (cGMP) and Good Laboratory Practices (GLP)
3. LFS/N0110: Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab
4. LFS/N0302: Coordinate with Manager, colleagues and auditors
5. LFS/N0314: To carry out reporting and documentation for Quality Control analysis in compliance with GDP, GLP and cGMP
6. LFS/N1307: Carry out process related checks in the quality control process
7. DGT/VSQ/N0103: Employability Skills (90 Hours)

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

Elective 1: Gas Chromatography (GC)

This Chemist-Quality Control is considered to be a Gas Chromatography specialist.

1. LFS/N1302: Perform QC Analysis using Gas Chromatography

Elective 2: Ultraviolet-visible Spectroscopy (UV)

This Chemist-Quality Control is considered to be a UV spectroscopy specialist.

1. LFS/N1303: Perform QC Analysis using Ultraviolet visible spectroscopy

Qualification Pack (QP) Parameters

Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Pharma Quality
Country	India
NSQF Level	5
Credits	30
Aligned to NCO/ISCO/ISIC Code	NCO-2015/2113.0601
Minimum Educational Qualification & Experience	Completed 2nd year of UG (UG Diploma) (Biochemistry/Biology/Chemistry/Immunology/ Biomedical Science/ Microbiology/ Pharma/ Biotechnology) OR Diploma (Diploma in Pharmacy (after 12th)) OR Post Graduate (Chemistry/ Analytical Chemistry / Industrial Chemistry)
Minimum Level of Education for Training in School	
Pre-Requisite License or Training	NA
Minimum Job Entry Age	18 Years
Last Reviewed On	NA
Next Review Date	17/12/2027
NSQC Approval Date	17/12/2024
Version	4.0

Qualification Pack

Reference code on NQR	QG-05-LS-03406-2024-V2-LSSSDC
NQR Version	2.0

Remarks:

NA

Qualification Pack

LFS/N0362: Discuss about Life Sciences industry and Basics of Quality Control

Description

This NOS is about the introducing the Life Sciences industry and Basics of Quality Control

Scope

The scope covers the following :

- Introduction to life sciences Industry
- Basics of Quality Control

Elements and Performance Criteria

Introduction to life sciences industry

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

PC1. Explain the principles of current Good Manufacturing Practices (cGMP), Good Laboratory Practices (GLP), and Good Documentation Practices (GDP) and their role in quality control in life sciences manufacturing.

PC2. Discuss the potential environmental impact of improper disposal of chemicals and non-compliance with environmental safety standards.

PC3. Explain the responsibilities of the QC Analyst in maintaining regulatory compliance and preventing non-conformance during product testing.

PC4. Use these QC terminologies appropriately to explain testing protocols and procedures in a quality control environment.

Basics of Quality Control

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

PC5. Explain key quality principles (e.g., safety, consistency, efficacy) that are essential in life sciences manufacturing.

PC6. Describe the Quality by Design (QbD) approach and its significance in product development and manufacturing.

PC7. Explain how QbD principles help in identifying critical quality attributes (CQA) and mitigating risks through Quality Risk Management (QRM).

PC8. Perform measurements and apply mathematical and statistical concepts (e.g., precision, accuracy, standard deviation) in quality control.

PC9. Explain methods of preserving samples to avoid contamination or degradation, ensuring accurate analysis.

PC10. Demonstrate awareness of emergency procedures (e.g., spill management, first aid) for hazardous substance exposure.

PC11. perform correct labeling and storage practices in alignment with safety regulations.

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. quality principles and concepts applied in life sciences sector

KU2. types of tests performed in quality control lab for various formulations, API and packaging material

KU3. legal and regulatory frameworks relevant to the quality control and further implications of failing to comply

KU4. measurement units and mathematical and statistical concepts

KU5. relevant regulatory guidelines along with ICH-GMP, GLP, Schedule M, NABL and WHO guidelines etc.

KU6. properties of reagents, solvents and hazardous chemicals, incompatibility of chemicals, hazards and storage procedures, safe storage of chemicals as per hazard classification

KU7. sample handling, processing and preservation procedures

KU8. handling procedures of hazardous and poisonous substances

KU9. pharmacopoeia and application of standards

KU10. interaction of environmental factors(Light, Temperature & Humidity) with sample matter

KU11. operating procedure of Lab Information Management System

KU12. operating procedure of analytical instruments and equipment

KU13. guidelines for change control management, Standard Testing Procedures(STP), protocols, equipment qualification documents, method development, and validation protocols

KU14. interpretation of graphs from analytical instruments and tests

KU15. 5S and design of quality control lab to enhance efficiency and effectiveness

KU16. concepts of data integrity and ALCOA PLUS

KU17. procedure for instrument calibration, instrument accuracy test and importance of preventive maintenance

KU18. procedures for laboratory investigations and validation tests performed in QC lab of life sciences sector

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, escalation matrix, procedures to be followed and to seek clarifications

GS4. use verbal communication skills to interact with teammates, researchers, assistants, lab in charge and cross functional teams

