Qualification Pack

Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device)

QP Code: LFS/Q0302

Version: 4.0

NSQF Level: 5

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LFS/Q0302: Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device)

Brief Job Description

Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device) performs in-process quality checks for all the manufacturing products while conducting documentation and verification exercise. The individual is responsible to ensure compliance to systems and procedures, undertakes risk control assessment, and conducts/ coordinates in internal/external audit. The role holder also carries out sampling of in-process, finished product.

Personal Attributes

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

Applicable National Occupational Standards (NOS)

Compulsory NOS:

1. LFS/N0363: Discuss about Life Sciences industry and basic of Quality Assurance
2. LFS/N0341: Perform quality checks in the manufacturing/ production units in compliance with regulatory guidelines
3. LFS/N0110: Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab
4. LFS/N0345: Perform reporting and documentation to meet regulatory standards
5. LFS/N0346: Coordinate with Supervisor, team members, cross-functional teams and auditors
6. DGT/VSQ/N0103: Employability Skills (90 Hours)

Qualification Pack (QP) Parameters

Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research, Medical Devices and In Vitro Diagnostic (IVD), Biotechnology

Qualification Pack

Occupation	Quality
Country	India
NSQF Level	5
Credits	17
Aligned to NCO/ISCO/ISIC Code	NCO 2015/ 2113.0901
Minimum Educational Qualification & Experience	Completed 2nd year of UG (UG Diploma) (Pharma/ Biotechnology / Chemical Engineering/ Instrumentation & Electronics) OR M.Sc (Chemistry/ Microbiology/ Biotechnology/ Life Sciences)
Minimum Level of Education for Training in School	Not Applicable
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-03407-2024-V2-LSSSDC
NQR Version	2.0

Remarks:

No remarks

Qualification Pack

LFS/N0363: Discuss about Life Sciences industry and basic of Quality Assurance

Description

This NOS is related to Discuss about Life Sciences industry and basic of Quality Assurance

Scope

The scope covers the following :

- Life Sciences industry and Quality assurance
- Quality Assurance for production

Elements and Performance Criteria

Life Sciences industry and Quality assurance

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

PC1. discuss the insight of the major segments within the life sciences industry (pharmaceuticals, biotechnology, medical devices, etc.).

PC2. explain the importance of current Good Manufacturing Practices (cGMP), ICH, ISO9001, ISO 13485, IEC-60601-2, ISO/IEC 27001, Global MDR and Good Documentation Practices (GDP) in quality assurance.

PC3. Describe the core skills required for a Quality Assurance, such as knowledge of QA processes, analytical techniques, documentation, and problem-solving.

PC4. use QA terminologies accurately in discussions about QA procedures and processes.

Quality Assurance for production

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

PC5. analyze how non-compliance can lead to product recalls, safety issues, regulatory action, and harm to the environment.

PC6. explain the significance of scheduled inspections and audits to maintain product quality.

PC7. identify typical QA procedures (e.g., sampling, in-process checks, final product inspections) and the frequency of these checks.

PC8. prepare a Master Validation Plan (MVP) for ensuring that manufacturing processes consistently produce high-quality products.

PC9. proper collection and storage of stability and control samples during packaging processes.

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. the standard operating procedures of the production unit

KU2. the policies and procedures for conducting/participating in audits

KU3. the legal and regulatory frameworks relevant to the production work

KU4. the quality assurance methods approved by the company

KU5. the format of presenting the information captured during quality checks

KU6. the composition/requirements of the product manufactured

KU7. how to interpret pharmacopoeia

KU8. the good manufacturing practices, good laboratory practices, GMP, ICH, ISO9001, ISO 13485, IEC-60601-2, ISO/IEC 27001, Global MDR and other guidelines

KU9. the packaging specifications for different products

KU10. the standard procedures of CAPA follow-up and closure

KU11. the qualification & validation procedures

KU12. instrument management and calibration procedures

KU13. QA procedures and schedules

KU14. the environment sustainable procedures for chemical disposal and their importance

KU15. the waste segregation methods

Generic Skills (GS)

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

GS1. use reading and comprehension skills to read and interpret manuals, SOPs, health and safety instructions, memos, reports, and notes/comments from the supervisor

GS2. use written communication skills to record and communicate details of work done to appropriate stakeholders by using written or computer-based record/electronic mail

