

## Qualification Pack



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

Process validation

QP Code: LFS/Q0313 Instantiated QP Code: LFS/Q0313-SI002

Version: 1.0

NSQF Level: 5.5



## Qualification Pack

Life Sciences Sector Skill Development Council || # 14, Rear 2nd Floor, Palam Marg, Vasant Vihar  
New Delhi-110057 || email:SHIVI.CHAUDHARY@LSSSDC.IN



## Qualification Pack

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## Qualification Pack

# LFS/Q0313-SI002: Specialist- Quality Assurance (Pharma, Biological Products and Medical Devices)

## Brief Job Description

A Specialist- Quality Assurance (Pharma, Biological Products and Medical Devices) performs physical checks, conducts document verification exercise, ensures compliance to quality management systems and procedures, undertakes risk control assessment, conducts/participates in internal/external audits and also carries out process and equipment validation and in-process sampling, finished product sampling activities.

## Personal Attributes

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

## Applicable National Occupational Standards (NOS)

### Compulsory NOS:

1. [LFS/N0125: Ensure adherence to Environment, health and safety guidelines in a Manufacturing facility and GMP controlled areas](#)
2. [LFS/N0302: Coordinate with Manager, colleagues and auditors](#)
3. [LFS/N0348: Ensure GxP compliance, respond to issues and non-conformance to maintain regulatory standards and procedure](#)
4. [DGT/VSQ/N0103: Employability Skills \(90 Hours\)](#)

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

Elective : Process validation

1. [LFS/N0305: Perform Process validation](#)
2. [LFS/N0351: Documentation for process validation](#)
3. [LFS/N0352: Perform Process Validation for change control](#)

## Qualification Pack (QP) Parameters



## Qualification Pack

<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceutical, Bio Pharmaceutical
<b>Occupation</b>	Quality
<b>Country</b>	India
<b>NSQF Level</b>	5.5
<b>Credits</b>	18
<b>Aligned to NCO/ISCO/ISIC Code</b>	NCO-2015/2131.1300
<b>Minimum Educational Qualification &amp; Experience</b>	<p>B.Tech ((in relevant field)) with 2 Years of experience Quality Assurance/Quality Control/production OR B.Pharma with 2 Years of experience Quality Assurance/Quality Control/production OR M.Sc (In relevant Subjects) with 2 Years of experience Quality Assurance/Quality Control/production OR M.Pharma (Final Year Student ) OR M.Tech ((in relevant field) final year student) OR Previous relevant Qualification of NSQF Level (Level 5 Certificate of Chemist- In-process Quality Assurance (Pharma, Biologics and Medical Device)) with 1-2 Years of experience OR Previous relevant Qualification of NSQF Level (Level 5 Certificate of Analyst/ChemistQuality Contro) with 1-2 Years of experience OR Previous relevant Qualification of NSQF Level (Level 5 Certificate of Chemist- Production (Pharma, Cosmetics &amp; Biologics)) with 1-2 Years of experience</p>
<b>Minimum Level of Education for Training in School</b>	
<b>Pre-Requisite License or Training</b>	NA
<b>Minimum Job Entry Age</b>	21 Years
<b>Last Reviewed On</b>	NA
<b>Next Review Date</b>	29/09/2026



## Qualification Pack

<b>NSQC Approval Date</b>	29/09/2023
<b>Version</b>	1.0
<b>Reference code on NQR</b>	QG-5.5-LS-00998-2023-V1-LSSSDC
<b>NQR Version</b>	1.0



## Qualification Pack

# LFS/N0125: Ensure adherence to Environment, health and safety guidelines in a Manufacturing facility and GMP controlled areas

## Description

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

## Scope

The scope covers the following :

- Follow health and hygiene protocols
- Adherence to safety and security procedures
- Adherence to emergency procedures

## Elements and Performance Criteria

### *Follow health and hygiene protocols*

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

- PC1.** comply with health and personal hygiene-related protocols as per WHO standards and cGMP guidelines
- PC2.** wash hands and feet before entering in the manufacturing area with soap/alcohol based sanitizers
- PC3.** report any communicable or contagious diseases allergy, sickness or any other environment-related breach before entering the work premises to the designated person
- PC4.** take preventive actions on the report of any allergy, sickness or any other environment-related breach reported by subordinates
- PC5.** follow gowning procedures as per SoP while entering an environment controlled work area and ensure adherence to the same by others