GS5. use team-building skills while interacting with teammates

GS6. apply problem-solving skills to find solutions for workflow-related difficulties using concepts of basic sciences (chemistry), mathematics, statistics

GS7. apply planning and organizing skills to plan and organize tools and material required to fulfil own work requirements in timely manner

GS8. apply critical thinking skills to analyze and identify when to report an issue/concern to the lab in charge

GS9. apply analytical skills to observe laboratory investigations and identify OOS/ OOT/ deviations/ abnormal incidents

GS10. apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Introduction to life sciences industry	**20**	**-**	**5**	**5**
PC1. Explain the principles of current Good Manufacturing Practices (cGMP), Good Laboratory Practices (GLP), and Good Documentation Practices (GDP) and their role in quality control in life sciences manufacturing.	-	-	-	-
PC2. Discuss the potential environmental impact of improper disposal of chemicals and non-compliance with environmental safety standards.	-	-	-	-
PC3. Explain the responsibilities of the QC Analyst in maintaining regulatory compliance and preventing non-conformance during product testing.	-	-	-	-
PC4. Use these QC terminologies appropriately to explain testing protocols and procedures in a quality control environment.	-	-	-	-
Basics of Quality Control	**20**	**30**	**10**	**10**
PC5. Explain key quality principles (e.g., safety, consistency, efficacy) that are essential in life sciences manufacturing.	-	-	-	-
PC6. Describe the Quality by Design (QbD) approach and its significance in product development and manufacturing.	-	-	-	-
PC7. Explain how QbD principles help in identifying critical quality attributes (CQA) and mitigating risks through Quality Risk Management (QRM).	-	-	-	-
PC8. Perform measurements and apply mathematical and statistical concepts (e.g., precision, accuracy, standard deviation) in quality control.	-	-	-	-
PC9. Explain methods of preserving samples to avoid contamination or degradation, ensuring accurate analysis.	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC10. Demonstrate awareness of emergency procedures (e.g., spill management, first aid) for hazardous substance exposure.	-	-	-	-
PC11. perform correct labeling and storage practices in alignment with safety regulations.	-	-	-	-
NOS Total	**40**	**30**	**15**	**15**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0362
NOS Name	Discuss about Life Sciences industry and Basics of Quality Control
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Quality
NSQF Level	5
Credits	1.00
Version	1.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024

LFS/N1306: Perform laboratory investigations and analysis in compliance with current Good Manufacturing Practices (cGMP) and Good Laboratory Practices (GLP)

Description

This NOS is about the job holder conducting routine analysis in lab to ensure compliance with current Good Manufacturing Practices (cGMP) and Good Laboratory Practices (GLP)

Scope

The scope covers the following :

- Perform pre-analysis checks
- Laboratory investigations and analysis

Elements and Performance Criteria

Perform pre-analysis checks

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

PC1. check the availability of resources (like Validated methods,work instructions) to undertake the work post receiving and logging of samples for testing

PC2. ensure the availability of appropriate measuring instruments, equipment, tools, accessories, MSDS and relevant personal protective equipment (PPE) as required

PC3. ensure the status and accuracy of instruments used for measurement

PC4. ensure that all the pre analysis checks are performed as per Standard Operating Procedure (SOP), cGMP and GLP guidelines

PC5. review the data given by junior quality analyst and ensure that it is as per the SOP approved within procedures

PC6. check and report on supplies for QC orders involving devices and reagents as per schedule

Laboratory investigations and analysis

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

PC7. perform laboratory investigations and check the validity/ stability of volumetric solutions/pH buffers, standards as part of daily routine and discard expired solutions/standards as per written procedures

PC8. collect inputs from cross-functional teams to integrate findings and recommendations

PC9. analyse the root cause for out-of-specification (OOS) and out-of-trend (OOT) products, deviations and incidents

PC10. recommend changes in compliance with SOP for corrective action and preventive action (CAPA) / Change Control Procedures to improve the product’s quality and to avoid future deviations

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. quality principles and concepts applied in life sciences sector

KU2. concepts of organic and analytical chemistry

KU3. types of tests performed in quality control lab for various formulations, API and packaging material

KU4. legal and regulatory frameworks relevant to the quality control and further implications of failing to comply

KU5. measurement units and mathematical and statistical concepts

KU6. relevant regulatory guidelines along with ICH-GMP, GLP, Schedule M, NABL and WHO guidelines etc.

