

## Qualification Pack



# Production Technician: Medical Device- Stents

Electropolishing

QP Code: LFS/Q6202 Instantiated QP Code: LFS/Q6202-SI003

Version: 1.0

NSQF Level: 5

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## Qualification Pack

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## Qualification Pack

### LFS/Q6202-SI003: Production Technician: Medical Device-Stents

#### Brief Job Description

The Production Technician for stent manufacturing is responsible for performing various processes like laser cutting, descaling, annealing, electropolishing, Ultrasonic Cleaning, drug coating and primary packaging of stent following Good Manufacturing Practices for the manufacturing of stent. The jobholder verifies the output to ensure that in batch manufacturing the quality parameters are met and ensures basic in-process quality checks for quality management. He/She also generates the critical records for every activity performed in compliance with data integrity rules. He/she also analyzes and report production/maintenance/quality related issues to the senior for solving work related problems. He/she also inspects products to verify conformance to specification.

#### Personal Attributes

The individual should have good communication skills in the regional language and able to comprehend the instructions and process documents in the English language. He/she should have good analytical skills. The job holder should be able to give attention to detail and understand the criticality of work.

#### Applicable National Occupational Standards (NOS)

##### Compulsory NOS:

1. [LFS/N6203: Perform pre-production check and preparation of various machines for manufacturing](#)
2. [LFS/N0130: Ensure adherence to environment, health and safety guidelines in manufacturing facility and controlled cleanroom area](#)
3. [LFS/N0131: Ensure a hygienic and clean work area to avoid contamination in manufacturing facility](#)
4. [LFS/N6211: Perform reporting and documentation with data integrity for medical devices and IVD](#)
5. [LFS/N0133: Coordinate and communicate with supervisor/ engineer, teams and auditors](#)
6. [DGT/VSQ/N0103: Employability Skills \(90 Hours\)](#)

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

Elective : Electropolishing

1. [LFS/N6206: Perform Electropolishing Process](#)

#### Qualification Pack (QP) Parameters



## Qualification Pack

|                                                           |                                                                                                                                                                                                                                    |
|-----------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Sector</b>                                             | Life Sciences                                                                                                                                                                                                                      |
| <b>Sub-Sector</b>                                         | Medical Devices and In Vitro Diagnostic (IVD)                                                                                                                                                                                      |
| <b>Occupation</b>                                         | Manufacturing - Medical Devices and IVD                                                                                                                                                                                            |
| <b>Country</b>                                            | India                                                                                                                                                                                                                              |
| <b>NSQF Level</b>                                         | 5                                                                                                                                                                                                                                  |
| <b>Credits</b>                                            | 14                                                                                                                                                                                                                                 |
| <b>Aligned to NCO/ISCO/ISIC Code</b>                      | NCO-2015- 3139.1400                                                                                                                                                                                                                |
| <b>Minimum Educational Qualification &amp; Experience</b> | Pursuing 2nd year of 2-year diploma after 12th (approved by AICTE or State Technical Education Regulatory Body in relevant field and continuous education)<br>OR<br>Pursuing 2nd year of UG ( in life sciences or relevant fields) |
| <b>Minimum Level of Education for Training in School</b>  | Not Applicable                                                                                                                                                                                                                     |
| <b>Pre-Requisite License or Training</b>                  | NA                                                                                                                                                                                                                                 |
| <b>Minimum Job Entry Age</b>                              | 18 Years                                                                                                                                                                                                                           |
| <b>Last Reviewed On</b>                                   | NA                                                                                                                                                                                                                                 |
| <b>Next Review Date</b>                                   | 01/11/2026                                                                                                                                                                                                                         |
| <b>NSQC Approval Date</b>                                 | 01/11/2023                                                                                                                                                                                                                         |
| <b>Version</b>                                            | 1.0                                                                                                                                                                                                                                |
| <b>Reference code on NQR</b>                              | QG-5-LS-01272-2023-V1-LSSSDC                                                                                                                                                                                                       |
| <b>NQR Version</b>                                        | 1                                                                                                                                                                                                                                  |



## Qualification Pack

# LFS/N6203: Perform pre-production check and preparation of various machines for manufacturing

## Description

This NOS is about performing pre-production checks and preparing machines for manufacturing operations

## Scope

The scope covers the following :

- The NOS Scope are :
- Material Check
- Pre-production Safety Check
- Preparation of various machines for manufacturing

## Elements and Performance Criteria

### Material Check

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

- PC1.** ensure stocks of required raw materials are ready and available as per minimum stock required
- PC2.** perform thorough inspection and verification of quality of all raw material
- PC3.** ensure that critical starting material, raw material are from a respective batch and analyzed by QC and approved by QA
- PC4.** match the Batch Code/ Item Code and Authorized Return (AR) No. of each compound/material with the Batch Code on the job schedule given by the planning department ensuring FIFO (First in First Out)
- PC5.** measure/weigh the starting material/ raw material/compound as per the desired specifications (shape, size and weight)
- PC6.** reach out to the supervisor for rejection control if disparities exist during visual inspection
- PC7.** return the unused material to warehouse with the appropriate label

### Pre-production Safety check

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

- PC8.** follow safe working instructions as per SOP and regulatory guidelines
- PC9.** ensure manufacturing process follows relevant safety regulations
- PC10.** perform comprehensive risk assessments to identify potential risks
- PC11.** Perform machinery and equipment basic function testing to ensure their proper working
- PC12.** Perform Job Safety Analysis in accordance with International/ National Standards
- PC13.** take secure permit/ authorization to work from appropriate authority

### Preparation of various machines for manufacturing

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

- PC14.** prepare machinery setup and configuration for stent manufacturing
- PC15.** ensure all the machines and equipments are calibrated & validated



