

## QUALIFICATIONS PACK - OCCUPATIONAL STANDARDS FOR LIFE SCIENCES INDUSTRY

### What are Occupational Standards (OS)?

- OS describe what individuals need to do, know and understand in order to carry out a particular job role or function
- OS are performance standards that individuals must achieve when carrying out functions in the workplace, together with specifications of the underpinning knowledge and understanding

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## Introduction

### Qualifications Pack-Bio Process Engineer

**SECTOR:** LIFE SCIENCES

**SUB-SECTOR:** PHARMACEUTICAL AND BIOPHARMACEUTICAL

**OCCUPATION:** MANUFACTURING

**REFERENCE ID:** LFS/Q0219

**ALIGNED TO:** NCO-2004/NIL

**BIO PROCESS ENGINEER** is responsible for providing technical support in the operational implementation and performance aspects of biochemical drug substance manufacturing plants. The role holder supports design, development, and evaluation of biological and health systems and products, such as artificial organs, prostheses, instrumentation, medical information systems, and health management and care delivery systems.

**Brief Job Description:** The Engineer is responsible for providing technical and scientific support for ongoing manufacturing operations of biopharmaceutical products. The role holder also helps in design and development of artificial organs, prostheses and innovative technologies.

**Personal Attributes:** The candidate must possess excellent written and oral communication skills, demonstrate advanced computer skills, and exhibit attention to detail and a mechanical aptitude.

Job Details	<b>Qualifications Pack Code</b>	<b>LFS/Q0219</b>		
	<b>Job Role</b>	<b>Bio Process Engineer</b>		
	<b>Credits(NSQF)</b>	<b>TBD</b>	<b>Version number</b>	<b>1.0</b>
	<b>Industry</b>	<b>Life Sciences</b>	<b>Drafted on</b>	<b>15/12/14</b>
	<b>Sub-sector</b>	Pharmaceutical and Biopharmaceutical	<b>Last reviewed on</b>	<b>01/08/16</b>
	<b>Occupation</b>	<b>Manufacturing</b>	<b>Next review date</b>	<b>01/08/19</b>
	<b>NSQC Clearance on</b>	<b>20/07/2015</b>		

<b>Job Role</b>	<b>Bio Process Engineer</b>
<b>Role Description</b>	Responsible for providing technical and scientific support for ongoing manufacturing operations of biopharmaceutical products. The role holder also helps in design and development of artificial organs, prostheses and innovative technologies.
<b>NSQF level</b>	4
<b>Minimum Educational Qualifications</b>	Graduation in biotechnology/biochemical/ chemical preferable or biological science or applied science or a closely related field
<b>Maximum Educational Qualifications</b>	Masters in biotechnology/biochemical/ chemical preferable or biological science or applied science or a closely related field
<b>Training</b> (Suggested but not mandatory)	On the job
<b>Minimum Job Entry Age</b>	20 Years
<b>Experience</b>	0 – 2 years
<b>Applicable National Occupational Standards (NOS)</b>	<p><b>Compulsory:</b></p> <ol style="list-style-type: none"> <li><a href="#">LFS/N0247: Provide operational support for daily manufacturing activities</a></li> <li><a href="#">LFS/N0248: Support R&amp;D capabilities</a></li> <li><a href="#">LFS/N0249: Assist in development and execution technical transfer plans, process transfer and validation protocols</a></li> </ol>

	<ol style="list-style-type: none"> <li>4. <a href="#">LFS/N0250: Carry out reporting and documentation for bioprocessing activities</a></li> <li>5. <a href="#">LFS/N0103: Ensure cleanliness in the work area</a></li> <li>6. <a href="#">LFS/N0251: Coordinate with manager and team members to carry out bioprocessing activities</a></li> <li>7. <a href="#">LFS/N0101: Maintain a healthy, safe and secure working environment in the life sciences facility</a></li> </ol> <p><b>Optional:</b> N.A.</p>
<p><b>Performance Criteria</b></p>	<p>As described in the relevant NOS units</p>