KU7. properties of reagents, solvents and hazardous chemicals, incompatibility of chemicals, hazards and storage procedures, safe storage of chemicals as per hazard classification

KU8. sample handling, processing and preservation procedures

KU9. handling procedures of hazardous and poisonous substances

KU10. pharmacopoeia and application of standards

KU11. interaction of environmental factors(Light, Temperature & Humidity) with sample matter

KU12. operating procedure of Lab Information Management System

KU13. operating procedure of analytical instruments and equipment

KU14. guidelines for change control management, Standard Testing Procedures(STP), protocols, equipment qualification documents, method development, and validation protocols

KU15. interpretation of graphs from analytical instruments and tests

KU16. 5S and design of quality control lab to enhance efficiency and effectiveness

KU17. concepts of data integrity and ALCOA PLUS

KU18. procedure for instrument calibration, instrument accuracy test and importance of preventive maintenance

KU19. procedures for laboratory investigations and validation tests performed in QC lab of life sciences sector

Generic Skills (GS)

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

GS1. use written communication skills to record information accurately in compliance with ALCOA principles as per SOP and cGMP guidelines in the English language

GS2. use reading and comprehension skills to read the various coding systems, instructions, guidelines, procedures, rules, and signages

GS3. use listening skills to understand the instructions, escalation matrix, procedures to be followed and to seek clarifications

GS4. use verbal communication skills to interact with teammates, researchers, assistants, lab in charge and cross functional teams

GS5. use team-building skills while interacting with teammates

GS6. apply problem-solving skills to find solutions for workflow-related difficulties using concepts of basic sciences (chemistry), mathematics, statistics

GS7. apply planning and organizing skills to plan and organize tools and material required to fulfil own work requirements in timely manner

GS8. apply critical thinking skills to analyze and identify when to report an issue/concern to the lab in charge

GS9. apply analytical skills to observe laboratory investigations and identify OOS/ OOT/ deviations/ abnormal incidents

GS10. apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Perform pre-analysis checks	**20**	**30**	**-**	**5**
PC1. check the availability of resources (like Validated methods,work instructions) to undertake the work post receiving and logging of samples for testing	-	-	-	-
PC2. ensure the availability of appropriate measuring instruments, equipment, tools, accessories, MSDS and relevant personal protective equipment (PPE) as required	-	-	-	-
PC3. ensure the status and accuracy of instruments used for measurement	-	-	-	-
PC4. ensure that all the pre analysis checks are performed as per Standard Operating Procedure (SOP), cGMP and GLP guidelines	-	-	-	-
PC5. review the data given by junior quality analyst and ensure that it is as per the SOP approved within procedures	-	-	-	-
PC6. check and report on supplies for QC orders involving devices and reagents as per schedule	-	-	-	-
Laboratory investigations and analysis	**15**	**25**	**-**	**5**
PC7. perform laboratory investigations and check the validity/ stability of volumetric solutions/pH buffers, standards as part of daily routine and discard expired solutions/standards as per written procedures	-	-	-	-
PC8. collect inputs from cross-functional teams to integrate findings and recommendations	-	-	-	-
PC9. analyse the root cause for out-of-specification (OOS) and out-of-trend (OOT) products, deviations and incidents	-	-	-	-
PC10. recommend changes in compliance with SOP for corrective action and preventive action (CAPA) / Change Control Procedures to improve the product's quality and to avoid future deviations	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
NOS Total	**35**	**55**	**-**	**10**

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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N1306
NOS Name	Perform laboratory investigations and analysis in compliance with current Good Manufacturing Practices (cGMP) and Good Laboratory Practices (GLP)
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Pharma Quality
NSQF Level	5
Credits	5.00
Version	3.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024

LFS/N0110: Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab

Description

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

Scope

The scope covers the following :

- Adhere to health and hygiene protocols
- Adhere to safety and security procedures
- Adhere to emergency procedures

Elements and Performance Criteria

Adhere to 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 ICH GMP guidelines

PC2. sanitize your hands before entering in laboratory and production area and ensure the adherence of same by subordinates as per SOP

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

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

PC5. wear lab coat all the time while working in a laboratory and ensure adherence of the same by every person visiting/ working in the lab area

PC6. follow gowning procedures while entering an environment controlled work area and ensure the adherence of the same by subordinates

Adhere to safety and security procedures

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

PC7. observe compliance by self and subordinates with safety and security policies and procedures

PC8. 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

PC9. use helmets, ropes, harness, and ladders while working at heights

PC10. use pulleys/ forklift (if available) to transport the material/ spares/ heavy assembly and tools

PC11. take preventive and corrective actions on the report of any identified breaches in safety and security policies and procedures by subordinates

PC12. segregate material and follow the 5S system at the storage area as per cGMP

PC13. adhere to storage and handling guidelines for hazardous material

PC14. supervise the disposal of waste/unused and expired reagents/ chemicals / biological waste using environmentally sustainable methods in the presence of EHS personnel

PC15. identify and correct any hazards that one can deal with safely, competently and within the limits of authority in consultation with EHS personnel

PC16. complete record the details of completed safety drills and training undertaken by self and subordinates

Adhere to emergency procedures

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

PC17. raise the alarm and report any hazards that one is not competent to deal with, to the relevant person in line with organizational procedures and warn other people who may be affected

PC18. follow emergency protocol for any alarms and ensure the safety of subordinates in the area under supervision

PC19. follow emergency procedures efficiently

PC20. 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. relevant legislative requirements and company's procedures for the environment, health and safety and individual's role and responsibilities in relation to this