## Qualification Pack

- PC16.** ensure that facilities, equipments and machinery are qualified by QA post cleaning validation and equipment validation
- PC17.** ensure proper loading of material into machine
- PC18.** Perform trial run and random tests to ensure accuracy
- PC19.** Perform routine maintenance of machinery and equipment
- PC20.** maintain history records and breakdown maintenance records
- PC21.** maintain electronic documentation for the trial runs and random test along with justifications for any wrong entries as applicable

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** organizational SOPs relevant to pre-production safety check and preparation of machines for manufacturing operations
- KU2.** Purpose of in-process checks and their procedures
- KU3.** SOP for change request and maintenance of machine
- KU4.** procedures for documentation, reporting and escalation
- KU5.** relevant Data Integrity Rule and defined ISO Class guidelines
- KU6.** equipments used for broad level checks and their operative procedures
- KU7.** common issues in machine operations and their solutions
- KU8.** procedure for changeover cleaning
- KU9.** machinery and equipment calibration process
- KU10.** process for generating electronic records
- KU11.** methods for randoms tests in stent manufacturing
- KU12.** critical parameters for specific production machines

## Generic Skills (GS)

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

- GS1.** record and communicate details of work done to appropriate people using written report or computer based record/electronic mail
- GS2.** understand the various coding systems as per company norms
- GS3.** communicate with cross functional team and supervisor
- GS4.** disclose information only to those who have the right and need to know it
- GS5.** suggest improvements(if any) in process based on experience
- GS6.** make decisions related to corrective maintenance and troubleshooting
- GS7.** analyse the readings of various operational variables and make informed decisions as per SOP
- GS8.** analyse any situation which needs an immediate escalation or emergency alarm





## Qualification Pack

### Assessment Criteria

| Assessment Criteria for Outcomes                                                                                                                                                                                 | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|-----------------|---------------|------------|
| <i>Material Check</i>                                                                                                                                                                                            | <b>10</b>    | <b>15</b>       | <b>5</b>      | <b>2</b>   |
| <b>PC1.</b> ensure stocks of required raw materials are ready and available as per minimum stock required                                                                                                        | -            | -               | -             | -          |
| <b>PC2.</b> perform thorough inspection and verification of quality of all raw material                                                                                                                          | -            | -               | -             | -          |
| <b>PC3.</b> ensure that critical starting material, raw material are from a respective batch and analyzed by QC and approved by QA                                                                               | -            | -               | -             | -          |
| <b>PC4.</b> match the Batch Code/ Item Code and Authorized Return (AR) No. of each compound/material with the Batch Code on the job schedule given by the planning department ensuring FIFO (First in First Out) | -            | -               | -             | -          |
| <b>PC5.</b> measure/weigh the starting material/ raw material/compound as per the desired specifications (shape, size and weight)                                                                                | -            | -               | -             | -          |
| <b>PC6.</b> reach out to the supervisor for rejection control if disparities exist during visual inspection                                                                                                      | -            | -               | -             | -          |
| <b>PC7.</b> return the unused material to warehouse with the appropriate label                                                                                                                                   | -            | -               | -             | -          |
| <i>Pre-production Safety check</i>                                                                                                                                                                               | <b>10</b>    | <b>15</b>       | <b>5</b>      | <b>3</b>   |
| <b>PC8.</b> follow safe working instructions as per SOP and regulatory guidelines                                                                                                                                | -            | -               | -             | -          |
| <b>PC9.</b> ensure manufacturing process follows relevant safety regulations                                                                                                                                     | -            | -               | -             | -          |
| <b>PC10.</b> perform comprehensive risk assessments to identify potential risks                                                                                                                                  | -            | -               | -             | -          |
| <b>PC11.</b> Perform machinery and equipment basic function testing to ensure their proper working                                                                                                               | -            | -               | -             | -          |
| <b>PC12.</b> Perform Job Safety Analysis in accordance with International/ National Standards                                                                                                                    | -            | -               | -             | -          |

### Qualification Pack

| Assessment Criteria for Outcomes                                                                                                                | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|-------------------------------------------------------------------------------------------------------------------------------------------------|--------------|-----------------|---------------|------------|
| <b>PC13.</b> take secure permit/ authorization to work from appropriate authority                                                               | -            | -               | -             | -          |
| <i>Preparation of various machines for manufacturing</i>                                                                                        | <b>10</b>    | <b>15</b>       | <b>5</b>      | <b>5</b>   |
| <b>PC14.</b> prepare machinery setup and configuration for stent manufacturing                                                                  | -            | -               | -             | -          |
| <b>PC15.</b> ensure all the machines and equipments are calibrated & validated                                                                  | -            | -               | -             | -          |
| <b>PC16.</b> ensure that facilities, equipments and machinery are qualified by QA post cleaning validation and equipment validation             | -            | -               | -             | -          |
| <b>PC17.</b> ensure proper loading of material into machine                                                                                     | -            | -               | -             | -          |
| <b>PC18.</b> Perform trial run and random tests to ensure accuracy                                                                              | -            | -               | -             | -          |
| <b>PC19.</b> Perform routine maintenance of machinery and equipment                                                                             | -            | -               | -             | -          |
| <b>PC20.</b> maintain history records and breakdown maintenance records                                                                         | -            | -               | -             | -          |
| <b>PC21.</b> maintain electronic documentation for the trial runs and random test along with justifications for any wrong entries as applicable | -            | -               | -             | -          |
| <b>NOS Total</b>                                                                                                                                | <b>30</b>    | <b>45</b>       | <b>15</b>     | <b>10</b>  |