GS3. apply problem-solving skills to find solutions for workflow-related difficulties

GS4. apply critical thinking skills to analyze and identify when to report an issue/concern to the in-charge and when to deal with a colleagues

GS5. apply problem solving skills in choosing a well-defined written smooth methods/instruction to resolve day to day problems

GS6. apply planning and organizing skills to plan and organize tools and material required to fulfil own work requirements on time

GS7. apply the analytical skill to analyse deviations and abnormal incidents in the production checks

GS8. apply customer-centricity to remain compliant with data integrity rules, GMP, ICH, ISO9001, ISO 13485, IEC-60601-2, ISO/IEC 27001, Global MDR guidelines and to evaluate the impact of wrongdoings

GS9. 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
Life Sciences industry and Quality assurance	**20**	**-**	**5**	**5**
PC1. discuss the insight of the major segments within the life sciences industry (pharmaceuticals, biotechnology, medical devices, etc.).	-	-	-	-
PC2. explain the importance of current Good Manufacturing Practices (cGMP), ICH, ISO9001, ISO 13485, IEC-60601-2, ISO/IEC 27001, Global MDR and Good Documentation Practices (GDP) in quality assurance.	-	-	-	-
PC3. Describe the core skills required for a Quality Assurance, such as knowledge of QA processes, analytical techniques, documentation, and problem-solving.	-	-	-	-
PC4. use QA terminologies accurately in discussions about QA procedures and processes.	-	-	-	-
Quality Assurance for production	**20**	**30**	**10**	**10**
PC5. analyze how non-compliance can lead to product recalls, safety issues, regulatory action, and harm to the environment.	-	-	-	-
PC6. explain the significance of scheduled inspections and audits to maintain product quality.	-	-	-	-
PC7. identify typical QA procedures (e.g., sampling, in-process checks, final product inspections) and the frequency of these checks.	-	-	-	-
PC8. prepare a Master Validation Plan (MVP) for ensuring that manufacturing processes consistently produce high-quality products.	-	-	-	-
PC9. proper collection and storage of stability and control samples during packaging processes.	-	-	-	-
NOS Total	**40**	**30**	**15**	**15**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0363
NOS Name	Discuss about Life Sciences industry and basic of Quality Assurance
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Quality
NSQF Level	5
Credits	3.00
Version	1.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024

Qualification Pack

LFS/N0341: Perform quality checks in the manufacturing/ production units in compliance with regulatory guidelines

Description

This NOS is about performing pre-production, in-process and post-production quality checks to ensure compliance with regulatory standards and procedures

Scope

The scope covers the following :

- Pre-Production checks
- In-Process checks
- Post-Production checks
- Environment Sustainability

Elements and Performance Criteria

Pre-production checks

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

PC1. check if the manufacturing facility (area & process)is meeting the basic cGMP, IEC 60601, ISO 9001, ISO/IEC 27001 and ISO 13485 requirements (e.g. facility upkeep, labeling policy, environmental conditions, cross-contamination guidelines, segregation of materials)

PC2. determine appropriate quality monitoring arrangements for the processes and procedures of manufacturing, quality control, warehouse and engineering departments

PC3. monitor the validation and qualification activities of machines as per validation master plan for compliances with regulatory guidelines

PC4. ensure regulatory policies and procedures in the manufacturing facility

In-Process checks

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

PC5. ensure in-process checks are conducted at relevant processing stages as per required specifications

PC6. perform material verification activities to check if the right material, in the right quantity for the batch has been issued as per cGMP, IEC 60601, ISO 9001, ISO/IEC 27001 and ISO 13485

PC7. collect control samples from each batch of finished goods, manufactured goods and raw material ingredients received

PC8. verify production area and equipment to ensure that there is no chance of contamination for the next product from the traces of previous product

PC9. ensure the quality management system (QMS) elements such as change control, incident management, CAPA management are adhered to on the shop floor as per cGMP guidelines and ISO 13485

PC10. carry out investigations related to complaints, batch failures, Out of Specification (OOS) incidents and report monthly and year-to-date comparisons

PC11. check the causes of any non-conformity from the standard protocols and work on its corrective/preventive action

PC12. carry out sampling activities for quality assurance audit across stages

PC13. provide document support to regulatory departments for the compilation of various regulatory documents as per cGMP guidelines and ISO 13485