### *Adherence to safety and security procedures*

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

- PC6.** comply with safety and security policies and procedures
- PC7.** ensure the use of appropriate safety gears like headgear, masks, gloves and other accessories as mentioned in the guidelines, by self and subordinates while carrying out work
- PC8.** take preventive and corrective actions based on the report of any identified deviations in safety and security policies and procedures by subordinates
- PC9.** ensure that discipline for material segregation and 5S system is followed at the storage area
- PC10.** comply with material handling, segregation, and storage guidelines for highly hazardous, poisonous and explosive material
- PC11.** take corrective actions for reported hazards in consultation with EHS personnel
- PC12.** complete the records of safety drills and trainings undertaken by self and subordinates

### *Adherence to emergency procedures*



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

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

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** company's procedures for the environment, health, and safety
- KU2.** implications that any non-compliance with health, safety and security may have on individuals and the organization
- KU3.** workplace hazards in the manufacturing facility in the life sciences sector, how and when to report hazards
- KU4.** limits of individual responsibility for dealing with hazards
- KU5.** chemical substances, their characteristics, and required precaution and safety measures
- KU6.** gowning procedure
- KU7.** the organization's emergency procedures for different emergencies and the importance of following these
- KU8.** evacuation procedures for employees, contract staff and visitors
- KU9.** health, safety and accident reporting procedures and the importance of reporting in GMP
- KU10.** different types of breaches in the environment, health, safety and security and how and when to report these
- KU11.** WHO guidelines for personal hygiene
- KU12.** type of safety gears and procedure to use them
- KU13.** the importance of material segregation and 5S system
- KU14.** WHO guidelines for handling and storing hazardous material

## Generic Skills (GS)

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

- GS1.** use reading and comprehension skills to understand the various coding systems and to read instructions, guidelines, procedures, rules, and signages to understand the procedure to be followed
- GS2.** use listening skills to follow the instructions and procedures during emergency alarms
- GS3.** use written communication skills to accurately record every information required to be reported as per SOP and GMP guidelines in the prescribed language



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- GS4.** apply planning and organizing skills to plan and organize tools and material required for work to fulfil environment, health, safety and security requirements
- GS5.** use critical thinking skills to take relevant actions on the accidents and breach in compliance with EHS protocols
- GS6.** apply decision-making skills to make balanced judgments within the authority while dealing with hazards and breaches
- GS7.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS8.** use verbal communication skills to communicate with supervisor/ manager/ EHS Incharge or any other concerned authority clearly for escalating any emergency or hazard

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### Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Follow health and hygiene protocols</i>	<b>10</b>	<b>15</b>	-	<b>5</b>
<b>PC1.</b> comply with health and personal hygiene-related protocols as per WHO standards and cGMP guidelines	-	-	-	-
<b>PC2.</b> wash hands and feet before entering in the manufacturing area with soap/alcohol based sanitizers	-	-	-	-
<b>PC3.</b> report any communicable or contagious diseases allergy, sickness or any other environment-related breach before entering the work premises to the designated person	-	-	-	-
<b>PC4.</b> take preventive actions on the report of any allergy, sickness or any other environment-related breach reported by subordinates	-	-	-	-
<b>PC5.</b> follow gowning procedures as per SoP while entering an environment controlled work area and ensure adherence to the same by others	-	-	-	-
<i>Adherence to safety and security procedures</i>	<b>10</b>	<b>25</b>	-	<b>5</b>
<b>PC6.</b> comply with safety and security policies and procedures	-	-	-	-
<b>PC7.</b> 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	-	-	-	-
<b>PC8.</b> take preventive and corrective actions based on the report of any identified deviations in safety and security policies and procedures by subordinates	-	-	-	-
<b>PC9.</b> ensure that discipline for material segregation and 5S system is followed at the storage area	-	-	-	-
<b>PC10.</b> comply with material handling, segregation, and storage guidelines for highly hazardous, poisonous and explosive material	-	-	-	-



### Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<b>PC11.</b> take corrective actions for reported hazards in consultation with EHS personnel	-	-	-	-
<b>PC12.</b> complete the records of safety drills and trainings undertaken by self and subordinates	-	-	-	-
<i>Adherence to emergency procedures</i>	<b>10</b>	<b>15</b>	-	<b>5</b>
<b>PC13.</b> report any hazards that he/she is not competent to deal with the relevant EHS personnel and warn other people who may be affected	-	-	-	-
<b>PC14.</b> raise the alarm and inform the concerned person immediately for action in the cases of spill, fall, injury, toxic inhale, fire or explosion	-	-	-	-
<b>PC15.</b> follow emergency protocols for any alarms and ensure the safety of subordinates in the area under supervision	-	-	-	-
<b>PC16.</b> follow emergency procedures efficiently	-	-	-	-
<b>PC17.</b> ensure injured employees are provided appropriate first aid and medical aid	-	-	-	-
<b>NOS Total</b>	<b>30</b>	<b>55</b>	-	<b>15</b>