## Qualification Pack

### National Occupational Standards (NOS) Parameters

|                            |                                                                                    |
|----------------------------|------------------------------------------------------------------------------------|
| <b>NOS Code</b>            | LFS/N6203                                                                          |
| <b>NOS Name</b>            | Perform pre-production check and preparation of various machines for manufacturing |
| <b>Sector</b>              | Life Sciences                                                                      |
| <b>Sub-Sector</b>          | Medical Devices and In Vitro Diagnostic (IVD)                                      |
| <b>Occupation</b>          | Manufacturing - Medical Devices and IVD                                            |
| <b>NSQF Level</b>          | 5                                                                                  |
| <b>Credits</b>             | 2.0                                                                                |
| <b>Version</b>             | 1.0                                                                                |
| <b>Last Reviewed Date</b>  | 01/11/2023                                                                         |
| <b>Next Review Date</b>    | 01/11/2026                                                                         |
| <b>NSQC Clearance Date</b> | 01/11/2023                                                                         |



## Qualification Pack

# LFS/N0130: Ensure adherence to environment, health and safety guidelines in manufacturing facility and controlled cleanroom area

## Description

This NOS is about ensuring adherence to environment, health and safety guidelines in manufacturing facility and controlled cleanroom area

## Scope

The scope covers the following :

- The NOS scope are:
- Follow health and hygiene protocols
- Follow safety and security procedures
- Follow 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 regulatory guidelines/defined ISO class guidelines
- PC2.** ensure cleanroom facilities adhere to strict cleanliness guidelines
- PC3.** wash hands before entering in the production area as per SOP
- PC4.** report any allergy, sickness, or any other environment-related breach before or after entering the work premises to the designated person
- PC5.** ensure wearing cleanroom specialized garments while entering an environment-controlled work area
- PC6.** ensure proper disposal of used accessories

### *Follow safety and security procedures*

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

- PC7.** comply with safety and security policies and procedures
- PC8.** use appropriate safety gears like gowns, shoecover, headgear, masks, gloves and other relevant safety accessories as per regulatory guidelines throughout the process
- PC9.** use pulleys/ forklift (if available) to transport the material/ spares/ heavy assembly and tools
- PC10.** report any identified breaches in safety and security policies and procedures to the designated person
- PC11.** segregate material and follow the 5S system at the storage area
- PC12.** adhere to storage and handling guidelines for hazardous material and volatile chemicals
- PC13.** identify and correct any hazards that one can deal with safely, competently and within the limits of authority
- PC14.** ensure proper disposal of biohazardous material and chemical waste

### *Follow emergency procedures*



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

- PC15.** raise the alarm and report any hazards which is not competent to deal with, to the relevant person in line with organizational procedures and warn other people who may get affected
- PC16.** inform the concerned person immediately about every unsafe act/ incident
- PC17.** follow emergency protocols efficiently

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** individual's role and responsibilities in maintaining healthy, hygienic, safe and secure working environment
- KU2.** company's procedures and protocols for the environment, health and safety
- KU3.** relevant legislative requirements as per local laws
- KU4.** implications that any non-compliance with health, safety and security may have on individuals and the organization
- KU5.** workplace hazards in the manufacturing/ research facility in the life sciences sector and reporting procedures for unhealthy/ unsafe act/incidents, hazards and accident as per defined ISO class
- KU6.** limits of individual responsibility for dealing with hazards
- KU7.** chemical substances, their characteristics, and required precaution and safety measures
- KU8.** cleanroom specialized garment
- KU9.** the organization's emergency procedures for different emergency situations and the importance of following these procedures
- KU10.** evacuation procedures for employees, contract staff and visitors
- KU11.** procedure to summon medical assistance and the emergency services, where necessary
- KU12.** different types of breaches in the environment, health, safety and security and how and when to report these
- KU13.** Indian Medical device Rules 2017 and ISO 13485 guidelines for personal hygiene
- KU14.** types of safety gears and procedure to use them
- KU15.** importance of material segregation and 5S system
- KU16.**
  - importance of material segregation and 5S system
  - 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 read instructions, guidelines, procedures, rules, and signages
- GS2.** use written communication skills to accurately record every information required to be reported as per SOP and defined ISO class guidelines in the language prescribed by the company's SOP



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- GS3.** apply planning and organizing skills to plan and organize tools and material required for work to fulfil environment, health, safety and security requirements
- GS4.** use critical thinking skills to ascertain the breach/ compliance of EHS protocols
- GS5.** apply customer centricity to remain compliant with data integrity rules, defined ISO class guidelines and to evaluate impact of wrongdoings
- GS6.** apply decision-making skills to make balanced judgments within the authority in different situations while dealing with hazards and breaches

## Qualification Pack

### Assessment Criteria

| Assessment Criteria for Outcomes                                                                                                                                                   | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|-----------------|---------------|------------|
| <i>Follow health and hygiene protocols</i>                                                                                                                                         | <b>15</b>    | <b>15</b>       | <b>5</b>      | <b>5</b>   |
| <b>PC1.</b> comply with health and personal hygiene-related protocols as per regulatory guidelines/defined ISO class guidelines                                                    | -            | -               | -             | -          |
| <b>PC2.</b> ensure cleanroom facilities adhere to strict cleanliness guidelines                                                                                                    | -            | -               | -             | -          |
| <b>PC3.</b> wash hands before entering in the production area as per SOP                                                                                                           | -            | -               | -             | -          |
| <b>PC4.</b> report any allergy, sickness, or any other environment-related breach before or after entering the work premises to the designated person                              | -            | -               | -             | -          |
| <b>PC5.</b> ensure wearing cleanroom specialized garments while entering an environment-controlled work area                                                                       | -            | -               | -             | -          |
| <b>PC6.</b> ensure proper disposal of used accessories                                                                                                                             | -            | -               | -             | -          |
| <i>Follow safety and security procedures</i>                                                                                                                                       | <b>15</b>    | <b>15</b>       | <b>3</b>      | <b>3</b>   |
| <b>PC7.</b> comply with safety and security policies and procedures                                                                                                                | -            | -               | -             | -          |
| <b>PC8.</b> use appropriate safety gears like gowns, shoe cover, headgear, masks, gloves and other relevant safety accessories as per regulatory guidelines throughout the process | -            | -               | -             | -          |
| <b>PC9.</b> use pulleys/ forklift (if available) to transport the material/ spares/ heavy assembly and tools                                                                       | -            | -               | -             | -          |
| <b>PC10.</b> report any identified breaches in safety and security policies and procedures to the designated person                                                                | -            | -               | -             | -          |
| <b>PC11.</b> segregate material and follow the 5S system at the storage area                                                                                                       | -            | -               | -             | -          |
| <b>PC12.</b> adhere to storage and handling guidelines for hazardous material and volatile chemicals                                                                               | -            | -               | -             | -          |