PC14. conduct the product quality review and communicate the findings to the quality management review members and regulatory bodies

PC15. assist the quality manager in continuous improvement initiatives to enhance product quality, compliance, and efficiency

Post-production checks

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

PC16. monitor adherence to various good manufacturing practices,activities and procedures in the receipt, storage, testing, processing and dispatch of products

PC17. review batch manufacturing/batch processing, packaging and analytical records, equipment logs etc. before batch release as per cGMP guidelines and ISO 13485

PC18. manage activities such as audits, regulatory agency inspections, or product recalls

PC19. communicate regulatory information to multiple departments for smooth flow of work

Environment Sustainability

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

PC20. ensure energy conservation by switching off the machine and equipment post operations

PC21. identify ways to optimize the usage of electricity/energy in various tasks/activities/processes

PC22. ensure energy conservation by optimizing the machine/ equipment performance

PC23. identify recyclable and non-recyclable, and hazardous waste generated

PC24. segregate waste into different categories to achieve minimum pollution of land and water

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. the standard operating procedures of the production unit

KU2. the policies and procedures for conducting/participating in audits

KU3. the legal and regulatory frameworks relevant to the production work

KU4. the quality assurance methods approved by the company

KU5. the format of presenting the information captured during quality checks

KU6. the composition/requirements of the product manufactured

KU7. how to interpret pharmacopoeia

KU8. the good manufacturing practices, good laboratory practices and good documentation practices and ISO guidelines

KU9. the packaging specifications for different products

KU10. the standard procedures of CAPA follow-up and closure

KU11. Critical Quality Attributes (CQA), Critical Process Parameters (CPP) and Critical Process Controls (CPC) and acceptance criteria

KU12. the qualification & validation procedures

KU13. incidents, deviations, OOS, OOT measures
KU14. instrument management and calibration procedures
KU15. QA procedures and schedules
KU16. the fundamental Science in API and Formulation Production and Packaging
KU17. the basics of Pharmaceutical Science and Chemistry
KU18. the environment sustainable procedures for chemical disposal and their importance
KU19. the waste segregation methods
KU20. details of cGMP, IEC 60601, ISO 9001, ISO/IEC 27001 and ISO 13485

Generic Skills (GS)