## Qualification Pack

### National Occupational Standards (NOS) Parameters

<b>NOS Code</b>	LFS/N0125
<b>NOS Name</b>	Ensure adherence to Environment, health and safety guidelines in a Manufacturing facility and GMP controlled areas
<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceutical, Bio Pharmaceutical, Contract Research
<b>Occupation</b>	Generic
<b>NSQF Level</b>	5.0
<b>Credits</b>	2.00
<b>Version</b>	1.0
<b>Last Reviewed Date</b>	29/09/2023
<b>Next Review Date</b>	29/09/2026
<b>NSQC Clearance Date</b>	29/09/2023



## 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 clear answers to the auditor's queries
- PC11.** produce the documented records of performed activities and operations to auditors
- PC12.** maintain data integrity while responding to auditors and regulatory inspectors

##### *Sensitivity towards all genders and people with disability*

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

- PC13.** respect all genders, religions, and caste
- PC14.** empathize with the people with disability
- PC15.** offer support or help to a person with disability only when asked
- PC16.** ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act
- PC17.** report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee



## Qualification Pack

### Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

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

### Generic Skills (GS)

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

- GS1.** use written communication skills to record information accurately in compliance with ALCOA principles as per SOP and GMP guidelines in the English language
- GS2.** use reading and comprehension skills to read the various coding systems, instructions, guidelines, procedures, rules, and signages
- GS3.** use listening skills to understand the instructions and procedures to be followed
- GS4.** use verbal communication skills to interact with colleagues effectively
- GS5.** use team-building skills while interacting with teammates and while managing the difficult/stressful or emotional situations at work
- GS6.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS7.** apply planning and organizing skills to plan and organize tools and material required to fulfil work requirements
- GS8.** apply critical thinking skills to analyze and identify when to report an issue/concern to the lab in charge and when to deal with a colleague individually, depending on the type of concern
- GS9.** apply customer-centricity to remain compliant with data integrity rules, GMP/GLP guidelines and to evaluate the impact of wrongdoings
- GS10.** apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations with clear choices and written instructions



## Qualification Pack

### Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Coordination with manager</i>	<b>10</b>	<b>20</b>	-	<b>5</b>
<b>PC1.</b> coordinate with the reporting manager to obtain work instructions	-	-	-	-
<b>PC2.</b> communicate to reporting supervisor about process-flow improvements, production defects received from the previous process, repairs and maintenance of equipment as required	-	-	-	-
<b>PC3.</b> communicate deviations / abnormal incidents to the reporting manager	-	-	-	-
<b>PC4.</b> communicate any potential hazards or expected process disruptions to the manager	-	-	-	-
<i>Coordination with colleagues and auditors</i>	<b>15</b>	<b>25</b>	-	<b>5</b>
<b>PC5.</b> support team members and colleagues of other departments in work	-	-	-	-
<b>PC6.</b> train lab assistants and trainees	-	-	-	-
<b>PC7.</b> find solutions to workflow related difficulties with mutual agreement	-	-	-	-
<b>PC8.</b> coordinate with QA for audit related documentation for QC analysis	-	-	-	-
<b>PC9.</b> maintain sense of calm/equilibrium in self as well as team members	-	-	-	-
<b>PC10.</b> provide clear answers to the auditor's queries	-	-	-	-
<b>PC11.</b> produce the documented records of performed activities and operations to auditors	-	-	-	-
<b>PC12.</b> maintain data integrity while responding to auditors and regulatory inspectors	-	-	-	-
<i>Sensitivity towards all genders and people with disability</i>	<b>10</b>	<b>10</b>	-	-
<b>PC13.</b> respect all genders, religions, and caste	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<b>PC14.</b> empathize with the people with disability	-	-	-	-
<b>PC15.</b> offer support or help to a person with disability only when asked	-	-	-	-
<b>PC16.</b> ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act	-	-	-	-
<b>PC17.</b> report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee	-	-	-	-
<b>NOS Total</b>	<b>35</b>	<b>55</b>	<b>-</b>	<b>10</b>



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### National Occupational Standards (NOS) Parameters

<b>NOS Code</b>	LFS/N0302
<b>NOS Name</b>	Coordinate with Manager, colleagues and auditors
<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceutical, Bio Pharmaceutical
<b>Occupation</b>	Quality
<b>NSQF Level</b>	5
<b>Credits</b>	2.00
<b>Version</b>	3.0
<b>Last Reviewed Date</b>	29/09/2023
<b>Next Review Date</b>	29/09/2026
<b>NSQC Clearance Date</b>	29/09/2023