## Qualification Pack

| Assessment Criteria for Outcomes                                                                                                                                                                  | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|-----------------|---------------|------------|
| <b>PC13.</b> identify and correct any hazards that one can deal with safely, competently and within the limits of authority                                                                       | -            | -               | -             | -          |
| <b>PC14.</b> ensure proper disposal of biohazardous material and chemical waste                                                                                                                   | -            | -               | -             | -          |
| <i>Follow emergency procedures</i>                                                                                                                                                                | <b>10</b>    | <b>10</b>       | <b>2</b>      | <b>2</b>   |
| <b>PC15.</b> raise the alarm and report any hazards which is not competent to deal with, to the relevant person in line with organizational procedures and warn other people who may get affected | -            | -               | -             | -          |
| <b>PC16.</b> inform the concerned person immediately about every unsafe act/ incident                                                                                                             | -            | -               | -             | -          |
| <b>PC17.</b> follow emergency protocols efficiently                                                                                                                                               | -            | -               | -             | -          |
| <b>NOS Total</b>                                                                                                                                                                                  | <b>40</b>    | <b>40</b>       | <b>10</b>     | <b>10</b>  |



## Qualification Pack

### National Occupational Standards (NOS) Parameters

|                            |                                                                                                                       |
|----------------------------|-----------------------------------------------------------------------------------------------------------------------|
| <b>NOS Code</b>            | LFS/N0130                                                                                                             |
| <b>NOS Name</b>            | Ensure adherence to environment, health and safety guidelines in manufacturing facility and controlled cleanroom area |
| <b>Sector</b>              | Life Sciences                                                                                                         |
| <b>Sub-Sector</b>          | Medical Devices and In Vitro Diagnostic (IVD)                                                                         |
| <b>Occupation</b>          | Generic                                                                                                               |
| <b>NSQF Level</b>          | 4.5                                                                                                                   |
| <b>Credits</b>             | 1.0                                                                                                                   |
| <b>Version</b>             | 1.0                                                                                                                   |
| <b>Last Reviewed Date</b>  | 01/11/2023                                                                                                            |
| <b>Next Review Date</b>    | 01/11/2026                                                                                                            |
| <b>NSQC Clearance Date</b> | 01/11/2023                                                                                                            |





## Qualification Pack

# LFS/N0131: Ensure a hygienic and clean work area to avoid contamination in manufacturing facility

## Description

This NOS is about ensuring a hygienic and clean work area to avoid contamination

## Scope

The scope covers the following :

- The NOS scope are:
- Sanitation activities before the start of work
- Sanitation activities during work
- Sanitation activities after completion of work

## Elements and Performance Criteria

### *Sanitation activities before the start of work*

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

- PC1.** ensure sanitation of cleanroom area as per SOP
- PC2.** check for validation tag on machines and equipments
- PC3.** ensure proper cleaning of machinery and equipments
- PC4.** ensure cleaning validation in the presence of authorized personnel or QA inspector
- PC5.** ensure adequate ventilation during work being carried out
- PC6.** ensure regular sterilization of machinery and equipment
- PC7.** handle the cleaning material/reagent only after wearing the personal protective equipment required for the cleaning method
- PC8.** segregate and store the material with an appropriate label in designated places to avoid contamination

### *Sanitation activities during work*

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

- PC9.** segregate and store the intermediate material with an appropriate label in designated places to avoid contamination
- PC10.** report any additional cleaning requirement that is outside one's purview, to the appropriate person
- PC11.** segregate, store and dispose of the rejected products or generated waste as per SOP under the supervision of supervisor and EHS personnel

### *Sanitation activities after completion of work*

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

- PC12.** ensure proper disposal of hazardous material and chemical waste
- PC13.** ensure removal of scrap material from work area
- PC14.** ensure cleaning of the equipment after every batch production as per SOP



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- PC15.** perform the cleaning validation of the equipment in the presence of designated authorized personnel and QA inspector
- PC16.** ensure clean and dry area after completion of work as per ISO requirement of sanitized premises

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** levels of hygiene required by production area and the importance of maintaining the same
- KU2.** methodology for production area inspection with methods and materials required for cleaning a variety of surfaces and equipment
- KU3.** methodology to check machinery and equipment on completion of cleaning
- KU4.** procedures for reporting any unidentified soiling or any deviation for cleaning validation
- KU5.** role of different materials, machinery and equipment in cleaning and sanitation of manufacturing area
- KU6.** defined ISO class guidelines for cleaning/ sanitation activity and maintaining hygiene
- KU7.** cleaning validation process

## Generic Skills (GS)

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

- GS1.** use written communication skills to record and communicate details of work done to appropriate people using written/typed report and electronic mail
- GS2.** use verbal communication skills to communicate with supervisor, cross-functional teams and auditors effectively
- GS3.** use critical thinking skills to interpret the various coding systems as per company norms and in identifying the non-compliance while performing the area inspection
- GS4.** apply customer centricity at work
- GS5.** apply problem-solving and decision making while dealing with any deviation