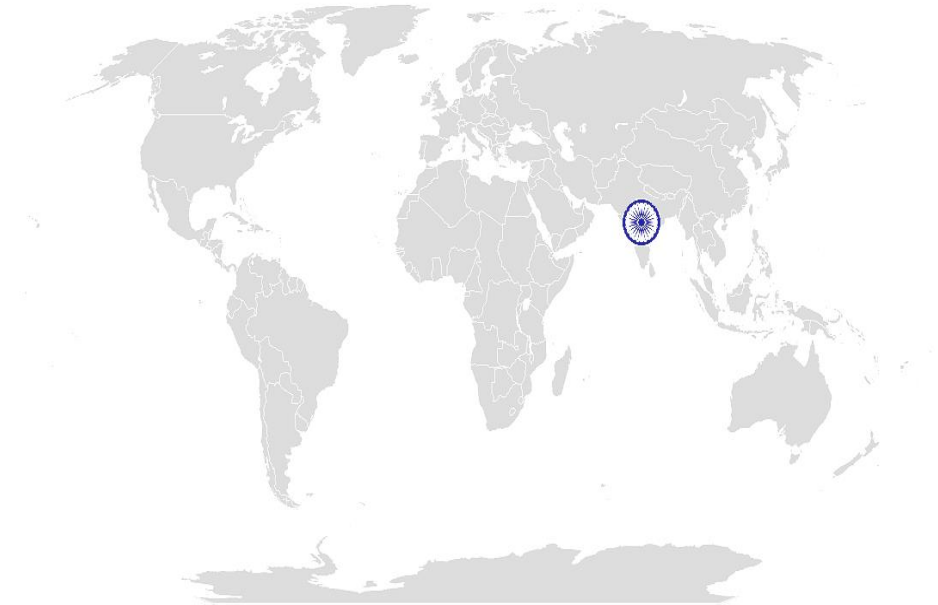
Keywords /Terms	Description
Core Skills/Generic Skills	Core Skills or Generic Skills are a group of skills that are key to learning and working in today's world. These skills are typically needed in any work environment. In the context of the NOS, these include communication related skills that are applicable to most job roles.
Description	Description gives a short summary of the unit content. This would be helpful to anyone searching on a database to verify that this is the appropriate NOS they are looking for.
Function	Function is an activity necessary for achieving the key purpose of the sector, occupation, or area of work, which can be carried out by a person or a group of persons. Functions are identified through functional analysis and form the basis of NOS.
Job role	Job role defines a unique set of functions that together form a unique employment opportunity in an organisation.
Knowledge and Understanding	Knowledge and Understanding are statements which together specify the technical, generic, professional and organisational specific knowledge that an individual needs in order to perform to the required standard.
National Occupational Standards (NOS)	NOS are Occupational Standards which apply uniquely in the Indian context.
Occupation	Occupation is a set of job roles, which perform similar/related set of functions in an industry.
Organisational Context	Organisational Context includes the way the organisation is structured and how it operates, including the extent of operative knowledge managers have of their relevant areas of responsibility.
Performance Criteria	Performance Criteria are statements that together specify the standard of performance required when carrying out a task.
Qualifications Pack(QP)	Qualifications Pack comprises the set of NOS, together with the educational, training and other criteria required to perform a job role. A Qualifications Pack is assigned a unique qualification pack code.
Qualifications Pack Code	Qualifications Pack Code is a unique reference code that identifies a qualifications pack.
Scope	Scope is the set of statements specifying the range of variables that an individual may have to deal with in carrying out the function which have a critical impact on the quality of performance required.
Sector	Sector is a conglomeration of different business operations having similar businesses and interests. It may also be defined as a distinct subset of the economy whose components share similar characteristics and interests.

Sub-Sector	Sub-sector is derived from a further breakdown based on the characteristics and interests of its components.
Sub-functions	Sub-functions are sub-activities essential to fulfil the achieving the objectives of the function.
Technical Knowledge	Technical Knowledge is the specific knowledge needed to accomplish specific designated responsibilities.
Unit Code	Unit Code is a unique identifier for an NOS unit, which can be denoted with an 'N'.
Unit Title	Unit Title gives a clear overall statement about what the incumbent should be able to do.
Keywords /Terms	Description
NOS	National Occupational Standard(s)
NSQF	National Skill Qualifications Framework
NCO-2004	National Classification of Occupations-2004
OS	Occupational Standard(s)
QP	Qualifications Pack
GMP	Good Manufacturing Practices
SOP	Standard Operation Procedure
ISO	International Organization for Standardization
OHSAS	Occupational Health and Safety Assessment Series
CIP / SIP	Cleaning-In-Place (CIP) / Sterilization-In-Place (SIP)

Acronyms

LFS/N0247 : Provide operational support for daily manufacturing activities

# National Occupational Standards



## Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Bio Process Engineer to provide operational support for daily manufacturing activities.

LFS/N0247 : Provide operational support for daily manufacturing activities

National Occupational Standard	<b>Unit Code</b>	LFS/N0247
	<b>Unit Title (Task)</b>	Provide operational support for daily manufacturing activities
	<b>Description</b>	This NOS is about a Bio Process Engineer evaluating raw materials and keeping up to date with emerging technologies in bioprocessing and manufacturing to deliver products of highest quality.
	<b>Scope</b>	<p>The unit covers the following:</p> <ul style="list-style-type: none"> <li>• Evaluation of raw materials</li> <li>• Operational support for daily manufacturing processes</li> <li>• Assembling and preparing equipment for production</li> <li>• Clean and sterilize tanks and filtration systems</li> <li>• Remain current with emerging technologies in bioprocessing and manufacturing to deliver products with highest quality</li> </ul>
<b>Performance Criteria (PC) w.r.t. the Scope</b>		
<b>Element</b>	<b>Performance Criteria</b>	
Evaluation of raw materials	<p>To be competent, the user/individual on the job must be able to:</p> <p>PC1. provide technical support for the evaluation of raw material to ensure manufacturing processes are robust, safe and adequate</p> <p>PC2. assist improvements in raw material testing regimes to ensure that the critical functional attributes are evaluated</p>	
Operational support for daily manufacturing processes	<p>PC3. provide support to manufacturing to meet production demands</p> <p>PC4. operate small-scale cell culture areas and systems by operating cleaning, set up, and maintaining batch reefed fermenters; inoculating and maintaining spinner seed cultures using aseptic techniques, maintaining cell banks; and performing general seed lab operation</p> <p>PC5. operate large scale column chromatography systems</p> <p>PC6. comply with safety requirements, GMP, SOP and manufacturing guidelines</p> <p>PC7. assist in the use of automation to perform production operations</p> <p>PC8. participate in continuous operational improvement of the manufacturing process</p> <p>PC9. apply the concepts in commercial-scale drug substance manufacturing</p> <p>PC10. anticipate potential problems and takes preventative action</p> <p>PC11. provide day-to-day bioprocess engineering support to upstream / downstream manufacturing operations</p> <p>PC12. support and participate in commissioning and start-up activities of biotech unit operations and equipment.</p> <p>PC13. initiate and implement facility and equipment upgrades to improve plant productivity and throughput</p>	

