

Qualification Pack



Chemist-Quality Control

Electives: High-Performance Liquid Chromatography (HPLC)

QP Code: LFS/Q1301 Instantiated QP Code: LFS/Q1301-SI001

Version: 4.0

NSQF Level: 5

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LFS/Q1301-SI001: 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 : High-Performance Liquid Chromatography (HPLC)

This Chemist-Quality Control is considered to be an HPLC specialist.



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1. [LFS/N1301: Perform QC Analysis using High-Performance Liquid Chromatography](#)

Qualification Pack (QP) Parameters

Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Pharma Quality
Country	India
NSQF Level	5
Credits	23
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
Reference code on NQR	QG-05-LS-03406-2024-V2-LSSSDC
NQR Version	2.0

Remarks:



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NA



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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)



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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



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- 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

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Introduction to life sciences industry</i>	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.	-	-	-	-
<i>Basics of Quality Control</i>	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.	-	-	-	-



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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



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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



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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:



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- 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



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- 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

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Perform pre-analysis checks</i>	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	-	-	-	-
<i>Laboratory investigations and analysis</i>	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	-	-	-	-



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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



Qualification Pack

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



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- 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:



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- 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

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Adhere to health and hygiene protocols</i>	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	-	-	-	-
<i>Adhere to safety and security procedures</i>	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	-	-	-	-

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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	-	-	-	-
<i>Adhere to emergency procedures</i>	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



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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



Qualification Pack

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



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Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

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

Generic Skills (GS)

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

- GS1.** use written communication skills to record information accurately in compliance with ALCOA principles as per SOP and 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

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Assessment Criteria

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



Qualification Pack

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



Qualification Pack

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



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- 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



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- 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

Qualification Pack

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Recording and reporting</i>	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	-	-	-	-
<i>Documentation compliance with GDP, GLP and cGMP</i>	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	-	-	-	-



Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Data Integrity</i>	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



Qualification Pack

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:



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- 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



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- 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

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Routine inspection of instruments</i>	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	-	-	-	-
<i>Identification of Non-conformities</i>	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	-	-	-	-
<i>Labelling</i>	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	-	-	-	-



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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	-	-	-	-
<i>Environment Sustainability</i>	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



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

Basic English Skills

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

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

Career Development & Goal Setting

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

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

Communication Skills

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

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

Diversity & Inclusion

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

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

Financial and Legal Literacy

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

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

Essential Digital Skills

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

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



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

Entrepreneurship

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

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

Customer Service

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

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

Getting ready for apprenticeship & Jobs

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

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

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

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



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

Generic Skills (GS)

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

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

Qualification Pack

Assessment Criteria

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

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

Qualification Pack

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



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



Qualification Pack

National Occupational Standards (NOS) Parameters

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



Qualification Pack

LFS/N1301: Perform QC Analysis using High-Performance Liquid Chromatography

Description

This occupation standard is about a Chemist-Quality Control performing analysis by using High-Performance Liquid Chromatography (HPLC)

Scope

The scope covers the following :

- HPLC analysis

Elements and Performance Criteria

HPLC analysis

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

- PC1.** follow the instrument cleaning procedure for the analysis before using the instrument
- PC2.** select the developed and validated method for HPLC analysis
- PC3.** prepare mobile phase, resolution solution, and standard solution
- PC4.** prepare the sample considering stability and storage requirement
- PC5.** validate system suitability to verify the chromatographic system
- PC6.** perform sample analysis using HPLC
- PC7.** record, analyze and document all the chromatogram
- PC8.** ensure to perform the calculation required for analysis
- PC9.** raise/log an incident in the Lab Management Information system for OOS, OOC, and OOT in case of non-conformity during sample analysis on HPLC
- PC10.** perform calibration of HPLC
- PC11.** ensure issuance, maintenance, and disposal of HPLC column

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, data integrity and ALCOA PLUS
- KU3.** measurement units and mathematical and statistical concepts
- KU4.** concepts of organic chemistry and analytical chemistry
- KU5.** types of tests performed on HPLC in quality control lab in various formulations, API and packaging material
- KU6.** relevant regulatory guidelines along with ICH-GMP, GLP, Schedule M, NABL and WHO guidelines and the Quality management system like ISO-9000, ISO-14001, OHSAS-18000

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- KU7.** pharmacopoeia and application of standards in HPLC analysis
- KU8.** the organizational coding system of raw materials, compounds
- KU9.** operating procedure of Lab Information Management System
- KU10.** the principle, types, application of HPLC and precautions to be taken while working on HPLC
- KU11.** components of HPLC like stationary phase, chromatographic column, mobile phase, apparatus, and gradient elution
- KU12.** procedure for HPLC instrument calibration, validation and importance of preventive maintenance
- KU13.** basics of method development and validation and how to use HPLC
- KU14.** procedure of common In-process tests in HPLC analysis recommended in GMP/ GLP
- KU15.** the standard method of drawing samples and preparing them for HPLC testing
- KU16.** about chromatograms
- KU17.** different techniques/inspection methods used to identify defects
- KU18.** procedures of routine maintenance of analytical column and HPLC
- KU19.** methods of disposing of materials, the importance of appropriate disposal and implications of not following the material disposal procedure
- KU20.** common errors in HPLC 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 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 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 compliant with data integrity rules, GMP/GLP guidelines and to evaluate impact of wrongdoings



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



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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>HPLC analysis</i>	35	55	-	10
PC1. follow the instrument cleaning procedure for the analysis before using the instrument	-	-	-	-
PC2. select the developed and validated method for HPLC analysis	-	-	-	-
PC3. prepare mobile phase, resolution solution, and standard solution	-	-	-	-
PC4. prepare the sample considering stability and storage requirement	-	-	-	-
PC5. validate system suitability to verify the chromatographic system	-	-	-	-
PC6. perform sample analysis using HPLC	-	-	-	-
PC7. record, analyze and document all the chromatogram	-	-	-	-
PC8. ensure to perform the calculation required for analysis	-	-	-	-
PC9. raise/log an incident in the Lab Management Information system for OOS, OOC, and OOT in case of non-conformity during sample analysis on HPLC	-	-	-	-
PC10. perform calibration of HPLC	-	-	-	-
PC11. ensure issuance, maintenance, and disposal of HPLC column	-	-	-	-
NOS Total	35	55	-	10



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N1301
NOS Name	Perform QC Analysis using High-Performance Liquid 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

Assessment Guidelines and Assessment Weightage

Assessment Guidelines

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



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assessment component.

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

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

Minimum Aggregate Passing % at QP Level : 70

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

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	5
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	20
LFS/N0110.Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab	30	55	-	15	100	10
LFS/N0302.Coordinate with Manager, colleagues and auditors	35	55	0	10	100	10

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National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0314.To carry out reporting and documentation for Quality Control analysis in compliance with GDP, GLP and cGMP	35	55	0	10	100	10
LFS/N1307.Carry out process related checks in the quality control process	30	50	0	20	100	10
DGT/VSQ/N0103.Employability Skills (90 Hours)	20	30	-	-	50	5
Total	225	330	15	80	650	70

Elective: 1 High-Performance Liquid Chromatography (HPLC)

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N1301.Perform QC Analysis using High-Performance Liquid Chromatography	35	55	0	10	100	30
Total	35	55	-	10	100	30