## Qualification Pack

### Assessment Criteria

| Assessment Criteria for Outcomes                                                                                                                       | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|-----------------|---------------|------------|
| <i>Sanitation activities before the start of work</i>                                                                                                  | <b>15</b>    | <b>15</b>       | <b>5</b>      | <b>5</b>   |
| <b>PC1.</b> ensure sanitation of cleanroom area as per SOP                                                                                             | -            | -               | -             | -          |
| <b>PC2.</b> check for validation tag on machines and equipments                                                                                        | -            | -               | -             | -          |
| <b>PC3.</b> ensure proper cleaning of machinery and equipments                                                                                         | -            | -               | -             | -          |
| <b>PC4.</b> ensure cleaning validation in the presence of authorized personnel or QA inspector                                                         | -            | -               | -             | -          |
| <b>PC5.</b> ensure adequate ventilation during work being carried out                                                                                  | -            | -               | -             | -          |
| <b>PC6.</b> ensure regular sterilization of machinery and equipment                                                                                    | -            | -               | -             | -          |
| <b>PC7.</b> handle the cleaning material/reagent only after wearing the personal protective equipment required for the cleaning method                 | -            | -               | -             | -          |
| <b>PC8.</b> segregate and store the material with an appropriate label in designated places to avoid contamination                                     | -            | -               | -             | -          |
| <i>Sanitation activities during work</i>                                                                                                               | <b>15</b>    | <b>15</b>       | <b>3</b>      | <b>3</b>   |
| <b>PC9.</b> segregate and store the intermediate material with an appropriate label in designated places to avoid contamination                        | -            | -               | -             | -          |
| <b>PC10.</b> report any additional cleaning requirement that is outside one's purview, to the appropriate person                                       | -            | -               | -             | -          |
| <b>PC11.</b> segregate, store and dispose of the rejected products or generated waste as per SOP under the supervision of supervisor and EHS personnel | -            | -               | -             | -          |
| <i>Sanitation activities after completion of work</i>                                                                                                  | <b>10</b>    | <b>10</b>       | <b>2</b>      | <b>2</b>   |



## Qualification Pack

| Assessment Criteria for Outcomes                                                                                                  | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|-----------------------------------------------------------------------------------------------------------------------------------|--------------|-----------------|---------------|------------|
| <b>PC12.</b> ensure proper disposal of hazardous material and chemical waste                                                      | -            | -               | -             | -          |
| <b>PC13.</b> ensure removal of scrap material from work area                                                                      | -            | -               | -             | -          |
| <b>PC14.</b> ensure cleaning of the equipment after every batch production as per SOP                                             | -            | -               | -             | -          |
| <b>PC15.</b> perform the cleaning validation of the equipment in the presence of designated authorized personnel and QA inspector | -            | -               | -             | -          |
| <b>PC16.</b> ensure clean and dry area after completion of work as per ISO requirement of sanitized premises                      | -            | -               | -             | -          |
| <b>NOS Total</b>                                                                                                                  | <b>40</b>    | <b>40</b>       | <b>10</b>     | <b>10</b>  |



## Qualification Pack

### National Occupational Standards (NOS) Parameters

|                            |                                                                                        |
|----------------------------|----------------------------------------------------------------------------------------|
| <b>NOS Code</b>            | LFS/N0131                                                                              |
| <b>NOS Name</b>            | Ensure a hygienic and clean work area to avoid contamination in manufacturing facility |
| <b>Sector</b>              | Life Sciences                                                                          |
| <b>Sub-Sector</b>          | Medical Devices and In Vitro Diagnostic (IVD)                                          |
| <b>Occupation</b>          | Generic                                                                                |
| <b>NSQF Level</b>          | 4.5                                                                                    |
| <b>Credits</b>             | 1.0                                                                                    |
| <b>Version</b>             | 1.0                                                                                    |
| <b>Last Reviewed Date</b>  | 01/11/2023                                                                             |
| <b>Next Review Date</b>    | 01/11/2026                                                                             |
| <b>NSQC Clearance Date</b> | 01/11/2023                                                                             |



## Qualification Pack

# LFS/N6211: Perform reporting and documentation with data integrity for medical devices and IVD

## Description

This NOS is about performing reporting and documentation with data integrity for medical devices and IVD

## Scope

The scope covers the following :

- The NOS scope are :
- Reporting and escalation of deviations
- Documentation

## Elements and Performance Criteria

### *Reporting and escalation of deviations*

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

- PC1.** identify non-conformities to quality assurance standards and product specifications
- PC2.** identify potential causes of non-conformities to quality assurance standards with the help of supervisor
- PC3.** implement the corrective and preventive actions as guided by the engineer and quality assurance team

### *Documentation*

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

- PC4.** identify documentation to be completed as per SOP and ISO class rules
- PC5.** record the required information of all significant activities, incidents and deviations as per recording formats in compliance with SOP and defined ISO class guidelines
- PC6.** maintain both electronic and manual records in the log books and other documentation required as per defined ISO class
- PC7.** update the Equipment log books , status boards & ensure in line with the process

## Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** procedures for documentation, reporting, and escalation of incidents and deviations
- KU2.** procedure for generating manual and electronic records
- KU3.** ALCOA Principles, Data integrity, and information security rules
- KU4.** procedure for line clearance

## Generic Skills (GS)

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



## Qualification Pack

- GS1.** use reading and comprehension skills to extract the relevant information from manuals, SOPs, health and safety instructions, memos, reports, job cards, and notes/comments
- GS2.** use reading and comprehension skills to read the various coding systems, instructions, guidelines, procedures, rules, and signages
- GS3.** use verbal communication skills to interact with teammates, and during interaction with regulatory inspectors and other people
- GS4.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS5.** apply critical thinking skills to analyze and identify what and when to report an issue to the concerned supervisor and to deal with a colleague individually, depending on the type of concern
- GS6.** use critical thinking skills in analyzing the impact of deviations, wastage, and rejects to the safety, environment and efficiency, compliance, and cost
- GS7.** apply customer-centricity to remain compliant with data integrity rules, and while responding to auditors and QA personnel