**LFS/N0247 : Provide operational support for daily manufacturing activities**

	PC14. facilitate the introduction of new products with associated new unit operations and equipment and ensure the bio-processing at the site stays current with emerging processing and equipment innovations
Assembling and preparing equipment / solutions for production	PC15. assemble and prepare equipment for production PC16. prepare solutions for the production process PC17. troubleshoot equipment and process problems
Clean and sterilize tanks and filtration systems	PC18. operate systems that clean and sterilize tanks and filtration systems PC19. operate fermenters, centrifuges, other harvest systems and protein purifications units
Remaining up to date with latest technologies	PC20. interact with internal and external business partners to remain updated on emerging technologies to best position the operations team with a competitive advantage in delivering products of the highest quality at the lowest cost PC21. develop recommendations for improvements to existing commercial-scale manufacturing processes to ensure reliability, robustness, and regulatory compliance

**Knowledge and Understanding (K)**

<b>A. Organisational Context</b> (Knowledge of the Company/ Organisation and its processes)	The user/individual on the job needs to know and understand:  KA1. theory, concepts, and regulations behind bio-pharm technology and processes KA2. different quality management systems (ISO-9000, ISO-14001, OHSAS-18000) and good laboratory and manufacturing practices KA3. details of bio-analytical and biopharmaceutical operations and quality systems KA4. organizational coding system of finished materials, compounds and company manual KA5. implications of not adhering to quality control procedures KA6. quality and damage checks to be performed and importance of the same KA7. quality control procedures followed by the company and importance of the same KA8. importance of identifying non-conforming products KA9. risk and impact of not following defined procedures/work instructions KA10. impact of poor practices on health, safety and environment KA11. impact of various practices on cost, quality, productivity, delivery and safety KA12. proper procedure for selecting the material/product and performing quality checks without affecting the material KA13. characteristics of the materials KA14. implications (impact on internal/external customers) of defective products, materials or components
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**LFS/N0247 : Provide operational support for daily manufacturing activities**

	KA15. correct methods for carrying out corrective actions outlined for each problem
<b>B. Technical Knowledge</b>	<p>The user/individual on the job needs to know and understand:</p> <p>KB1. importance of sterile conditions</p> <p>KB2. process of fermentation and product separation technologies</p> <p>KB3. industrial enzymatic reactions</p> <p>KB4. downstream biopharmaceutical unit operations involved with bioreactor design and control, SIP/CIP, filtration etc.</p> <p>KB5. method of designing or commissioning of a mammalian cell-based biopharmaceutical manufacturing plant</p> <p>KB6. how to operate purification or related bioprocess manufacturing in an established biotech production operation</p>
<b>Skills (S)</b>	
<b>A. Core Skills/ Generic Skills</b>	<b>Writing skills</b>
	<p>The user/ individual on the job needs to know and understand how to:</p> <p>SA1. record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail</p> <p>SA2. maintain proper records as per given format</p> <p>SA3. write reports</p>
	<b>Reading and Understanding skills</b>
	<p>The user/individual on the job needs to know and understand how to:</p> <p>SA4. read and understand manuals, SOPs, health and safety instructions, memos, reports, job cards, etc.</p> <p>SA5. read images, graphs, diagrams</p> <p>SA6. use and interpret the various coding systems as per company norms</p>
	<b>Oral Communication (Listening and Speaking skills)</b>
<p>The user/individual on the job needs to know and understand how to:</p> <p>SA7. communicate with upstream and downstream teams</p> <p>SA8. communicate with job owners like sample originating section, supplier etc.</p> <p>SA9. disclose information only to those who have the right and need to know it</p> <p>SA10. communicate confidential and sensitive information discretely to authorized person as per sop</p> <p>SA11. maintain confidentiality of information</p>	
	<b>Plan and Organize</b>

**LFS/N0247 : Provide operational support for daily manufacturing activities**

<b>B. Professional Skills</b>	The user/individual on the job needs to know and understand how to:
	SB1. plan and prioritize work, including taking responsibility for completing one's own work assignment
	SB2. multi-task and adapt to effectively support multiple activities at one time
	SB3. take responsibility for completing one's own work assignment
	<b>Problem solving</b>
	The user/individual on the job needs to know and understand how to:
	SB4. seek clarification on problems from others
	SB5. identify, define and resolve problems using a structured methodology
	SB6. apply basic sciences (chemistry), mathematics, statistics to work-related requirements
	SB7. act objectively, rather than impulsively or emotionally when faced with difficult/stressful or emotional situations
SB8. explore new ways of doing things	
<b>Analytical Thinking</b>	
The user/individual on the job needs to know and understand how to:	
SB9. suggest improvements (if any) in process based on experience	
SB10. pay attention to detail	
<b>Decision Making</b>	
NA	
<b>Critical Thinking</b>	
NA	
<b>Customer Centricity</b>	
NA	