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

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

KU4. limits of individual responsibility for dealing with hazards

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

KU6. gowning procedure in life sciences facility

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

KU8. evacuation procedures for employees, contract staff and visitors

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

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

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

KU12. WHO guidelines for personal hygiene

KU13. types of safety gears and procedure to use them

KU14. importance of material segregation and 5S system

KU15. WHO guidelines for handling and storing hazardous material

Generic Skills (GS)

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

GS1. use 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, procedures and alarms

GS4. use verbal communication skills to interact with teammates, lab in charge and cross functional teams to communicate hazards, safety instructions and accidents

GS5. apply problem-solving skills to find solutions for workflow-related difficulties

GS6. apply planning and organizing skills to plan and organize tools and material required for work to fulfil environment, health, safety and security requirements

GS7. 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

GS8. use critical thinking skills to ascertain the breach/ compliance of EHS protocols

GS9. apply customer-centricity to remain compliant with data integrity rules, cGMP guidelines and to evaluate the impact of errors

GS10. apply decision making skills to make balanced judgments within the authority to different situations while dealing with hazards and breaches

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Adhere to health and hygiene protocols	**10**	**15**	**-**	**5**
PC1. comply with health and personal hygiene-related protocols as per WHO standards and ICH GMP guidelines	-	-	-	-
PC2. sanitize your hands before entering in laboratory and production area and ensure the adherence of same by subordinates as per SOP	-	-	-	-
PC3. report any allergy, sickness or any other environment-related breach before or after entering the work premises to the designated person	-	-	-	-
PC4. take preventive actions on the report of any allergy, sickness or any other environment-related breach by subordinates	-	-	-	-
PC5. wear lab coat all the time while working in a laboratory and ensure adherence of the same by every person visiting/ working in the lab area	-	-	-	-
PC6. follow gowning procedures while entering an environment controlled work area and ensure the adherence of the same by subordinates	-	-	-	-
Adhere to safety and security procedures	**10**	**25**	**-**	**5**
PC7. observe compliance by self and subordinates with safety and security policies and procedures	-	-	-	-
PC8. 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	-	-	-	-
PC9. use helmets, ropes, harness, and ladders while working at heights	-	-	-	-
PC10. use pulleys/ forklift (if available) to transport the material/ spares/ heavy assembly and tools	-	-	-	-
PC11. take preventive and corrective actions on the report of any identified breaches in safety and security policies and procedures by subordinates	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. segregate material and follow the 5S system at the storage area as per cGMP	-	-	-	-
PC13. adhere to storage and handling guidelines for hazardous material	-	-	-	-
PC14. supervise the disposal of waste/unused and expired reagents/ chemicals / biological waste using environmentally sustainable methods in the presence of EHS personnel	-	-	-	-
PC15. identify and correct any hazards that one can deal with safely, competently and within the limits of authority in consultation with EHS personnel	-	-	-	-
PC16. complete record the details of completed safety drills and training undertaken by self and subordinates	-	-	-	-
Adhere to emergency procedures	**10**	**15**	**-**	**5**
PC17. raise the alarm and report any hazards that one is not competent to deal with, to the relevant person in line with organizational procedures and warn other people who may be affected	-	-	-	-
PC18. follow emergency protocol for any alarms and ensure the safety of subordinates in the area under supervision	-	-	-	-
PC19. follow emergency procedures efficiently	-	-	-	-
PC20. ensure injured employees are provided appropriate first aid and medical aid	-	-	-	-
NOS Total	**30**	**55**	**-**	**15**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0110
NOS Name	Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Generic
NSQF Level	5
Credits	1.00
Version	3.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024

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 appropriate 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 cGMP 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, cGMP/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 appropriate 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	4.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024

LFS/N0314: To carry out reporting and documentation for Quality Control analysis in compliance with GDP, GLP and cGMP

Description

This NOS unit is about the job holder carrying out reporting and documentation while ensuring that final documents meet regulatory and compliance requirements

Scope

The scope covers the following :

- Recording and reporting
- Documentation compliance with GDP, GLP and cGMP
- Data integrity

Elements and Performance Criteria

Recording and reporting

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

PC1. review and update the test methods and procedures as per the schedule or when a regulatory requirement arises according to the written procedures

PC2. fill logbooks, worksheet (an analytical record), reference standard entries, calibration records, parameters of column, reagent, volumetric solution and working standards as per cGMP

PC3. report defects/problem/incidents/quality issues/test results as applicable in a timely manner to the appropriate authority as per SOP

PC4. prepare analytical reports for detailed findings and recommendations as per SOPs

PC5. prepare quality control reports for raw materials, packing materials, in-process sample, and finished products

PC6. prepare certificate of analysis (CoA) for finished products and stability reports

PC7. provide reports of validations, deviations and OOS and OOT incidents to production and quality assurance team

PC8. write and update the inspection procedures, protocols, and checklists as per cGMP

PC9. prepare inspection reports as per the inspection activity performed

Documentation compliance with GDP, GLP and cGMP

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

PC10. identify documentation to be completed relating to one’s role

PC11. ensure that the final document meets regulatory and compliance requirements as per GDP, GLP and cGMP