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

GS1. use reading and comprehension skills to read and interpret manuals, SOPs, health and safety instructions, memos, reports, and notes/comments from the supervisor
GS2. use written communication skills to record and communicate details of work done to appropriate stakeholders by using written or computer-based record/electronic mail
GS3. apply problem-solving skills to find solutions for workflow-related difficulties
GS4. apply critical thinking skills to analyze and identify when to report an issue/concern to the in-charge and when to deal with a colleagues
GS5. apply problem solving skills in choosing a well-defined written smooth methods/instruction to resolve day to day problems
GS6. apply planning and organizing skills to plan and organize tools and material required to fulfil own work requirements on time
GS7. apply the analytical skill to analyse deviations and abnormal incidents in the production checks
GS8. apply customer-centricity to remain compliant with data integrity rules, cGMP, IEC 60601, ISO 9001, ISO/IEC 27001 and ISO 13485, guidelines and to evaluate the impact of wrongdoings
GS9. 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
Pre-production checks	**8**	**15**	**3**	**4**
PC1. check if the manufacturing facility (area & process)is meeting the basic cGMP, IEC 60601, ISO 9001, ISO/IEC 27001 and ISO 13485 requirements (e.g. facility upkeep, labeling policy, environmental conditions, cross-contamination guidelines, segregation of materials)	-	-	-	-
PC2. determine appropriate quality monitoring arrangements for the processes and procedures of manufacturing, quality control, warehouse and engineering departments	-	-	-	-
PC3. monitor the validation and qualification activities of machines as per validation master plan for compliances with regulatory guidelines	-	-	-	-
PC4. ensure regulatory policies and procedures in the manufacturing facility	-	-	-	-
In-Process checks	**8**	**15**	**3**	**4**
PC5. ensure in-process checks are conducted at relevant processing stages as per required specifications	-	-	-	-
PC6. perform material verification activities to check if the right material, in the right quantity for the batch has been issued as per cGMP, IEC 60601, ISO 9001, ISO/IEC 27001 and ISO 13485	-	-	-	-
PC7. collect control samples from each batch of finished goods, manufactured goods and raw material ingredients received	-	-	-	-
PC8. verify production area and equipment to ensure that there is no chance of contamination for the next product from the traces of previous product	-	-	-	-
PC9. ensure the quality management system (QMS) elements such as change control, incident management, CAPA management are adhered to on the shop floor as per cGMP guidelines and ISO 13485	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC10. carry out investigations related to complaints, batch failures, Out of Specification (OOS) incidents and report monthly and year-to-date comparisons	-	-	-	-
PC11. check the causes of any non-conformity from the standard protocols and work on its corrective/preventive action	-	-	-	-
PC12. carry out sampling activities for quality assurance audit across stages	-	-	-	-
PC13. provide document support to regulatory departments for the compilation of various regulatory documents as per cGMP guidelines and ISO 13485	-	-	-	-
PC14. conduct the product quality review and communicate the findings to the quality management review members and regulatory bodies	-	-	-	-
PC15. assist the quality manager in continuous improvement initiatives to enhance product quality, compliance, and efficiency	-	-	-	-
Post-production checks	**5**	**10**	**3**	**2**
PC16. monitor adherence to various good manufacturing practices,activities and procedures in the receipt, storage, testing, processing and dispatch of products	-	-	-	-
PC17. review batch manufacturing/batch processing, packaging and analytical records, equipment logs etc. before batch release as per cGMP guidelines and ISO 13485	-	-	-	-
PC18. manage activities such as audits, regulatory agency inspections, or product recalls	-	-	-	-
PC19. communicate regulatory information to multiple departments for smooth flow of work	-	-	-	-
Environment Sustainability	**5**	**10**	**3**	**2**
PC20. ensure energy conservation by switching off the machine and equipment post operations	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC21. identify ways to optimize the usage of electricity/energy in various tasks/activities/processes	-	-	-	-
PC22. ensure energy conservation by optimizing the machine/ equipment performance	-	-	-	-
PC23. identify recyclable and non-recyclable, and hazardous waste generated	-	-	-	-
PC24. segregate waste into different categories to achieve minimum pollution of land and water	-	-	-	-
NOS Total	**26**	**50**	**12**	**12**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0341
NOS Name	Perform quality checks in the manufacturing/ production units in compliance with regulatory guidelines
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Quality
NSQF Level	5
Credits	6
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**

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/N0345: Perform reporting and documentation to meet regulatory standards

Description

This NOS unit is about the Chemist- In-process Quality Assurance carrying out reporting and documentation to meet quality standards and ensuring that the final documents comply with regulatory requirements

Scope

The scope covers the following :

- Reporting
- Recording and documentation
- Data Integrity

Elements and Performance Criteria

Reporting

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

PC1. follow the reporting procedures and formats as prescribed by the company

PC2. prepare external and internal reports and other documentation required by regulatory agencies, or customers, to support the quality assurance function

PC3. prepare process validation protocols and summary reports based on the analytical results and batch documents data

Recording and documentation

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

PC4. perform the documentation for all the observations in a prescribed format

PC5. complete all documentation within the stipulated time as per company procedure

PC6. prepare documents required for forthcoming quality audits

PC7. compile statistical data and writes narrative reports summarizing quality assurance findings, along with a review of documents

PC8. maintain complete and accurate documentary evidence concerning Qualification, and Validation exercises

PC9. ensure that the final document meets regulatory and compliance requirements as per GDP, cGMP, IEC 60601, ISO 9001, ISO/IEC 27001 and ISO 13485

Data Integrity

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

PC10. maintain all original and controlled document files and quality records in a timely and accurate manner as per ALCOA PLUS principles

PC11. respond to requests for information in an appropriate manner whilst following organizational procedures

PC12. 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. the procedures for change control management, version control, Issue & retrieval of documents, management of standard operating procedures, standard testing procedures, protocols, equipment qualification documents, method validation protocols & reports

KU2. the procedures for reporting non-conformance, deviations, OOS/OOT, validation results

KU3. procedure for reporting incidents where standard operating procedures are not followed

KU4. documentation related guidelines from Good Manufacturing Practices, 21CFR and Good Laboratory Practices

KU5. procedures for QA documentation as per Good Documentation Practices (GDP)

KU6. ALCOA Plus principles

KU7. types of documents required for audits

KU8. method of preparing audit plans, audit reports, audit responses

KU9. statistical concepts and application of statistical tools

KU10. guidelines like GDP, cGMP, IEC 60601, ISO 9001, ISO/IEC 27001 and ISO 13485