LFS/N0247 : Provide operational support for daily manufacturing activities

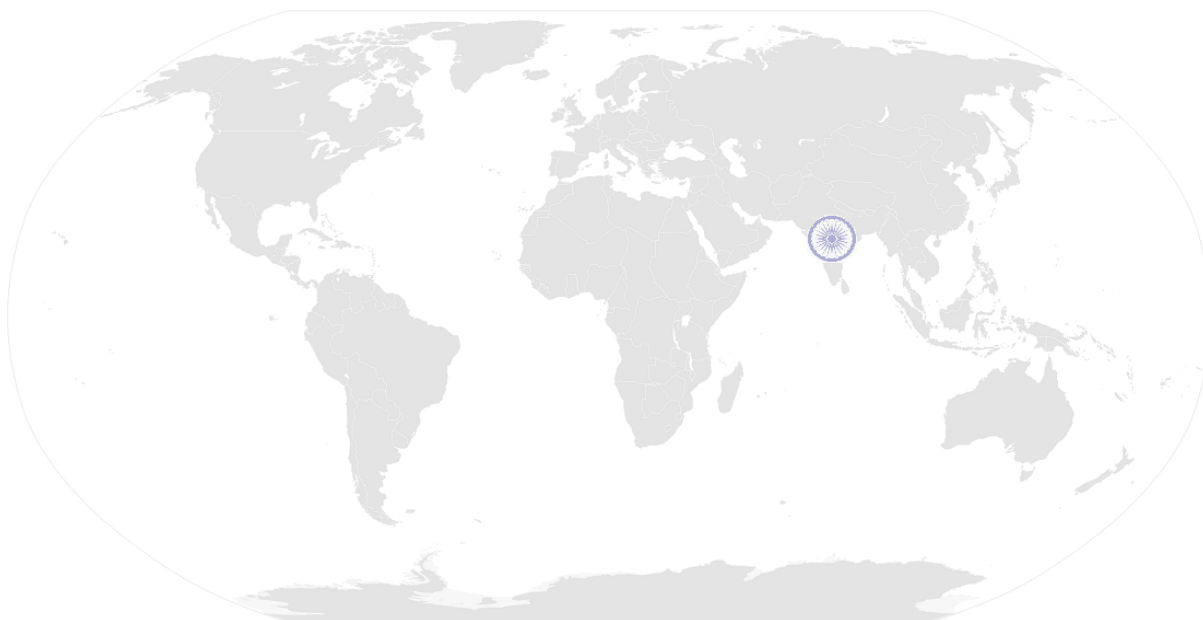
**NOS Version Control**

NOS Code	LFS/N0247		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	15/12/14
Industry Sub-sector	Pharmaceutical and Biopharmaceutical	Last reviewed on	01/08/16
Occupation	Manufacturing	Next review date	01/08/19



LFS/N0248 : Support R&D capabilities

# National Occupational Standards



## Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Bio Process Engineer to support research and development capabilities.

### LFS/N0248 : Support R&D capabilities

National Occupational Standard	<b>Unit Code</b>	LFS/N0248
	<b>Unit Title (Task)</b>	Support R&D capabilities
	<b>Description</b>	This NOS is about a Bio Process Engineer assisting in the development and design of organization's novel technologies.
	<b>Scope</b>	<p>The unit covers the following:</p> <ul style="list-style-type: none"> <li>Support research and development capabilities</li> <li>Assistance in the development and design of organization's novel technologies</li> </ul>
	<b>Performance Criteria (PC) w.r.t. the Scope</b>	
	<b>Element</b>	<b>Performance Criteria</b>
	Support research and development capabilities	<p>To be competent, the user/individual on the job must be able to:</p> <p>PC1. establish process development scale-up to extend the company's research and development capabilities</p> <p>PC2. optimize growth and productivity parameters of suspension cell lines and assist, as needed, in the hands-on experiments to define these variables</p> <p>PC3. conduct research along with life scientists, chemists, and medical scientists, on the engineering aspects of the biological systems of humans and animals</p> <p>PC4. diagnose and interpret bioelectric data, using signal processing techniques</p> <p>PC5. design and develop medical diagnostic and clinical instrumentation, equipment, and procedures, using the principles of engineering and bio-behavioural sciences</p> <p>PC6. develop models or computer simulations of human bio-behavioural systems to obtain data for measuring or controlling life processes</p>
	Assistance in the development and design of organization's novel technologies	<p>PC7. assist in design, development, and evaluation of biological and health systems and products, such as artificial organs, prostheses, instrumentation, medical information systems, and health management and care delivery systems</p> <p>PC8. participate in the creation, development and design of the organization's novel technologies by interfacing with vector design, downstream and analytical teams</p> <p>PC9. research new materials to be used for products, such as implanted artificial organs</p>
	<b>Knowledge and Understanding (K)</b>	
	<b>A. Organisational Context</b> (Knowledge of the Company/Organisation and its processes)	<p>The user/individual on the job needs to know and understand:</p> <p>KA1. different quality management systems (ISO-9000, ISO-14001, OHSAS-18000) and good laboratory and manufacturing practices</p> <p>KA2. method of reporting incidents where standard operating procedures are not followed</p>

**LFS/N0248 : Support R&D capabilities**

	<p>KA3. impact of various practices on cost, quality, productivity, delivery and safety</p> <p>KA4. details of bio-analytical and biopharmaceutical operations and quality systems</p> <p>KA5. use of monitoring and measuring devices</p> <p>KA6. the reason and impact of the occurrence of problems</p> <p>KA7. measures, steps and possible solutions that have been taken/identified to address the previous problems</p>
<p><b>B. Technical Knowledge</b></p>	<p>The user/individual on the job needs to know and understand:</p> <p>KB1. bioprocess technology transfer and/or scale-up technology manufacturing and upstream mammalian cell culture</p> <p>KB2. downstream biopharmaceutical unit operations involved with bioreactor design and control, SIP/CIP, filtration etc.</p> <p>KB3. methods and techniques involved in evaluating information</p> <p>KB4. method of using instruments and equipment used in the laboratory</p>
<p><b>Skills (S)</b></p>	
<p><b>A. Core Skills/ Generic Skills</b></p>	<p><b>Writing skills</b></p> <p>The user/ individual on the job needs to know and understand how to:</p> <p>SA1. record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail</p> <p>SA2. maintain proper records as per given format</p> <p>SA3. write reports</p> <p><b>Reading and Understanding skills</b></p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SA4. read and understand manuals, sops, health and safety instructions, memos, reports, job cards, etc.</p> <p>SA5. read images, graphs, diagrams</p> <p>SA6. use and interpret the various coding systems as per company norms</p> <p><b>Oral Communication (Listening and Speaking skills)</b></p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SA7. communicate with upstream and downstream teams</p> <p>SA8. communicate with job owners like sample originating section, supplier etc.</p> <p>SA9. work in a team and other behavioural skills required to support the small group activities (e.g. quality circle, cross functional team, suggestion scheme)</p> <p>SA10. disclose information only to those who have the right and need to know it</p> <p>SA11. communicate confidential and sensitive information discretely to authorized person as per the SOP</p> <p>SA12. maintain confidentiality of information</p>
	<p><b>Plan and Organize</b></p>