Data Integrity

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

PC12. document the results of the testing and analysis accurately

PC13. maintain all original and controlled document files and quality records in a timely and accurate manner following ALCOA PLUS principles

PC14. respond to requests for information in an appropriate manner whilst following organizational procedures

PC15. make sure documents are available to all appropriate authorities to inspect/ audit

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. procedures for reporting any unresolved issues and hazards

KU2. procedures for change control management, version control, issue & retrieval of documents, management of Standard Operating Procedures (SOPs), Standard Testing Procedures (STPs), protocols, Equipment Qualification documents, method validation protocols & reports

KU3. procedures for reporting non-conformance, deviations, OOS/OOT, validation results

KU4. procedure for reporting incidents where standard operating procedures are not followed

KU5. documentation related guidelines from current Good Manufacturing Practices, 21CFR and Good Laboratory Practices

KU6. formats used in quality control lab for recording and reporting in Life Sciences Sector

KU7. procedures related to certificate of analysis and its importance in regulatory framework

KU8. procedure to use e-Lab Note Book (eLNB)

KU9. procedures and responsibility for reporting QC analysis information as per Good Documentation Practices (GDP), ALCOA Plus principles

KU10. operating procedure of lab information management system (LIMS) and software applications like MS Office

KU11. statistical concepts and application of statistical tools

KU12. guidelines for electronic records and signatures, audit trails, date and time stamps, data integrity in the Life Sciences Sector

Generic Skills (GS)

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

GS1. use written communication skills to record information accurately in compliance with ALCOA principles as per SOP and cGMP guidelines in the English language

GS2. use reading and comprehension skills to 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 teammates, researchers, assistants, lab in charge and cross functional teams for coordination and to communicate confidential and sensitive information discretely to the authorized person

GS5. use team-building skills while interacting with teammates

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 documentation related requirements

GS8. apply critical thinking skills to analyze and identify what and when to report an issue/concern to the lab in charge/ QA team / any other stakeholder

GS9. apply customer centricity while generating and securing documents

GS10. apply customer-centricity to remain compliant with data integrity rules, cGMP guidelines and to evaluate impact of wrongdoings

GS11. apply decision making skills to make balanced judgments within the authority while dealing with daily work-life situations

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Recording and reporting	**15**	**25**	**-**	**5**
PC1. review and update the test methods and procedures as per the schedule or when a regulatory requirement arises according to the written procedures	-	-	-	-
PC2. fill logbooks, worksheet (an analytical record), reference standard entries, calibration records, parameters of column, reagent, volumetric solution and working standards as per cGMP	-	-	-	-
PC3. report defects/problem/incidents/quality issues/test results as applicable in a timely manner to the appropriate authority as per SOP	-	-	-	-
PC4. prepare analytical reports for detailed findings and recommendations as per SOPs	-	-	-	-
PC5. prepare quality control reports for raw materials, packing materials, in-process sample, and finished products	-	-	-	-
PC6. prepare certificate of analysis (CoA) for finished products and stability reports	-	-	-	-
PC7. provide reports of validations, deviations and OOS and OOT incidents to production and quality assurance team	-	-	-	-
PC8. write and update the inspection procedures, protocols, and checklists as per cGMP	-	-	-	-
PC9. prepare inspection reports as per the inspection activity performed	-	-	-	-
Documentation compliance with GDP, GLP and cGMP	**10**	**15**	**-**	**5**
PC10. identify documentation to be completed relating to one's role	-	-	-	-
PC11. ensure that the final document meets regulatory and compliance requirements as per GDP, GLP and cGMP	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Data Integrity	**10**	**15**	**-**	**-**
PC12. document the results of the testing and analysis accurately	-	-	-	-
PC13. maintain all original and controlled document files and quality records in a timely and accurate manner following ALCOA PLUS principles	-	-	-	-
PC14. respond to requests for information in an appropriate manner whilst following organizational procedures	-	-	-	-
PC15. make sure documents are available to all appropriate authorities to inspect/ audit	-	-	-	-
NOS Total	**35**	**55**	**-**	**10**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0314
NOS Name	To carry out reporting and documentation for Quality Control analysis in compliance with GDP, GLP and cGMP
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Pharma Quality
NSQF Level	5
Credits	2.00
Version	4.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024

LFS/N1307: Carry out process related checks in the quality control process

Description

This NOS unit is about the job holder carrying out quality checks in the quality control process

Scope

The scope covers the following :

- Routine inspection of instruments
- Identification of non-conformities
- Labeling
- Environment sustainability

Elements and Performance Criteria

Routine inspection of instruments

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

PC1. monitor and conduct regular checks of equipment and instrument conditions and document calibrations

PC2. coordinate with maintenance team for preventive maintenance

PC3. follow preventive maintenance schedules and maintain the logs for instrument maintenance

PC4. investigate “out-of-calibration” lab instrument (if any), and ascertain the impact of calibration error on previously analyzed products