## Qualification Pack

### LFS/N0348: Ensure GxP compliance, respond to issues and non-conformance to maintain regulatory standards and procedure

#### Description

This Job function is about the job holder ensuring the GxP compliance, respond to issues and non-conformance to maintain regulatory standards and procedure

#### Scope

The scope covers the following :

- The Scope covers the following:
- Regulatory Compliance and Non -Conformance
- Risk Assessment and Quality Management
- Handle Corrective Action and Preventive Action (CAPA)

#### Elements and Performance Criteria

##### *Regulatory Compliance and Non -Conformance*

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

- PC1.** Identify key GxP (GMP ,GLP, GCP, GDP) regulations and their specific requirements in maintaining product quality, patient safety, and regulatory compliance.
- PC2.** Evaluate the potential consequences of non-conformance on product quality and regulatory compliance.
- PC3.** Collect information regarding the nature, context, and scope of the non-conformance incident.
- PC4.** maintain routine monitoring and auditing requirements as specified by SOPs and in accordance to GMP
- PC5.** ensure validation processes are in place and appropriately monitored and reviewed in line with SOPs and guidelines
- PC6.** plan and participate in self-inspections for various departments on the site as per predefined schedules and coordinate with cross functional teams
- PC7.** Apply root cause analysis techniques to investigate non-conformance incidents.
- PC8.** Analyse the potential consequences and risks associated with the non-conformance incident and determine the level of impact on product quality, patient safety, and regulatory compliance.

##### *Risk Assessment and Quality Management*

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

- PC9.** Perform risk assessments to evaluate potential impact and likelihood of non-conformance.
- PC10.** Design risk mitigation strategies to ensure product quality and patient safety.
- PC11.** Document non-conformance incidents accurately, including relevant evidence
- PC12.** Prepare comprehensive reports suitable for cross-functional communication and regulatory purposes.



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- PC13.** Communicate effectively to present issues, discuss solutions, and ensure coordinated actions.
- PC14.** Apply continuous improvement principles to suggest enhancements based on non-conformance insights.
- PC15.** Organize and maintain documentation for regulatory inspections related to non-conformance incidents.
- PC16.** Demonstrate readiness and competence during regulatory audits by explaining organizational processes.

### *Handle Corrective Action and Preventive Action (CAPA)*

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

- PC17.** take appropriate corrective and or preventative action in response to compliance issues
- PC18.** Conduct root cause analyses to determine the underlying causes of compliance issues.
- PC19.** communicate appropriately to the organization for any corrective and preventative actions in response to compliance Issues
- PC20.** provide document support to regulatory departments for compilation of various regulatory documents, including verification of in-process quality check documentation
- PC21.** collaborate with the production/packaging teams for providing line clearance regular documentation (online/offline) of all the activities to remove compliance
- PC22.** Monitor and report compliance metrics to track performance and identify areas for improvement.

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** Understanding the key regulations such as Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Good Clinical Practices (GCP), and Good Distribution Practices (GDP) and their specific requirements.
- KU2.** Familiarity with Standard Operating Procedures (SOPs) and guidelines for routine monitoring, auditing, and validation processes.
- KU3.** Competence in root cause analysis techniques to investigate non-conformance incidents.
- KU4.** Ability to assess the potential consequences and risks associated with non-conformance incidents.
- KU5.** Understanding of continuous improvement principles and their application based on non-conformance insights.
- KU6.** Ability to organize and maintain documentation for regulatory inspections.
- KU7.** Effective communication within the organization regarding corrective and preventive actions.
- KU8.** Knowledge of appropriate corrective and preventive action procedures in response to compliance issues.
- KU9.** Understanding quality control and assurance principles, including the ability to ensure product quality meets established standards.
- KU10.** Proficiency in data analysis tools and techniques to assess compliance metrics and identify areas for improvement.

## Generic Skills (GS)



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

- GS1.** use reading and comprehension skills to understand the various coding systems and to read instructions, guidelines, procedures, rules, and signages to understand the procedure to be followed
- GS2.** use listening skills to follow the instructions and procedures during emergency alarms
- GS3.** use written communication skills to accurately record every information required to be reported as per SOP and GMP guidelines in the prescribed language
- GS4.** apply planning and organizing skills to plan and organize tools and material required for work to fulfil environment, health, safety and security requirements
- GS5.** apply decision-making skills to make balanced judgments within the authority while dealing with hazards and breaches
- GS6.** use critical thinking skills to take relevant actions on the accidents and breach in compliance with EHS protocols
- GS7.** use problem-solving skills to determine the root cause and devise a corrective action plan to address it effectively.