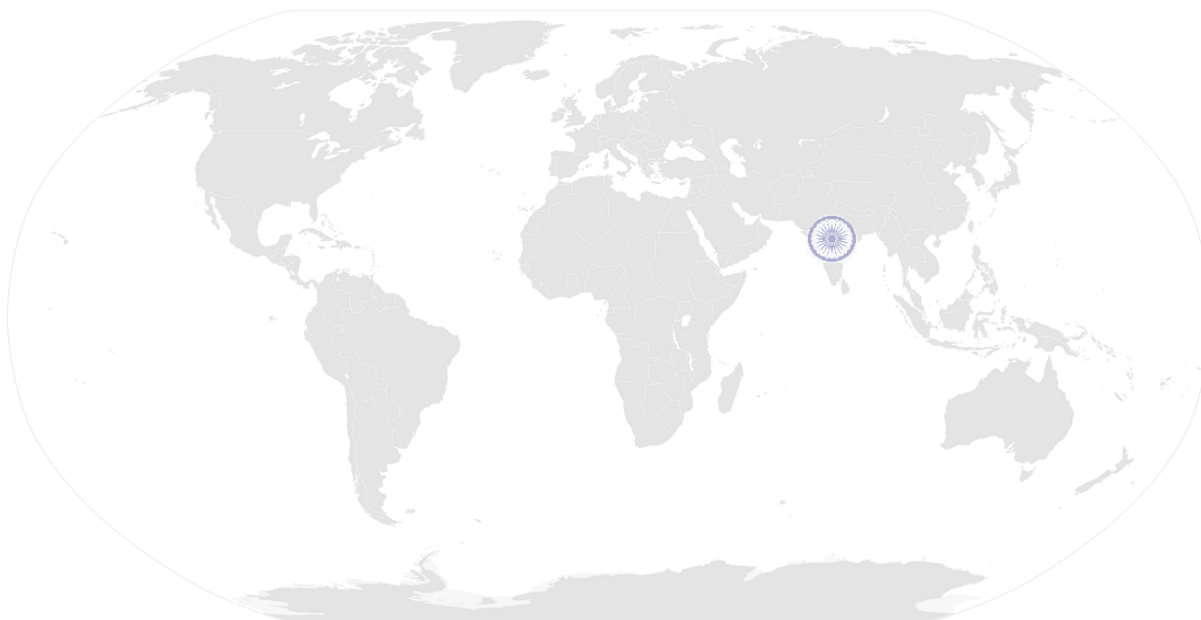
LFS/N0248 : Support R&D capabilities

<b>B. Professional Skills</b>	The user/individual on the job needs to know and understand how to:  SB1. multi-task and adapt to effectively support multiple activities at one time SB2. take responsibility for completing one’s own work assignment
	<b>Problem solving</b>
	The user/individual on the job needs to know and understand how to:  SB3. seek clarification on problems from others SB4. identify, define and resolve problems using a structured methodology SB5. explore new ways of doing things
	<b>Critical Thinking</b>
	The user/individual on the job needs to know and understand how to:  SB6. apply, analyse and evaluate information to define action steps
	<b>Critical Thinking</b>
	NA
	<b>Decision Making</b>
	NA
<b>Customer Centricity</b>	
NA	

LFS/N0248 : Support R&D capabilities

**NOS Version Control**

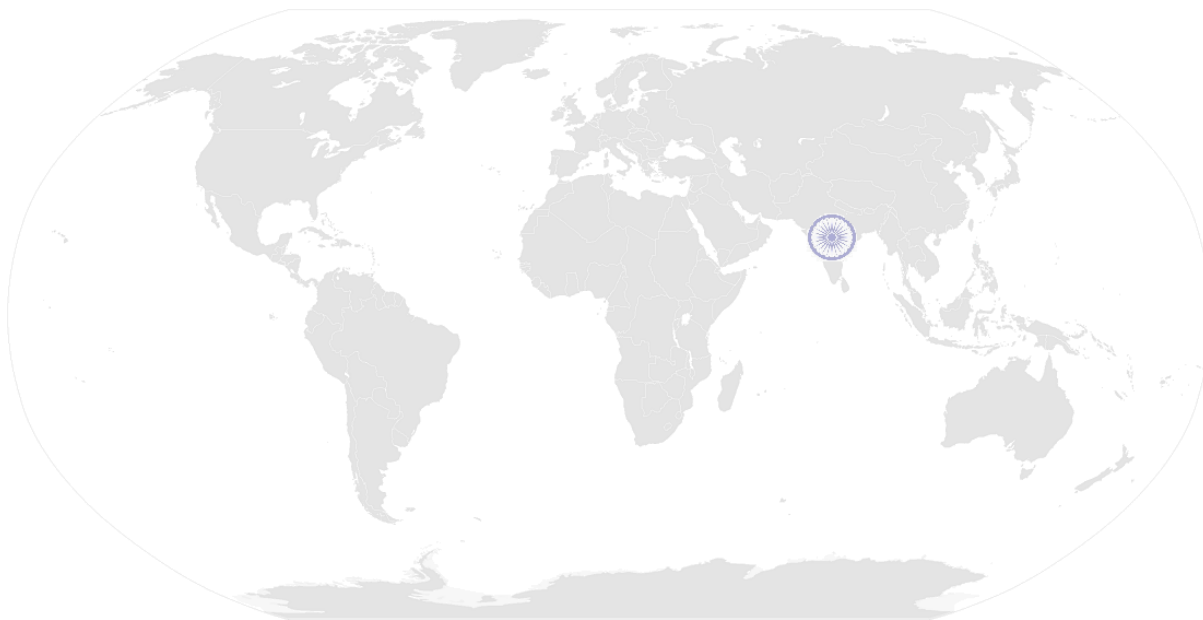
<b>NOS Code</b>	<b>LFS/N0248</b>		
<b>Credits(NSQF)</b>	<b>TBD</b>	<b>Version number</b>	<b>1.0</b>
<b>Industry</b>	<b>Life Sciences</b>	<b>Drafted on</b>	<b>15/12/14</b>
<b>Industry Sub-sector</b>	<b>Pharmaceutical and Biopharmaceutical</b>	<b>Last reviewed on</b>	<b>01/08/16</b>
<b>Occupation</b>	<b>Manufacturing</b>	<b>Next review date</b>	<b>01/08/19</b>





LFS/N0249 : Assist in development and execution of technical transfer plans, process transfer and validation protocols

# National Occupational Standards



## Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Bio Process Engineer to assist in the development and execution of technical transfer plans, process transfer and validation protocols.