Identification of Non-conformities

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

PC5. identify non-conformities to working standards (quality assurance standards)

PC6. identify the impact on final product due to non-conformance to quality assurance standards

PC7. evaluate the need for action to ensure that problems do not recur

PC8. suggest corrective action to address the problem

PC9. review the effectiveness of corrective action

Labelling

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

PC10. ensure all samples are clearly identified by labels and remain permanently attached to the sample containers under all storage conditions

PC11. ensure compliance with relevant national regulations and international agreements for labels of radiopharmaceutical products

PC12. cross-check that the proper dosages and storage conditions are mentioned on labels

PC13. check the appearance of a label/leaflet on package for specific product information and indications

Environment Sustainability

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

PC14. ensure energy conservation by switching off the machine and equipment post lab operations

PC15. ensure no leakage of water in the laboratory

PC16. choose and apply environment-friendly methods given in SOPs for waste disposal

PC17. create awareness in the team about organizational environment sustainability guidelines and procedures to achieve energy and water conservation as well as zero pollution of land, water, and air

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. quality principles and concepts applied in life sciences sector

KU2. basic concept of Quality by Design (QbD) and its application in quality control, quality risk management

KU3. types of tests performed in quality control lab in various formulations, API and packaging material

KU4. importance of legal and regulatory frameworks relevant to the quality control and their further implications

KU5. measurement units and mathematical and statistical concepts

KU6. relevant regulatory guidelines along with ICH-GMP, GLP, Schedule M, NABL and WHO guidelines etc.

KU7. properties of reagents, solvents and hazardous chemicals, incompatibility of chemicals, hazards and storage procedures, safe storage of chemicals as per Hazard Classification

KU8. sample handling, processing and preservation procedures

KU9. handling procedures of hazardous and poisonous substances

KU10. pharmacopoeia and application of standards

KU11. guidelines for Electronic Records & Electronic Signatures, Audit Trails, Date and Time Stamps, Data Integrity in life sciences sector

KU12. interaction of environmental factors(Light, Temperature & Humidity) with sample matter

KU13. operating procedure of Lab Information Management System

KU14. operating procedure of analytical instruments and equipment

KU15. guidelines for Change control management, Standard Testing Procedures, Protocols, Equipment Qualification documents

KU16. 5S and design of quality control lab to enhance efficiency and effectiveness

KU17. concepts of data integrity and ALCOA PLUS

KU18. procedure for instrument calibration, instrument accuracy test and importance of preventive maintenance

Generic Skills (GS)

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

GS1. use written communication skills to record information accurately in compliance with ALCOA principles as per SOP and cGMP guidelines in the English language

GS2. use reading and comprehension skills to read the various coding systems, instructions,guidelines, procedures, rules, and signages

GS3. use listening skills to interpret the instructions, escalation matrix, procedures to be followed and to seek clarifications

GS4. use verbal communication skills to interact with teammates, researchers, assistants, lab in charge and cross functional teams

GS5. use team-building skills while dealing with teammates

GS6. apply problem-solving skills to find solutions for deviations found during process related checks, non-conformities in standards and labelling

GS7. apply planning and organizing skills to plan and organize tools and material required to fulfill own work requirements in timely manner

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 process error individually, depending on the type of concern

GS9. apply analytical skills to perform process related checks in the quality control process

GS10. apply customer centricity to remain compliant with data integrity rules, cGMP/GLP guidelines and to evaluate impact of wrongdoings

GS11. apply decision making skills to make balanced judgments within the authority while dealing with daily work-life situations

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Routine inspection of instruments	**8**	**12**	**-**	**5**
PC1. monitor and conduct regular checks of equipment and instrument conditions and document calibrations	-	-	-	-
PC2. coordinate with maintenance team for preventive maintenance	-	-	-	-
PC3. follow preventive maintenance schedules and maintain the logs for instrument maintenance	-	-	-	-
PC4. investigate “out-of-calibration” lab instrument (if any), and ascertain the impact of calibration error on previously analyzed products	-	-	-	-
Identification of Non-conformities	**10**	**15**	**-**	**5**
PC5. identify non-conformities to working standards (quality assurance standards)	-	-	-	-
PC6. identify the impact on final product due to non-conformance to quality assurance standards	-	-	-	-
PC7. evaluate the need for action to ensure that problems do not recur	-	-	-	-
PC8. suggest corrective action to address the problem	-	-	-	-
PC9. review the effectiveness of corrective action	-	-	-	-
Labelling	**10**	**20**	**-**	**5**
PC10. ensure all samples are clearly identified by labels and remain permanently attached to the sample containers under all storage conditions	-	-	-	-
PC11. ensure compliance with relevant national regulations and international agreements for labels of radiopharmaceutical products	-	-	-	-
PC12. cross-check that the proper dosages and storage conditions are mentioned on labels	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC13. check the appearance of a label/leaflet on package for specific product information and indications	-	-	-	-
Environment Sustainability	**2**	**3**	**-**	**5**
PC14. ensure energy conservation by switching off the machine and equipment post lab operations	-	-	-	-
PC15. ensure no leakage of water in the laboratory	-	-	-	-
PC16. choose and apply environment-friendly methods given in SOPs for waste disposal	-	-	-	-
PC17. create awareness in the team about organizational environment sustainability guidelines and procedures to achieve energy and water conservation as well as zero pollution of land, water, and air	-	-	-	-
NOS Total	**30**	**50**	**-**	**20**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N1307
NOS Name	Carry out process related checks in the quality control process
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Pharma Quality
NSQF Level	5
Credits	2.00
Version	3.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024