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### Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Regulatory Compliance and Non -Conformance</i>	<b>10</b>	<b>15</b>	<b>3</b>	<b>3</b>
<b>PC1.</b> Identify key GxP (GMP ,GLP, GCP, GDP) regulations and their specific requirements in maintaining product quality, patient safety, and regulatory compliance.	-	-	-	-
<b>PC2.</b> Evaluate the potential consequences of non-conformance on product quality and regulatory compliance.	-	-	-	-
<b>PC3.</b> Collect information regarding the nature, context, and scope of the non-conformance incident.	-	-	-	-
<b>PC4.</b> maintain routine monitoring and auditing requirements as specified by SOPs and in accordance to GMP	-	-	-	-
<b>PC5.</b> ensure validation processes are in place and appropriately monitored and reviewed in line with SOPs and guidelines	-	-	-	-
<b>PC6.</b> plan and participate in self-inspections for various departments on the site as per predefined schedules and coordinate with cross functional teams	-	-	-	-
<b>PC7.</b> Apply root cause analysis techniques to investigate non-conformance incidents.	-	-	-	-
<b>PC8.</b> Analyse the potential consequences and risks associated with the non-conformance incident and determine the level of impact on product quality, patient safety, and regulatory compliance.	-	-	-	-
<i>Risk Assessment and Quality Management</i>	<b>10</b>	<b>15</b>	<b>3</b>	<b>3</b>
<b>PC9.</b> Perform risk assessments to evaluate potential impact and likelihood of non-conformance.	-	-	-	-
<b>PC10.</b> Design risk mitigation strategies to ensure product quality and patient safety.	-	-	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<b>PC11.</b> Document non-conformance incidents accurately, including relevant evidence	-	-	-	-
<b>PC12.</b> Prepare comprehensive reports suitable for cross-functional communication and regulatory purposes.	-	-	-	-
<b>PC13.</b> Communicate effectively to present issues, discuss solutions, and ensure coordinated actions.	-	-	-	-
<b>PC14.</b> Apply continuous improvement principles to suggest enhancements based on non-conformance insights.	-	-	-	-
<b>PC15.</b> Organize and maintain documentation for regulatory inspections related to non-conformance incidents.	-	-	-	-
<b>PC16.</b> Demonstrate readiness and competence during regulatory audits by explaining organizational processes.	-	-	-	-
<i>Handle Corrective Action and Preventive Action (CAPA)</i>	<b>10</b>	<b>20</b>	<b>4</b>	<b>4</b>
<b>PC17.</b> take appropriate corrective and or preventative action in response to compliance issues	-	-	-	-
<b>PC18.</b> Conduct root cause analyses to determine the underlying causes of compliance issues.	-	-	-	-
<b>PC19.</b> communicate appropriately to the organization for any corrective and preventative actions in response to compliance Issues	-	-	-	-
<b>PC20.</b> provide document support to regulatory departments for compilation of various regulatory documents, including verification of in-process quality check documentation	-	-	-	-
<b>PC21.</b> collaborate with the production/packaging teams for providing line clearance regular documentation (online/offline) of all the activities to remove compliance	-	-	-	-
<b>PC22.</b> Monitor and report compliance metrics to track performance and identify areas for improvement.	-	-	-	-



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



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### National Occupational Standards (NOS) Parameters

<b>NOS Code</b>	LFS/N0348
<b>NOS Name</b>	Ensure GxP compliance, respond to issues and non-conformance to maintain regulatory standards and procedure
<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceutical, Bio Pharmaceutical
<b>Occupation</b>	Quality
<b>NSQF Level</b>	5.5
<b>Credits</b>	4.0
<b>Version</b>	1.0
<b>Last Reviewed Date</b>	29/09/2023
<b>Next Review Date</b>	29/09/2026
<b>NSQC Clearance Date</b>	29/09/2023



## 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>	<b>1</b>	<b>1</b>	-	-
<b>PC1.</b> understand the significance of employability skills in meeting the current job market requirement and future of work	-	-	-	-
<b>PC2.</b> identify and explore learning and employability relevant portals	-	-	-	-
<b>PC3.</b> research about the different industries, job market trends, latest skills required and the available opportunities	-	-	-	-
<i>Constitutional values - Citizenship</i>	<b>1</b>	<b>1</b>	-	-
<b>PC4.</b> 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.	-	-	-	-
<b>PC5.</b> follow environmentally sustainable practices	-	-	-	-
<i>Becoming a Professional in the 21st Century</i>	<b>1</b>	<b>3</b>	-	-
<b>PC6.</b> recognize the significance of 21st Century Skills for employment	-	-	-	-
<b>PC7.</b> 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	-	-	-	-
<b>PC8.</b> adopt a continuous learning mindset for personal and professional development	-	-	-	-
<i>Basic English Skills</i>	<b>3</b>	<b>4</b>	-	-
<b>PC9.</b> use basic English for everyday conversation in different contexts, in person and over the telephone	-	-	-	-

## Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<b>PC10.</b> read and understand routine information, notes, instructions, mails, letters etc. written in English	-	-	-	-
<b>PC11.</b> write short messages, notes, letters, e-mails etc. in English	-	-	-	-
<i>Career Development &amp; Goal Setting</i>	<b>1</b>	<b>2</b>	-	-
<b>PC12.</b> identify career goals based on the skills, interests, knowledge, and personal attributes	-	-	-	-
<b>PC13.</b> prepare a career development plan with short- and long-term goals	-	-	-	-
<i>Communication Skills</i>	<b>2</b>	<b>2</b>	-	-
<b>PC14.</b> follow verbal and non-verbal communication etiquette while communicating in professional and public settings	-	-	-	-
<b>PC15.</b> use active listening techniques for effective communication	-	-	-	-
<b>PC16.</b> communicate in writing using appropriate style and format based on formal or informal requirements	-	-	-	-
<b>PC17.</b> work collaboratively with others in a team	-	-	-	-
<i>Diversity &amp; Inclusion</i>	<b>1</b>	<b>1</b>	-	-
<b>PC18.</b> communicate and behave appropriately with all genders and PwD	-	-	-	-
<b>PC19.</b> escalate any issues related to sexual harassment at workplace according to POSH Act	-	-	-	-
<i>Financial and Legal Literacy</i>	<b>2</b>	<b>3</b>	-	-
<b>PC20.</b> identify and select reliable institutions for various financial products and services such as bank account, debit and credit cards, loans, insurance etc.	-	-	-	-
<b>PC21.</b> 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
<b>PC22.</b> identify common components of salary and compute income, expenses, taxes, investments etc	-	-	-	-
<b>PC23.</b> identify relevant rights and laws and use legal aids to fight against legal exploitation	-	-	-	-
<i>Essential Digital Skills</i>	<b>3</b>	<b>5</b>	-	-
<b>PC24.</b> operate digital devices and use their features and applications securely and safely	-	-	-	-
<b>PC25.</b> 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.	-	-	-	-
<b>PC26.</b> display responsible online behaviour while using various social media platforms	-	-	-	-
<b>PC27.</b> create a personal email account, send and process received messages as per requirement	-	-	-	-
<b>PC28.</b> carry out basic procedures in documents, spreadsheets and presentations using respective and appropriate applications	-	-	-	-
<b>PC29.</b> utilize virtual collaboration tools to work effectively	-	-	-	-
<i>Entrepreneurship</i>	<b>2</b>	<b>3</b>	-	-
<b>PC30.</b> identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research	-	-	-	-
<b>PC31.</b> develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion	-	-	-	-
<b>PC32.</b> identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity	-	-	-	-
<i>Customer Service</i>	<b>1</b>	<b>2</b>	-	-
<b>PC33.</b> identify different types of customers and ways to communicate with them	-	-	-	-



### Qualification Pack

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



## Qualification Pack

### National Occupational Standards (NOS) Parameters

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



## Qualification Pack

### LFS/N0305: Perform Process validation

#### Description

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

#### Scope

The scope covers the following :

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

#### Elements and Performance Criteria

##### *Carrying out various activities of process validation.*

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

- PC1.** coordination and performance of QC method qualifications, validations and transfers
- PC2.** responsible for the preparation and execution of process validation protocols for new products and for changes to existing products
- PC3.** support in making related changes to the process if the same have become obsolete.
- PC4.** organisation and execution of process development trials
- PC5.** develop testing strategies and rationale for equipment and systems.
- PC6.** manage the change requests and Corrective And Preventive Action Systems (CAPAS) that relate to process validation
- PC7.** develop and execute risk assessments.

##### *Preparing process validation documents*

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

- PC8.** maintain complete and accurate documentary evidence concerning Qualification and Validation exercises that the processes of the company (specific manufacturing process of the product) would consistently produce the desired quality of product meeting its predetermined specification
- PC9.** contribute towards company procedures (SOPs) regarding validations
- PC10.** create documents to ensure compliance with applicable quality objectives and regulatory requirements
- PC11.** maintain organization and archive of completed validation and qualification document packages

##### *Providing support in quality assurance activities applicable to process validation*

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

- PC12.** participate in establishing standard quality and validation practice.