**LFS/N0249 : Assist in development and execution of technical transfer plans, process transfer and validation protocols**

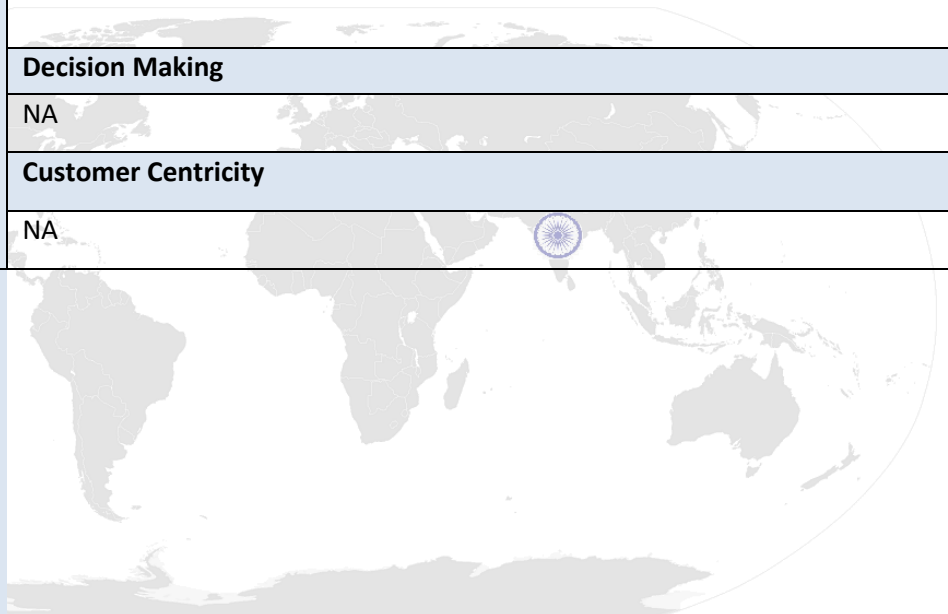
National Occupational Standard	<b>Unit Code</b>	<b>LFS/N0249</b>
	<b>Unit Title (Task)</b>	<b>Assist in development and execution of technical transfer plans, process transfer and validation protocols</b>
	<b>Description</b>	This NOS is about a Bio Process Engineer contributing technical support to develop and execute technical transfer plans
	<b>Scope</b>	The unit covers the following: <ul style="list-style-type: none"> <li>• Contribution of technical support to develop and execute technical transfer plans</li> <li>• Technical guidance to R&amp;D cell-line development and media optimization functions</li> <li>• Designing and execution of protocols</li> </ul>
	<b>Performance Criteria (PC) w.r.t. the Scope</b>	
	<b>Element</b>	<b>Performance Criteria</b>
	Technical Support	To be competent, the user/individual on the job must be able to: PC1. contribute technical support to develop and execute technical transfer plans (including transfer of existing products or new products under development), which includes preparation of process transfer protocols, process validation protocols, and supporting regulatory documents.
	Technical guidance to R&D cell-line development and media optimization functions	PC2. provide technical guidance to R&D cell-line development and media optimization functions to ensure manufacturing suitability and regulatory compliance of proposed strategies while maximizing process yields and/or reducing cost of goods PC3. serve as technical support on capital projects related to manufacturing processes and equipment, and as a bioprocessing functional area subject matter expert on the internal mammalian cell culture manufacturing
	Designing and execution of protocols	PC4. assist in design and execution of test protocols to optimize unit operations PC5. assist in processing data to manufacturing performance management meetings to establish and monitor process metrics, extract key learnings
	<b>Knowledge and Understanding (K)</b>	
<b>A. Organisational Context</b> (Knowledge of the Company/ Organisation and its processes)	The user/individual on the job needs to know and understand: <ul style="list-style-type: none"> <li>KA1. methods of maintaining records and implications of non-maintenance of the same</li> <li>KA2. bio-analytical and biopharmaceutical operations and quality systems</li> <li>KA3. importance of complete and accurate documentation</li> <li>KA4. different quality management systems (ISO-9000, ISO-14001, OHSAS-18000 and good laboratory and manufacturing practices)</li> </ul>	

**LFS/N0249 : Assist in development and execution of technical transfer plans, process transfer and validation protocols**