Generic Skills (GS)

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

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

GS2. use verbal communication skills to interact with supervisor, teammates, cross-functional teams for coordination and to communicate confidential and sensitive information discretely to the authorized person

GS3. apply problem-solving skills to find solutions for workflow-related difficulties

GS4. apply planning and organizing skills to plan and organize tools and material required to fulfil documentation related requirements

GS5. apply customer-centricity while interacting with different stakeholders

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Reporting	**10**	**15**	**5**	**5**
PC1. follow the reporting procedures and formats as prescribed by the company	-	-	-	-
PC2. prepare external and internal reports and other documentation required by regulatory agencies, or customers, to support the quality assurance function	-	-	-	-
PC3. prepare process validation protocols and summary reports based on the analytical results and batch documents data	-	-	-	-
Recording and documentation	**10**	**15**	**5**	**5**
PC4. perform the documentation for all the observations in a prescribed format	-	-	-	-
PC5. complete all documentation within the stipulated time as per company procedure	-	-	-	-
PC6. prepare documents required for forthcoming quality audits	-	-	-	-
PC7. compile statistical data and writes narrative reports summarizing quality assurance findings, along with a review of documents	-	-	-	-
PC8. maintain complete and accurate documentary evidence concerning Qualification, and Validation exercises	-	-	-	-
PC9. ensure that the final document meets regulatory and compliance requirements as per GDP, cGMP, IEC 60601, ISO 9001, ISO/IEC 27001 and ISO 13485	-	-	-	-
Data Integrity	**10**	**15**	**3**	**2**
PC10. maintain all original and controlled document files and quality records in a timely and accurate manner as per ALCOA PLUS principles	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC11. respond to requests for information in an appropriate manner whilst following organizational procedures	-	-	-	-
PC12. make sure documents are available to all appropriate authorities to inspect/ audit	-	-	-	-
NOS Total	**30**	**45**	**13**	**12**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0345
NOS Name	Perform reporting and documentation to meet regulatory standards
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	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

LFS/N0346: Coordinate with Supervisor, team members, cross-functional teams and auditors

Description

This NOS unit is about how to coordinate with supervisor, team members, cross-functional teams, and auditors

Scope

The scope covers the following :

- Coordination with the supervisor
- Coordination with team members
- Coordination with cross-functional teams and auditors
- Sensitivity towards all genders and people with disability

Elements and Performance Criteria

Coordination with Supervisor

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

PC1. provide support to supervisor for carrying out investigations related to complaints, batch failures, OOS/ OOT, incidents etc.

PC2. communicate any potential hazards or expected process disruptions to the supervisor

PC3. provide the requisite information, documents, clarifications to the supervisor during actual audits

PC4. submit completed work reports to supervisor on time

Coordination with team members

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

PC5. work as a team with colleagues and share work as per their workload

PC6. collect data to be recorded in logbooks and batch documents from team members and colleagues

PC7. support team members during internal and external audit activities

PC8. communicate workflow related difficulties to find solutions with mutual agreement

PC9. maintain their own as well as team members sense of calm/equilibrium

Coordination with cross-functional teams and auditors

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

PC10. train staff of other departments in regulatory policies or procedures

PC11. support colleagues of other departments in work

PC12. coordinate with cross-functional teams while performing inspections for various departments as per predefined schedules

PC13. coordinate with production, quality team for line clearance, change control approvals as well as calibration and validation activities

PC14. respond appropriately to the queries of auditors , maintaining integrity and confidence

PC15. provide appropriate documented records of performed activities and operations to auditors

Sensitivity towards all genders and people with disability

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

PC16. respect all genders, religions, and caste

PC17. empathize with people with disability

PC18. offer support or help to a person with disability only when asked

PC19. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act

PC20. 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. the company's policies on preferred language of communication, reporting and escalation policy, quality delivery standards, and personnel management

KU2. the reporting structure of the organization

KU3. type of audits in the life sciences sector for the manufacturing plant

KU4. the required regulatory and statutory compliance rule related to documentation

KU5. the guidelines for data integrity, ethics, and compliance in the life sciences industry

KU6. the guidelines laid on Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act