## Qualification Pack

### Assessment Criteria

| Assessment Criteria for Outcomes                                                                                                                                                     | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|-----------------|---------------|------------|
| <i>Reporting and escalation of deviations</i>                                                                                                                                        | <b>20</b>    | <b>20</b>       | <b>5</b>      | <b>5</b>   |
| <b>PC1.</b> identify non-conformities to quality assurance standards and product specifications                                                                                      | -            | -               | -             | -          |
| <b>PC2.</b> identify potential causes of non-conformities to quality assurance standards with the help of supervisor                                                                 | -            | -               | -             | -          |
| <b>PC3.</b> implement the corrective and preventive actions as guided by the engineer and quality assurance team                                                                     | -            | -               | -             | -          |
| <i>Documentation</i>                                                                                                                                                                 | <b>20</b>    | <b>20</b>       | <b>5</b>      | <b>5</b>   |
| <b>PC4.</b> identify documentation to be completed as per SOP and ISO class rules                                                                                                    | -            | -               | -             | -          |
| <b>PC5.</b> record the required information of all significant activities, incidents and deviations as per recording formats in compliance with SOP and defined ISO class guidelines | -            | -               | -             | -          |
| <b>PC6.</b> maintain both electronic and manual records in the log books and other documentation required as per defined ISO class                                                   | -            | -               | -             | -          |
| <b>PC7.</b> update the Equipment log books , status boards & ensure in line with the process                                                                                         | -            | -               | -             | -          |
| <b>NOS Total</b>                                                                                                                                                                     | <b>40</b>    | <b>40</b>       | <b>10</b>     | <b>10</b>  |





## Qualification Pack

### National Occupational Standards (NOS) Parameters

|                            |                                                                                     |
|----------------------------|-------------------------------------------------------------------------------------|
| <b>NOS Code</b>            | LFS/N6211                                                                           |
| <b>NOS Name</b>            | Perform reporting and documentation with data integrity for medical devices and IVD |
| <b>Sector</b>              | Life Sciences                                                                       |
| <b>Sub-Sector</b>          | Medical Devices and In Vitro Diagnostic (IVD)                                       |
| <b>Occupation</b>          | Manufacturing - Medical Devices and IVD                                             |
| <b>NSQF Level</b>          | 5                                                                                   |
| <b>Credits</b>             | 1                                                                                   |
| <b>Version</b>             | 1.0                                                                                 |
| <b>Last Reviewed Date</b>  | 01/11/2023                                                                          |
| <b>Next Review Date</b>    | 01/11/2026                                                                          |
| <b>NSQC Clearance Date</b> | 01/11/2023                                                                          |



## Qualification Pack

### LFS/N0133: Coordinate and communicate with supervisor/ engineer, teams and auditors

#### Description

This NOS unit is about coordinating and communicating with supervisor/ engineer, teams and auditors

#### Scope

The scope covers the following :

- Coordination with supervisor/engineer
- Team coordination
- Respond to audit queries
- Sensitivity towards all genders and people with disability

#### Elements and Performance Criteria

##### *Coordination with supervisor/engineer*

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

- PC1.** follow work instructions received from the reporting supervisor
- PC2.** adhere to the production plan to meet timelines
- PC3.** communicate process-flow improvements, production defects received from the previous process, repairs and maintenance of equipment to reporting supervisor
- PC4.** ensure timely intimation to supervisor/ production engineer about planned absence/ illness/ dizziness during work/ critical issues requiring his/her intervention
- PC5.** engage with supervisor on work-related and behavioral feedback and demonstrate continual learning and self-direction

##### *Team coordination*

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

- PC6.** support team members and colleagues of other departments in work
- PC7.** take handover from previous shift operator and give handover to next shift operator as per SOP
- PC8.** guide manufacturing and packaging assistants during manufacturing process
- PC9.** coordinate with warehouse team for material dispensing and issuance
- PC10.** find solutions for workflow related difficulties with mutual agreement
- PC11.** coordinate with maintenance team for preventive and corrective maintenance, break down and calibration errors
- PC12.** coordinate with quality control team for sample collection, batch release and in-process checks
- PC13.** coordinate with quality assurance team for machine/ equipment validation at a routine interval as per SOP
- PC14.** provide inputs to the concerned stakeholders in periodic fence line review to detect non-compliance



## Qualification Pack

**PC15.** coordinate with EHS team for any safety incident, accident and emergency

*Respond to audit queries*

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

**PC16.** ensure interact with auditor in a preferable language

**PC17.** provide an honest and clear answer to the raised queries

**PC18.** maintain data integrity while responding to auditors or while producing the documented records for activities performed

*Sensitivity towards all genders and people with disability*

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

**PC19.** respect all genders, religions, and caste

**PC20.** empathize with the people with disability

**PC21.** offer support or help to a person with disability only when asked

**PC22.** ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act

**PC23.** 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 the preferred language of communication, reporting and escalation policy

**KU2.** the reporting structure of the organization

**KU3.** types of audits in the life sciences sector for the manufacturing operations

**KU4.** the required regulatory and statutory compliance-related 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.** importance of team coordination

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

**KU10.** the challenges faced by PwD

**KU11.** the 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 gender identities, religion, caste, and culture

**KU15.** method to receive the performance feedback

## Generic Skills (GS)

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



## Qualification Pack

- 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 or computer-based record/ electronic mail in a given format and compliant with ALCOA principle
- 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 skills while responding to auditors and QA personnel