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- PC13.** ensure compliance with applicable quality objectives and regulatory requirements
- PC14.** liaise with QA, Production, technical services and NPI when necessary on process validation issues.
- PC15.** plan and coordinate all process validation testing with QC and review validation analytical data.
- PC16.** conduct reviews of previous qualifications and establish re-qualification programme where appropriate.
- PC17.** troubleshoot / investigate validation-related deviations.

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

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

- PC18.** monitor regulatory and inspection trends and report to the higher authorities
- PC19.** responsible for ensuring conformance with current process validation regulations.
- PC20.** responsible person to liaise with auditors on process validation.
- PC21.** maintain routine programs and processes to ensure high quality products and compliance with current Good Manufacturing Practices (GMPs) and Good Laboratory Practices (GLPs)

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** In-depth knowledge of process validation methodologies and principles, including risk assessment, and validation protocols.
- KU2.** Understanding of industry-specific regulatory requirements and the ability to ensure compliance with these regulations.
- KU3.** Familiarity with change control procedures and the ability to manage changes to processes and equipment effectively.
- KU4.** Understanding of the importance of accurate documentation and maintaining complete records of validation exercises.
- KU5.** Knowledge of quality assurance principles and the ability to support quality assurance activities related to process validation.
- KU6.** Ability to investigate and troubleshoot validation-related deviations and implement corrective and preventive actions
- KU7.** Understanding of how to facilitate audits and address audit findings.
- KU8.** Understanding of how to contribute to the development and maintenance of Standard Operating Procedures (SOPs).
- KU9.** how to develop testing strategies for equipment and systems, including data analysis.

## Generic Skills (GS)

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

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



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- GS2.** use listening skills to follow the instructions and procedures during emergency alarms
- GS3.** use written communication skills to accurately record every information required to be reported as per SOP and GMP guidelines in the prescribed language
- GS4.** apply planning and organizing skills to plan and organize tools and material required for work to fulfil environment, health, safety and security requirements
- GS5.** use critical thinking skills to take relevant actions on the accidents and breach in compliance with EHS protocols
- GS6.** apply decision-making skills to make balanced judgments within the authority while dealing with hazards and breaches
- GS7.** apply problem-solving skills to find solutions for workflow-related difficulties



## Qualification Pack

### Assessment Criteria

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



## Qualification Pack

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



## Qualification Pack

### National Occupational Standards (NOS) Parameters

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



## Qualification Pack

### LFS/N0351: Documentation for process validation

#### Description

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

#### Scope

The scope covers the following :

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

#### Elements and Performance Criteria

##### *To Provide Process Documentation review*

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

- PC1.** Conduct review of process validation documentation to ensure alignment with regulatory requirements and internal procedures.
- PC2.** Ensures that all process validation documentation complies with both internal procedures and industry guidelines.
- PC3.** Review process validation protocols, reports, and records for accuracy, completeness, and consistency.
- PC4.** Validate that all required documentation is present and properly filled out.
- PC5.** Verify that validation procedures and tests were executed in accordance with defined parameters.
- PC6.** Evaluate the integrity and traceability of data recorded in the documentation.

##### *Documentation Compliance and Process Enhancement*

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

- PC7.** Ensure that process validation documentation as per follows established SOPs.
- PC8.** Review documentation to confirm that risk assessment activities were conducted appropriately.
- PC9.** Assess how deviations and non-conformances encountered during process validation were documented and addressed.
- PC10.** Confirm that corrective actions and preventive measures were implemented effectively.
- PC11.** Collaborate with validation team members and other stakeholders to address documentation-related issues and concerns.
- PC12.** Provide guidance and support in resolving documentation challenges and ensuring alignment with requirements.
- PC13.** Identify opportunities to improve documentation processes and enhance the efficiency and effectiveness of equipment validation.



## Qualification Pack

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

### Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** Knowledge of relevant industry-specific regulations and standards governing process validation documentation.
- KU2.** Understanding of document review procedures, including accuracy, completeness, and consistency checks.
- KU3.** Knowledge of maintaining data integrity and traceability within documentation.
- KU4.** Familiarity with quality control and assurance processes in documentation review.
- KU5.** Knowledge of risk assessment methodologies and how they apply to documentation review
- KU6.** Understanding of how deviations and non-conformances are documented and addressed during process validation.
- KU7.** Ability to identify opportunities for process enhancement, streamline review procedures, and promote best practices in documentation.
- KU8.** Proficiency in assessing and confirming the effectiveness of CAPAs in addressing issues.