Qualification Pack

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	22/10/2024
Next Review Date	22/10/2027
NSQC Clearance Date	22/10/2024

LFS/N1302: Perform QC Analysis using Gas Chromatography

Description

This occupation standard is about a Chemist-Quality Control by using Gas Chromatography (GC)

Scope

The scope covers the following :

- Gas chromatography analysis

Elements and Performance Criteria

Gas Chromatography Analysis

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

PC1. identify and select the correct types of columns, injections and detectors used in Gas Chromatograph

PC2. prepare the sample considering stability and storage requirement

PC3. analyze the sample using Gas Chromatograph

PC4. record, analyze and document all the chromatogram

PC5. calculate and derive ideal coefficient correlation as per the respective SOP

PC6. raise/log an incident in the system SAP, OOS, OOC, and OOT in case of non-conformity during sample analysis

PC7. perform calibration of Gas Chromatograph

PC8. ensure issuance, maintenance, and disposal of sample in Gas Chromatography column

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. types of tests performed on GC in quality control lab in various formulations, API and packaging material

KU2. relevant regulatory guidelines along with ICH-GMP, GLP, Schedule M, NABL and WHO, and the Quality management system like ISO-9000, ISO-14001, OHSAS-18000

KU3. pharmacopoeia and application of standards in GC analysis

KU4. the organizational coding system of raw materials, compounds

KU5. operating procedure of Lab Information Management System

KU6. the principle, types, application of GC and precautions to be taken while working on GC

KU7. components of GC like injection system, a separation column, detectors, integrators, apparatus (inclining headspace), and programming temperature, Stationary phase, mobile carrier gas phase

KU8. procedure for GC instrument calibration, validation and importance of preventive maintenance

KU9. operating procedure of GC and basics of method development and validation

KU10. procedure of common In-process tests in GC analysis recommended by GMP/ GLP

KU11. the standard method of drawing samples and preparing them for GC testing

KU12. about chromatograms

KU13. different techniques/inspection methods used to identify defects

KU14. procedures of routine maintenance of analytical column, injections and GC

KU15. methods of disposing of materials, the importance of appropriate disposal and implications of not following the material disposal procedure

KU16. common errors in GC analysis and their troubleshooting procedures

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 interpret the instructions, escalation matrix, procedures to be followed and to seek clarifications

GS4. use verbal communication skills to interact with teammates, researchers, assistants, lab in charge and cross functional teams

GS5. use team-building skills while dealing 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 and for troubleshooting

GS7. apply planning and organizing skills to plan and organize tools and material required to fulfil own work requirements in timely manner

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 analytical skills to observe results of analysis and to identify OOS/ OOT/ deviations/ abnormal incidents

GS10. apply customer-centricity to remain in compliance with data integrity rules, cGMP/GLP guidelines and to evaluate impact of wrongdoings

GS11. apply decision making skills to make balanced judgments within the authority while dealing with daily work-life situations

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Gas Chromatography Analysis	**35**	**55**	**-**	**10**
PC1. identify and select the correct types of columns, injections and detectors used in Gas Chromatograph	-	-	-	-
PC2. prepare the sample considering stability and storage requirement	-	-	-	-
PC3. analyze the sample using Gas Chromatograph	-	-	-	-
PC4. record, analyze and document all the chromatogram	-	-	-	-
PC5. calculate and derive ideal coefficient correlation as per the respective SOP	-	-	-	-
PC6. raise/log an incident in the system SAP, OOS, OOC, and OOT in case of non-conformity during sample analysis	-	-	-	-
PC7. perform calibration of Gas Chromatograph	-	-	-	-
PC8. ensure issuance, maintenance, and disposal of sample in Gas Chromatography column	-	-	-	-
NOS Total	**35**	**55**	**-**	**10**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N1302
NOS Name	Perform QC Analysis using Gas Chromatography
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Pharma Quality
NSQF Level	5
Credits	7.00
Version	3.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024

LFS/N1303: Perform QC Analysis using Ultraviolet visible spectroscopy

Description

This occupation standard is about a Chemist-Quality Control by using Ultraviolet (UV)- visible spectroscopy

Scope

The scope covers the following :

- Ultraviolet (UV)- visible spectroscopy Analysis

Elements and Performance Criteria

Ultraviolet (UV)- visible spectroscopy Analysis

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

PC1. prepare the samples for analysis by UV- visible spectroscopy

PC2. select the correct developed and validated method for analysis

PC3. set the desired wavelength with the knob in increasing order as per the developed and validated method