## Qualification Pack

### Assessment Criteria

| Assessment Criteria for Outcomes                                                                                                                                              | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|-----------------|---------------|------------|
| <i>Coordination with supervisor/engineer</i>                                                                                                                                  | <b>10</b>    | <b>10</b>       | <b>4</b>      | <b>4</b>   |
| <b>PC1.</b> follow work instructions received from the reporting supervisor                                                                                                   | -            | -               | -             | -          |
| <b>PC2.</b> adhere to the production plan to meet timelines                                                                                                                   | -            | -               | -             | -          |
| <b>PC3.</b> communicate process-flow improvements, production defects received from the previous process, repairs and maintenance of equipment to reporting supervisor        | -            | -               | -             | -          |
| <b>PC4.</b> ensure timely intimation to supervisor/ production engineer about planned absence/ illness/ dizziness during work/ critical issues requiring his/her intervention | -            | -               | -             | -          |
| <b>PC5.</b> engage with supervisor on work-related and behavioral feedback and demonstrate continual learning and self-direction                                              | -            | -               | -             | -          |
| <i>Team coordination</i>                                                                                                                                                      | <b>10</b>    | <b>10</b>       | <b>2</b>      | <b>2</b>   |
| <b>PC6.</b> support team members and colleagues of other departments in work                                                                                                  | -            | -               | -             | -          |
| <b>PC7.</b> take handover from previous shift operator and give handover to next shift operator as per SOP                                                                    | -            | -               | -             | -          |
| <b>PC8.</b> guide manufacturing and packaging assistants during manufacturing process                                                                                         | -            | -               | -             | -          |
| <b>PC9.</b> coordinate with warehouse team for material dispensing and issuance                                                                                               | -            | -               | -             | -          |
| <b>PC10.</b> find solutions for workflow related difficulties with mutual agreement                                                                                           | -            | -               | -             | -          |
| <b>PC11.</b> coordinate with maintenance team for preventive and corrective maintenance, break down and calibration errors                                                    | -            | -               | -             | -          |

### Qualification Pack

| Assessment Criteria for Outcomes                                                                                                             | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|----------------------------------------------------------------------------------------------------------------------------------------------|--------------|-----------------|---------------|------------|
| <b>PC12.</b> coordinate with quality control team for sample collection, batch release and in-process checks                                 | -            | -               | -             | -          |
| <b>PC13.</b> coordinate with quality assurance team for machine/ equipment validation at a routine interval as per SOP                       | -            | -               | -             | -          |
| <b>PC14.</b> provide inputs to the concerned stakeholders in periodic fence line review to detect non-compliance                             | -            | -               | -             | -          |
| <b>PC15.</b> coordinate with EHS team for any safety incident, accident and emergency                                                        | -            | -               | -             | -          |
| <i>Respond to audit queries</i>                                                                                                              | <b>10</b>    | <b>10</b>       | <b>2</b>      | <b>2</b>   |
| <b>PC16.</b> ensure interact with auditor in a preferable language                                                                           | -            | -               | -             | -          |
| <b>PC17.</b> provide an honest and clear answer to the raised queries                                                                        | -            | -               | -             | -          |
| <b>PC18.</b> maintain data integrity while responding to auditors or while producing the documented records for activities performed         | -            | -               | -             | -          |
| <i>Sensitivity towards all genders and people with disability</i>                                                                            | <b>10</b>    | <b>10</b>       | <b>2</b>      | <b>2</b>   |
| <b>PC19.</b> respect all genders, religions, and caste                                                                                       | -            | -               | -             | -          |
| <b>PC20.</b> empathize with the people with disability                                                                                       | -            | -               | -             | -          |
| <b>PC21.</b> offer support or help to a person with disability only when asked                                                               | -            | -               | -             | -          |
| <b>PC22.</b> ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace(Prevention, Prohibition and Redressal) Act | -            | -               | -             | -          |
| <b>PC23.</b> report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee                          | -            | -               | -             | -          |
| <b>NOS Total</b>                                                                                                                             | <b>40</b>    | <b>40</b>       | <b>10</b>     | <b>10</b>  |



## Qualification Pack

### National Occupational Standards (NOS) Parameters

|                            |                                                                          |
|----------------------------|--------------------------------------------------------------------------|
| <b>NOS Code</b>            | LFS/N0133                                                                |
| <b>NOS Name</b>            | Coordinate and communicate with supervisor/ engineer, teams and auditors |
| <b>Sector</b>              | Life Sciences                                                            |
| <b>Sub-Sector</b>          | Medical Devices and In Vitro Diagnostic (IVD)                            |
| <b>Occupation</b>          | Generic                                                                  |
| <b>NSQF Level</b>          | 4.5                                                                      |
| <b>Credits</b>             | 1                                                                        |
| <b>Version</b>             | 1.0                                                                      |
| <b>Last Reviewed Date</b>  | 01/11/2023                                                               |
| <b>Next Review Date</b>    | 01/11/2026                                                               |
| <b>NSQC Clearance Date</b> | 01/11/2023                                                               |



## 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





## Qualification Pack

- 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



## Qualification Pack

- 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



## Qualification Pack

- 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/N6206: Perform Electropolishing Process

#### Description

The NOS is about performing electropolishing process

#### Scope

The scope covers the following :

- The NOS Scope is :
- Electropolishing Operations

#### Elements and Performance Criteria

##### *Electropolishing Operations*

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

- PC1.** perform electropolishing process to achieve ultra-smooth shiny surface and final stent dimension
- PC2.** ensure temperature of electrolyte is maintained as per SOP
- PC3.** ensure proper composition of metal alloy undergoing electropolishing as per SOP
- PC4.** ensure proper electrolyte composition as per SOP
- PC5.** perform loading of metal stent over a holder and immerse it into liquid electrolytic solution along with a metal cathode
- PC6.** perform applying electric current flow through stent
- PC7.** ensure density and time of exposure of electric current as per SOP
- PC8.** ensure preferential removal of protruding portions of surface structure to get smoother metal surface
- PC9.** perform visual inspection and maintain dimensional measurement of electropolished stent
- PC10.** ensure passed electropolished stents are placed in a designated container

#### Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** clean room behaviour practices and gowning procedures
- KU2.** SOP for entry and exit from manufacturing area
- KU3.** PPE used in electropolishing process and their work instructions
- KU4.** material segregation, handling and storage guidelines
- KU5.** type of machinery and equipment used for electropolishing and their critical parameters
- KU6.** care and maintenance of equipment and machinery
- KU7.** removing and replacing components or parts of machinery and equipment
- KU8.** specialized techniques used in electropolishing process
- KU9.** utilities used in electropolishing process