KU7. the methods of workplace communication

KU8. the methods of team coordination

KU9. the types of possible disabilities among people with disability (PWD)

KU10. the challenges faced by PWD

KU11. importance of displaying empathy towards PWD

KU12. the right way to use the laws, acts, and provisions defined for PWD by the statutory bodies

KU13. the importance of awareness for gender sensitization and prevention of sexual harassment (POSH) act

KU14. importance of respecting all religion, caste, and culture in an organization

Generic Skills (GS)

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

GS1. use reading and comprehension skills to gauge the relevant information manuals, SOPs, health and safety instructions, memos, reports, job cards, and notes/comments

GS2. use written communication skills to record and communicate details of work done to appropriate stakeholders by using written/typed report or computer-based record/electronic mail

GS3. use verbal communication skills to communicate confidential and sensitive information discretely to the authorized person while interacting with teammates

GS4. use team-building skills during the interaction with teammates while managing the difficult/stressful or emotional situations at work

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

GS6. apply critical thinking skills to analyze and identify when to report an issue/concern to the supervisor and to deal with a colleague individually, depending on the type of concern

GS7. apply customer-centricity while responding to auditors, customer representatives and QA personnel

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Coordination with Supervisor	**10**	**15**	**3**	**2**
PC1. provide support to supervisor for carrying out investigations related to complaints, batch failures, OOS/ OOT, incidents etc.	-	-	-	-
PC2. communicate any potential hazards or expected process disruptions to the supervisor	-	-	-	-
PC3. provide the requisite information, documents, clarifications to the supervisor during actual audits	-	-	-	-
PC4. submit completed work reports to supervisor on time	-	-	-	-
Coordination with team members	**10**	**15**	**3**	**2**
PC5. work as a team with colleagues and share work as per their workload	-	-	-	-
PC6. collect data to be recorded in logbooks and batch documents from team members and colleagues	-	-	-	-
PC7. support team members during internal and external audit activities	-	-	-	-
PC8. communicate workflow related difficulties to find solutions with mutual agreement	-	-	-	-
PC9. maintain their own as well as team members sense of calm/equilibrium	-	-	-	-
Coordination with cross-functional teams and auditors	**5**	**10**	**3**	**2**
PC10. train staff of other departments in regulatory policies or procedures	-	-	-	-
PC11. support colleagues of other departments in work	-	-	-	-
PC12. coordinate with cross-functional teams while performing inspections for various departments as per predefined schedules	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC13. coordinate with production, quality team for line clearance, change control approvals as well as calibration and validation activities	-	-	-	-
PC14. respond appropriately to the queries of auditors , maintaining integrity and confidence	-	-	-	-
PC15. provide appropriate documented records of performed activities and operations to auditors	-	-	-	-
Sensitivity towards all genders and people with disability	**5**	**10**	**3**	**2**
PC16. respect all genders, religions, and caste	-	-	-	-
PC17. empathize with people with disability	-	-	-	-
PC18. offer support or help to a person with disability only when asked	-	-	-	-
PC19. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act	-	-	-	-
PC20. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee	-	-	-	-
NOS Total	**30**	**50**	**12**	**8**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0346
NOS Name	Coordinate with Supervisor, team members, cross-functional teams and auditors
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	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**	**-**	**-**

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	18/02/2025
Next Review Date	18/02/2028
NSQC Clearance Date	18/02/2025

Assessment Guidelines and Assessment Weightage

Assessment Guidelines

1.Criteria for assessment for each Qualification Pack will be created by Life Sciences Sector Skill Development Council (LSSSDC)

2. Each Element will be assigned marks proportional to its importance in NOS. LSSSDC will also lay down the proportion of marks for Theory, Practical, Project, and Viva for each Element.

3. The assessment for the theory part will be based on the knowledge bank of questions created by the LSSSDC.

4. Assessment will be conducted for all compulsory NOS, and where applicable, on the selected elective/option NOS/set of NOS.

5. LSSSDC as assessment and awarding body will create unique evaluations for each assessment component i.e. theory, practical, project and via for every student at each examination/training center based on this criterion.

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

assessment component.