	KA5. implications (impact on internal/external customers) of defective products, materials or components
<b>B. Technical Knowledge</b>	KB1. method of designing or commissioning of a mammalian cell-based biopharmaceutical manufacturing plant KB2. bioprocess technology transfer and/or scale-up technology manufacturing and upstream mammalian cell culture (required)
<b>Skills (S)</b>	
<b>A. Core Skills/ Generic Skills</b>	<b>Writing skills</b>
	The user/ individual on the job needs to know and understand how to:  SA1. record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail SA2. maintain proper records as per given format SA3. write reports
	<b>Reading and Understanding skills</b>
	The user/individual on the job needs to know and understand how to:  SA4. read and understand manuals, sops, health and safety instructions, memos, reports, job cards, etc. SA5. read images, graphs, diagrams SA6. use and interpret the various coding systems as per company norms
	<b>Oral Communication (Listening and Speaking skills)</b>
	The user/individual on the job needs to know and understand how to:  SA7. communicate with upstream and downstream teams SA8. communicate with job owners like sample originating section, supplier etc. SA9. work in a team and other behavioural skills required to support the small group activities (e.g. quality circle, cross functional team, suggestion scheme) SA10. disclose information only to those who have the right and need to know it SA11. communicate confidential and sensitive information discretely to authorized person as per the SOP
<b>B. Professional Skills</b>	<b>Plan and Organize</b>
	The user/individual on the job needs to know and understand how to:  SB1. multi-task and adapt to effectively support multiple activities at one time SB2. take responsibility for completing one's own work assignment SB3. plan and prioritize work basis criticality and urgency
	<b>Problem solving</b>

**LFS/N0249 : Assist in development and execution of technical transfer plans, process transfer and validation protocols**

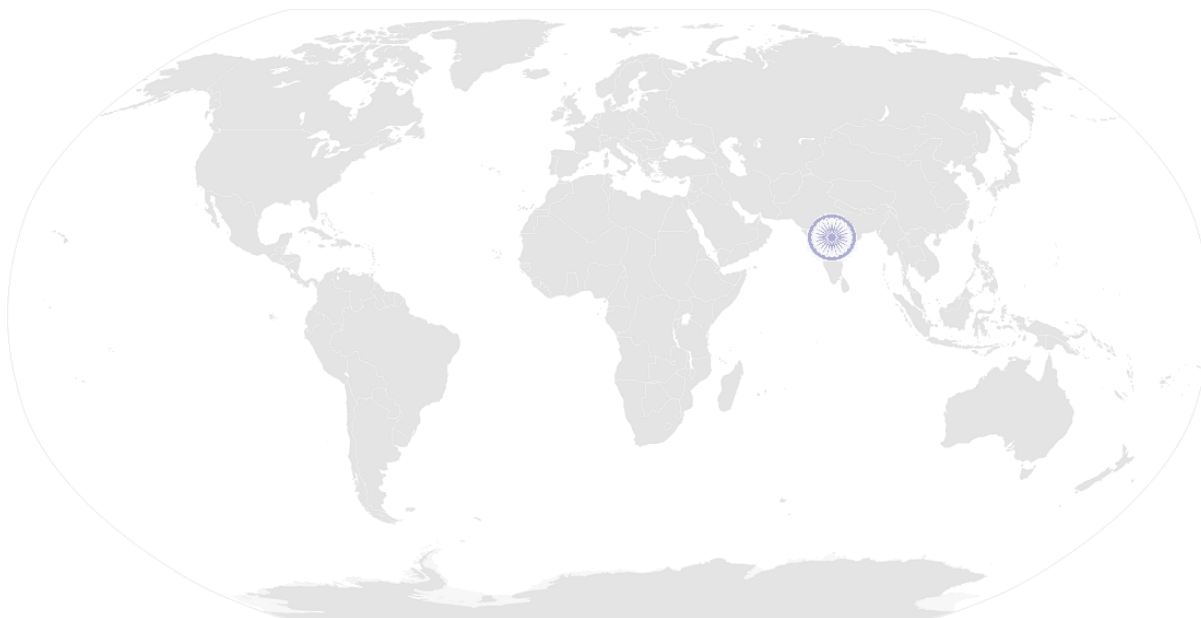
	The user/individual on the job needs to know and understand how to:  SB4. identify, define and resolve problems using a structured methodology SB5. explore new ways of doing things
	<b>Critical Thinking</b>
	The user/individual on the job needs to know and understand how to:  SB6. apply, analyse and evaluate information to define action steps
	<b>Analytical Thinking</b>
	The user/individual on the job needs to know and understand how to:  SB7. suggest improvements based on observation, analysis and experience SB8. use available data and computer software to identify trends
	<b>Decision Making</b>
	NA
	<b>Customer Centricity</b>
NA	



LFS/N0249 : Assist in development and execution of technical transfer plans, process transfer and validation protocols