PC4. operate the UV spectrophotometer as per SOP

PC5. handle cuvette with loaded samples

PC6. record the readings for different samples and make the entry in instrument logbook

PC7. perform calibration and performance qualification of UV spectrophotometer

PC8. perform maintenance of UV spectrophotometer

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. process of absorption of light in the UV/Visible part of the spectrum (190nm-800nm) and concepts of spectral analysis and photometric analysis

KU2. types of tests performed on UV-Visible mass spectrophotometer in quality control lab in various formulations, API and packaging material

KU3. relevant regulatory guidelines along with ICH-GMP, GLP, Schedule M, NABL and WHO, and the Quality management system like ISO-9000, ISO-14001, OHSAS-18000

KU4. pharmacopoeia and application of standards in UV-Visible mass spectrophotometer analysis

KU5. the organizational coding system of raw materials, compounds

KU6. operating procedure of Lab Information Management System

KU7. the principle, types, application of UV-Visible mass spectrophotometer and precautions to be taken while working on UV-Visible mass spectrophotometer

KU8. process of UV-Visible mass spectrophotometer instrument calibration, validation and importance of preventive maintenance

KU9. operating procedure of UV-Visible mass spectrophotometer and basics of method development and validation

KU10. procedure of common In-process tests in UV-Visible mass spectrophotometer analysis recommended by GMP/ GLP

KU11. the standard method of drawing samples and preparing them for UV-Visible mass spectrophotometer testing

KU12. different techniques/inspection methods used to identify defects

KU13. procedures of routine maintenance of UV-Visible mass spectrophotometer

KU14. methods of disposing of materials, the importance of appropriate disposal and implications of not following the material disposal procedure

KU15. common errors in UV-Visible mass spectrophotometer analysis and their troubleshooting procedures

KU16. procedure for other tests to crosscheck chemical, mechanical and environmental interactions of containers like - pH test, alkalinity test, fold and crease tests, permeability to water vapors, odors, oils and gases

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 interpret the instructions, escalation matrix, procedures to be followed and to seek clarifications

GS4. use verbal communication skills to interact with teammates, researchers, assistants, lab in charge and cross functional teams

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GS9. apply analytical skills to observe results of analysis and to identify OOS/ OOT/ deviations/ abnormal incidents

GS10. apply customer centricity to remain compliant with data integrity rules, cGMP/GLP guidelines and to evaluate impact of wrongdoings

GS11. apply decision making skills to make balanced judgments within the authority while dealing with daily work-life situations

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Ultraviolet (UV)- visible spectroscopy Analysis	**35**	**55**	**-**	**10**
PC1. prepare the samples for analysis by UV-visible spectroscopy	-	-	-	-
PC2. select the correct developed and validated method for analysis	-	-	-	-
PC3. set the desired wavelength with the knob in increasing order as per the developed and validated method	-	-	-	-
PC4. operate the UV spectrophotometer as per SOP	-	-	-	-
PC5. handle cuvette with loaded samples	-	-	-	-
PC6. record the readings for different samples and make the entry in instrument logbook	-	-	-	-
PC7. perform calibration and performance qualification of UV spectrophotometer	-	-	-	-
PC8. perform maintenance of UV spectrophotometer	-	-	-	-
NOS Total	**35**	**55**	**-**	**10**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N1303
NOS Name	Perform QC Analysis using Ultraviolet visible spectroscopy
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Pharma Quality
NSQF Level	5
Credits	7.00
Version	3.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024

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.)

Assessment Weightage

Compulsory NOS

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0362.Discuss about Life Sciences industry and Basics of Quality Control	40	30	15	15	100	3.85
LFS/N1306.Perform laboratory investigations and analysis in compliance with current Good Manufacturing Practices (cGMP) and Good Laboratory Practices (GLP)	35	55	0	10	100	15.38
LFS/N0110.Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab	30	55	-	15	100	7.69
LFS/N0302.Coordinate with Manager, colleagues and auditors	35	55	0	10	100	7.69
LFS/N0314.To carry out reporting and documentation for Quality Control analysis in compliance with GDP, GLP and cGMP	35	55	0	10	100	7.69

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N1307.Carry out process related checks in the quality control process	30	50	0	20	100	7.69
DGT/VSQ/N0103.Employability Skills (90 Hours)	20	30	-	-	50	3.85
Total	**225**	**330**	**15**	**80**	**650**	**53.839999999999996**

Elective: 1 Gas Chromatography (GC)

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N1302.Perform QC Analysis using Gas Chromatography	35	55	0	10	100	23.08
Total	**35**	**55**	**-**	**10**	**100**	**23.08**

Elective: 2 Ultraviolet-visible Spectroscopy (UV)

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N1303.Perform QC Analysis using Ultraviolet visible spectroscopy	35	55	0	10	100	23.08
Total	**35**	**55**	**-**	**10**	**100**	**23.08**