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

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

Minimum Aggregate Passing % at QP Level : 70

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

Minimum Passing % at NOS Level: 70

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

Assessment Weightage

Compulsory NOS

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0363.Discuss about Life Sciences industry and basic of Quality Assurance	40	30	15	15	100	20
LFS/N0341.Perform quality checks in the manufacturing/ production units in compliance with regulatory guidelines	26	50	12	12	100	20
LFS/N0110.Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab	30	55	0	15	100	15
LFS/N0345.Perform reporting and documentation to meet regulatory standards	30	45	13	12	100	20
LFS/N0346.Coordinate with Supervisor, team members, cross-functional teams and auditors	30	50	12	8	100	15

Qualification Pack

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
DGT/VSQ/N0103.Employability Skills (90 Hours)	20	30	-	-	50	10
Total	**176**	**260**	**52**	**62**	**550**	**100**

Acronyms

NOS	National Occupational Standard(s)
NSQF	National Skills Qualifications Framework
QP	Qualifications Pack
TVET	Technical and Vocational Education and Training
AA	Assessment Agency
AB	Awarding Body
ISCO	International Standard Classification of Occupations
NCO	National Classification of Occupations
NCrF	National Credit Framework
NOS	National Occupational Standard(s)
NQR	National Qualification Register
NSQF	National Skills Qualification Framework
OJT	On the Job Training
AA	Assessment Agency
AB	Awarding Body
ISCO	International Standard Classification of Occupations
NCO	National Classification of Occupations
NCrF	National Credit Framework
NOS	National Occupational Standard(s)
NQR	National Qualification Register
NSQF	National Skills Qualification Framework
OJT	On the Job Training
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NQR	National Qualification Register
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OJT	On the Job Training
AA	Assessment Agency
AB	Awarding Body
ISCO	International Standard Classification of Occupations
NCO	National Classification of Occupations
NCrF	National Credit Framework
NOS	National Occupational Standard(s)
NQR	National Qualification Register
NSQF	National Skills Qualification Framework
OJT	On the Job Training
MDR	Medical Device Regulations
ISO	International Organization for Standardization

AA	Assessment Agency
AB	Awarding Body
ISCO	International Standard Classification of Occupations
NCO	National Classification of Occupations
NCrF	National Credit Framework
NOS	National Occupational Standard(s)
NQR	National Qualification Register
NSQF	National Skills Qualification Framework
OJT	On the Job Training
MDR	Medical Device Regulations
ISO	International Organization for Standardization
AA	Assessment Agency
AB	Awarding Body
ISCO	International Standard Classification of Occupations
NCO	National Classification of Occupations
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NSQF	National Skills Qualification Framework
OJT	On the Job Training
AA	Assessment Agency
AB	Awarding Body
ISCO	International Standard Classification of Occupations
NCO	National Classification of Occupations
NCrF	National Credit Framework
NOS	National Occupational Standard(s)
NQR	National Qualification Register
NSQF	National Skills Qualification Framework
OJT	On the Job Training

Glossary

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

Organisational Context	Organisational context includes the way the organisation is structured and how it operates, including the extent of operative knowledge managers have of their relevant areas of responsibility.
Technical Knowledge	Technical knowledge is the specific knowledge needed to accomplish specific designated responsibilities.
Core Skills/ Generic Skills (GS)	Core skills or Generic Skills (GS) are a group of skills that are the key to learning and working in today's world. These skills are typically needed in any work environment in today's world. These skills are typically needed in any work environment. In the context of the OS, these include communication related skills that are applicable to most job roles.
Electives	Electives are NOS/set of NOS that are identified by the sector as contributive to specialization in a job role. There may be multiple electives within a QP for each specialized job role. Trainees must select at least one elective for the successful completion of a QP with Electives.
Options	Options are NOS/set of NOS that are identified by the sector as additional skills. There may be multiple options within a QP. It is not mandatory to select any of the options to complete a QP with Options.
National Occupational Standard	NOS defines the measurable performance outcomes required from an individual engaged in a particular task. They list down what an individual performing that task should know and also do.
Qualification	A formal outcome of an assessment and validation process is obtained when a the competent body determines that an individual has achieved learning outcomes to given standards
Qualification File	A Qualification File is a template designed to capture necessary information about a Qualification from the perspective of NSQF compliance. The Qualification File will be normally submitted by the awarding body for the qualification.
Sector	A grouping of professional activities on the basis of their main economic function, product, service, or technology.
Long Term Training	Long-term skilling means any vocational training program undertaken for a year and above. https://ncvet.gov.in/sites/default/files/NCVET.pdf
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