## Qualification Pack

- KU10.** basic in-process checks for electropolishing process
- KU11.** procedure of set up of electropolishing system
- KU12.** procedure of electropolishing
- KU13.** procedure of troubleshooting equipments and manufacturing issues

## Generic Skills (GS)

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

- GS1.** use reading and comprehension skills to extract the relevant information from manuals, SOPs, health and safety instructions, memos, reports, job cards, and notes/comments
- GS2.** use written communication skills to maintain proper and concise records as per given format and compliant with ALCOA principle
- GS3.** use verbal communication skills in communicating the details of work done to appropriate people and during interaction with regulatory inspectors and other teammates
- GS4.** use planning and organizing skills in every activity planned and performed in stent operations and to achieve resource optimization
- GS5.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS6.** apply critical 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.** use critical skills in analyzing impact of deviations, wastage and rejects to the environment and efficiency, complianc and cost
- GS8.** demonstrate decision making while making necessary adjustments in parameters to achieve quality specifications
- GS9.** apply customer-centricity while responding to auditors and QA personnel

## Qualification Pack

### Assessment Criteria

| Assessment Criteria for Outcomes                                                                                                     | Theory Marks | Practical Marks | Project Marks | Viva Marks |
|--------------------------------------------------------------------------------------------------------------------------------------|--------------|-----------------|---------------|------------|
| <i>Electropolishing Operations</i>                                                                                                   | <b>30</b>    | <b>50</b>       | <b>10</b>     | <b>10</b>  |
| <b>PC1.</b> perform electropolishing process to achieve ultra-smooth shiny surface and final stent dimension                         | -            | -               | -             | -          |
| <b>PC2.</b> ensure temperature of electrolyte is maintained as per SOP                                                               | -            | -               | -             | -          |
| <b>PC3.</b> ensure proper composition of metal alloy undergoing electropolishing as per SOP                                          | -            | -               | -             | -          |
| <b>PC4.</b> ensure proper electrolyte composition as per SOP                                                                         | -            | -               | -             | -          |
| <b>PC5.</b> perform loading of metal stent over a holder and immerse it into liquid electrolytic solution along with a metal cathode | -            | -               | -             | -          |
| <b>PC6.</b> perform applying electric current flow through stent                                                                     | -            | -               | -             | -          |
| <b>PC7.</b> ensure density and time of exposure of electric current as per SOP                                                       | -            | -               | -             | -          |
| <b>PC8.</b> ensure preferential removal of protruding portions of surface structure to get smoother metal surface                    | -            | -               | -             | -          |
| <b>PC9.</b> perform visual inspection and maintain dimensional measurement of electropolished stent                                  | -            | -               | -             | -          |
| <b>PC10.</b> ensure passed electropolished stents are placed in a designated container                                               | -            | -               | -             | -          |
| <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/N6206                                     |
| <b>NOS Name</b>            | Perform Electropolishing Process              |
| <b>Sector</b>              | Life Sciences                                 |
| <b>Sub-Sector</b>          | Medical Devices and In Vitro Diagnostic (IVD) |
| <b>Occupation</b>          | Manufacturing - Medical Devices and IVD       |
| <b>NSQF Level</b>          | 5                                             |
| <b>Credits</b>             | 4.0                                           |
| <b>Version</b>             | 1.0                                           |
| <b>Last Reviewed Date</b>  | 01/11/2023                                    |
| <b>Next Review Date</b>    | 01/11/2026                                    |
| <b>NSQC Clearance Date</b> | 01/11/2023                                    |

## Assessment Guidelines and Assessment Weightage

### Assessment Guidelines

1. Criteria for assessment for each Qualification Pack will be created by Life Sciences Sector Skill Development Council (LSSSDC)
2. Each Element will be assigned marks proportional to its importance in NOS. LSSSDC will also lay down the proportion of marks for Theory, Practical, Project, and Viva for each Element.
3. The assessment for the theory part will be based on the knowledge bank of questions created by the LSSSDC.
4. Assessment will be conducted for all compulsory NOS, and where applicable, on the selected elective/option NOS/set of NOS.
5. LSSSDC as assessment and awarding body will create unique evaluations for each assessment component i.e. theory, practical, project and 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



## Qualification Pack

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/N6203.Perform pre-production check and preparation of various machines for manufacturing                                    | 30           | 45              | 15            | 10         | 100         | 20        |
| LFS/N0130.Ensure adherence to environment, health and safety guidelines in manufacturing facility and controlled cleanroom area | 40           | 40              | 10            | 10         | 100         | 10        |
| LFS/N0131.Ensure a hygienic and clean work area to avoid contamination in manufacturing facility                                | 40           | 40              | 10            | 10         | 100         | 10        |
| LFS/N6211.Perform reporting and documentation with data integrity for medical devices and IVD                                   | 40           | 40              | 10            | 10         | 100         | 10        |
| LFS/N0133.Coordinate and communicate with supervisor/ engineer, teams and auditors                                              | 40           | 40              | 10            | 10         | 100         | 10        |



### 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        |
| <b>Total</b>                                  | <b>210</b>   | <b>235</b>      | <b>55</b>     | <b>50</b>  | <b>550</b>  | <b>70</b> |

Elective: 1 Electropolishing

| National Occupational Standards            | Theory Marks | Practical Marks | Project Marks | Viva Marks | Total Marks | Weightage |
|--------------------------------------------|--------------|-----------------|---------------|------------|-------------|-----------|
| LFS/N6206.Perform Electropolishing Process | 30           | 50              | 10            | 10         | 100         | 30        |
| <b>Total</b>                               | <b>30</b>    | <b>50</b>       | <b>10</b>     | <b>10</b>  | <b>100</b>  | <b>30</b> |