### Generic Skills (GS)

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

- GS1.** use reading and comprehension skills to understand the various coding systems and to read instructions, guidelines, procedures, rules, and signages to understand the procedure to be followed
- GS2.** use listening skills to follow the instructions and procedures during emergency alarms
- GS3.** use written communication skills to accurately record every information required to be reported as per SOP and GMP guidelines in the prescribed language
- GS4.** apply planning and organizing skills to plan and organize tools and material required for work to fulfil environment, health, safety and security requirements
- GS5.** use critical thinking skills to take relevant actions on the accidents and breach in compliance with EHS protocols
- GS6.** apply decision-making skills to make balanced judgments within the authority while dealing with hazards and breaches
- GS7.** apply problem-solving skills to find solutions for workflow-related difficulties



## Qualification Pack

### Assessment Criteria

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



## Qualification Pack

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



## Qualification Pack

### National Occupational Standards (NOS) Parameters

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



## Qualification Pack

### LFS/N0352: Perform Process Validation for change control

#### Description

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

#### Scope

The scope covers the following :

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

#### Elements and Performance Criteria

##### *Change Control and Validation Strategy Development*

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

- PC1.** Evaluate proposed changes to equipment and processes, assessing their impact on validation requirements.
- PC2.** Analyze the scope and extent of the changes to determine the necessary validation activities
- PC3.** Develop comprehensive validation protocols that cover all critical aspects of the process changes.
- PC4.** Ensure validation protocols align with regulatory guidelines, industry best practices, and internal quality standards.
- PC5.** Conduct a thorough risk assessment to identify potential risks associated with process changes.
- PC6.** Collaborate with relevant stakeholders, including engineering, production, and quality teams, to gather input and ensure alignment on validation plans.
- PC7.** Identifies areas for improving process validation processes within change control.

##### *Execution and Data Collection*

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

- PC8.** Conduct equipment testing, including all relevant parameters functional, performance, and qualification testing, as per the validation protocols.
- PC9.** Collect accurate and reliable data during validation activities, ensuring adherence to predefined data collection methods.
- PC10.** Analyze collected data to draw conclusions and make informed decisions regarding the validation outcomes.
- PC11.** Verify that validation documentation meets regulatory expectations and internal change control procedures

##### *Documentation and Reporting*

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

- PC12.** Reviews change control documentation comprehensively to understand modifications.
- PC13.** Identifies potential impacts on process performance, reliability, and regulatory compliance.



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

**PC15.** Validates that changes will maintain compliance throughout process validation

### Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** Understanding of relevant regulatory requirements and guidelines governing change control and validation processes.
- KU2.** Knowledge of how to assess the impact of proposed changes on equipment and processes in terms of validation requirements.
- KU3.** Ability to conduct in-depth risk assessments to identify and mitigate potential risks associated with process changes.
- KU4.** Knowledge of process improvement methodologies
- KU5.** Ability to identify areas for enhancing the process validation process within change control.
- KU6.** Proficiency in collecting accurate and reliable data during validation activities and analyzing it to make informed decisions
- KU7.** Understanding of how to ensure that proposed changes comply with relevant regulations and industry standards throughout the process validation.

### Generic Skills (GS)

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

- GS1.** use reading and comprehension skills to understand the various coding systems and to read instructions, guidelines, procedures, rules, and signages to understand the procedure to be followed
- GS2.** use listening skills to follow the instructions and procedures during emergency alarms
- GS3.** use written communication skills to accurately record every information required to be reported as per SOP and GMP guidelines in the prescribed language
- GS4.** apply planning and organizing skills to plan and organize tools and material required for work to fulfil environment, health, safety and security requirements
- GS5.** use critical thinking skills to take relevant actions on the accidents and breach in compliance with EHS protocols
- GS6.** apply decision-making skills to make balanced judgments within the authority while dealing with hazards and breaches
- GS7.** apply problem-solving skills to find solutions for workflow-related difficulties

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### Assessment Criteria

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



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



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### National Occupational Standards (NOS) Parameters

<b>NOS Code</b>	LFS/N0352
<b>NOS Name</b>	Perform Process Validation for change control
<b>Sector</b>	Life Sciences
<b>Sub-Sector</b>	Pharmaceutical, Bio Pharmaceutical
<b>Occupation</b>	Quality
<b>NSQF Level</b>	5.5
<b>Credits</b>	2.0
<b>Version</b>	1.0
<b>Last Reviewed Date</b>	29/09/2023
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## 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.)

### Minimum Passing % at NOS Level: 70

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

## Assessment Weightage

Compulsory NOS

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

Elective: 1 Process validation



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