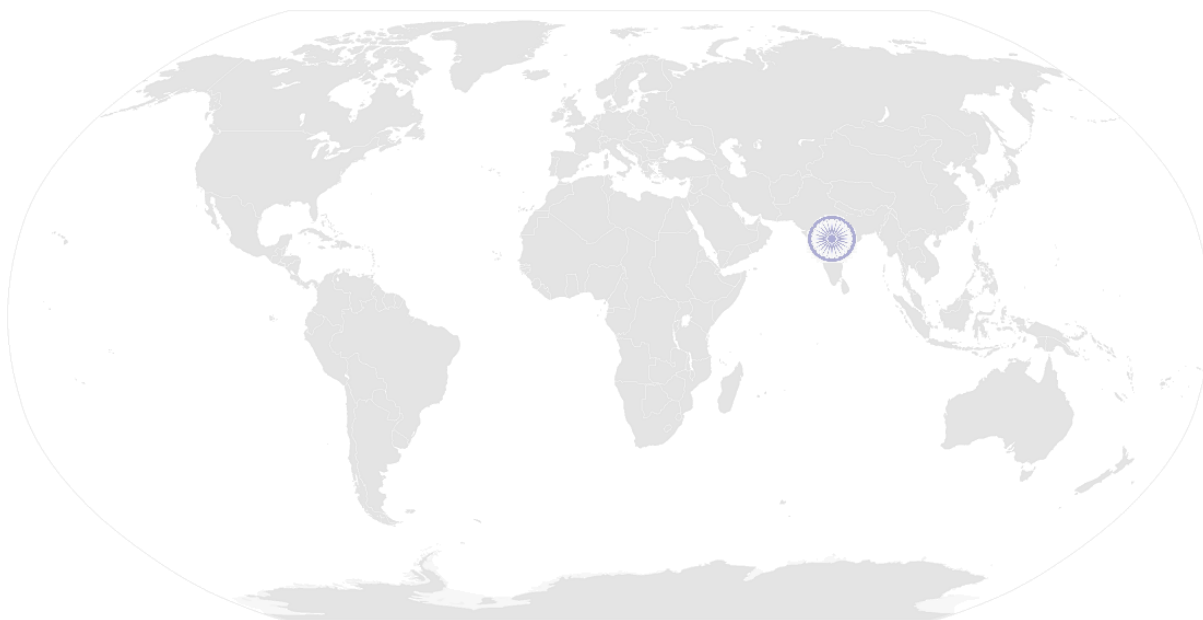
### NOS Version Control

NOS Code	LFS/N0243		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	15/12/14
Industry Sub-sector	Pharmaceutical and Biopharmaceutical	Last reviewed on	01/08/16
Occupation	Manufacturing	Next review date	01/08/19



LFS/N0250 : Carry out reporting and documentation for bioprocessing activities

# National Occupational Standards



## Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Bio Process Engineer to carry out reporting and documentation for bioprocessing activities.

**LFS/N0250 : Carry out reporting and documentation for bioprocessing activities**

National Occupational Standard	<b>Unit Code</b>	<b>LFS/N0250</b>
	<b>Unit Title (Task)</b>	<b>Carry out reporting and documentation for bioprocessing activities</b>
	<b>Description</b>	This NOS is about a Bio Process Engineer reporting quality issues and test results and documenting bioprocessing records
	<b>Scope</b>	The unit covers the following: <ul style="list-style-type: none"> <li>Reporting problems / incidents / quality issues and test results</li> <li>Recording and documentation of bioprocessing records</li> </ul>
	<b>Performance Criteria (PC) w.r.t. the Scope</b>	
	<b>Element</b>	<b>Performance Criteria</b>
	Reporting problems / incidents / quality issues and test results	To be competent, the user/individual on the job must be able to: <ul style="list-style-type: none"> <li>PC1. support the team in technical transfer of data, processes and technical specifications to CMOs for the implementation of large-scale manufacturing operations for clinical and commercial development of targeted products</li> <li>PC2. follow reporting procedures as prescribed by the company</li> <li>PC3. identify and report defects/anomalies to the appropriate authority</li> </ul>
	Recording and documentation of bioprocessing records	<ul style="list-style-type: none"> <li>PC4. prepare comprehensive summaries of bioprocessing information and other documents necessary for regulatory submission</li> <li>PC5. maintain, update and archive study related files and documents</li> <li>PC6. identify documentation to be completed relating to one's role</li> <li>PC7. record details accurately in the appropriate format</li> <li>PC8. ensure that the final document meets regulatory and compliance requirements</li> <li>PC9. perform review of records and other documentation for compliance to established procedures and good documentation practices</li> <li>PC10. respond to requests for information in an appropriate manner whilst following organizational procedures</li> <li>PC11. inform the appropriate authority of requests for information received</li> </ul>
	<b>Knowledge and Understanding (K)</b>	
	<b>A. Organisational Context</b> (Knowledge of the Company/ Organisation and its processes)	The user/individual on the job needs to know and understand: <ul style="list-style-type: none"> <li>KA1. escalation matrix for reporting identified issues</li> <li>KA2. method of maintaining records and implications of non-maintenance of the same</li> <li>KA3. importance of complete and accurate documentation</li> <li>KA4. risk and impact of not following defined procedures/work instructions</li> </ul>
<b>B. Technical Knowledge</b>	The user/individual on the job needs to know and understand:	

**LFS/N0250 : Carry out reporting and documentation for bioprocessing activities**

	<p>KB1. method of preparing project summaries/reports</p> <p>KB2. method of entering, transcribing, recording, storing, or maintaining information in written or electronic/magnetic form</p> <p>KB3. use of computer software for maintaining data</p>
<p><b>Skills (S)</b></p>	
<p><b>A. Core Skills/ Generic Skills</b></p>	<p><b>Writing skills</b></p>
	<p>The user/ individual on the job needs to know and understand how to:</p> <p>SA1. record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail</p> <p>SA2. maintain proper records as per given format</p>
	<p><b>Reading and Understanding skills</b></p>
	<p>The user/individual on the job needs to know and understand how to:</p> <p>SA3. read and understand manuals, SOPs, health and safety instructions, memos, reports, job cards, etc.</p> <p>SA4. read images, graphs, diagrams</p> <p>SA5. use and interpret the various coding systems as per company norms</p>
	<p><b>Oral Communication (Listening and Speaking skills)</b></p>
	<p>The user/individual on the job needs to know and understand how to:</p> <p>SA6. communicate with upstream and downstream teams</p> <p>SA7. work in a team and other behavioural skills required to support the small group activities (e.g. quality circle, cross functional team, suggestion scheme)</p> <p>SA8. disclose information only to those who have the right and need to know it</p> <p>SA9. communicate confidential and sensitive information discretely to authorized person as per the SOP</p>
<p><b>B. Professional Skills</b></p>	<p><b>Plan and Organize</b></p>
	<p>The user/individual on the job needs to know and understand how to:</p> <p>SB1. take responsibility for completing one's own work assignment</p> <p>SB2. plan and prioritize work based on criticality and urgency</p>
	<p><b>Analytical Thinking</b></p>
	<p>The user/individual on the job needs to know and understand how to:</p> <p>SB3. use available data and computer software to create required documentation</p> <p>SB4. pay attention to detail</p>
	<p><b>Decision Making</b></p>
	<p>NA</p> <p><b>Critical Thinking</b></p> <p>NA</p>

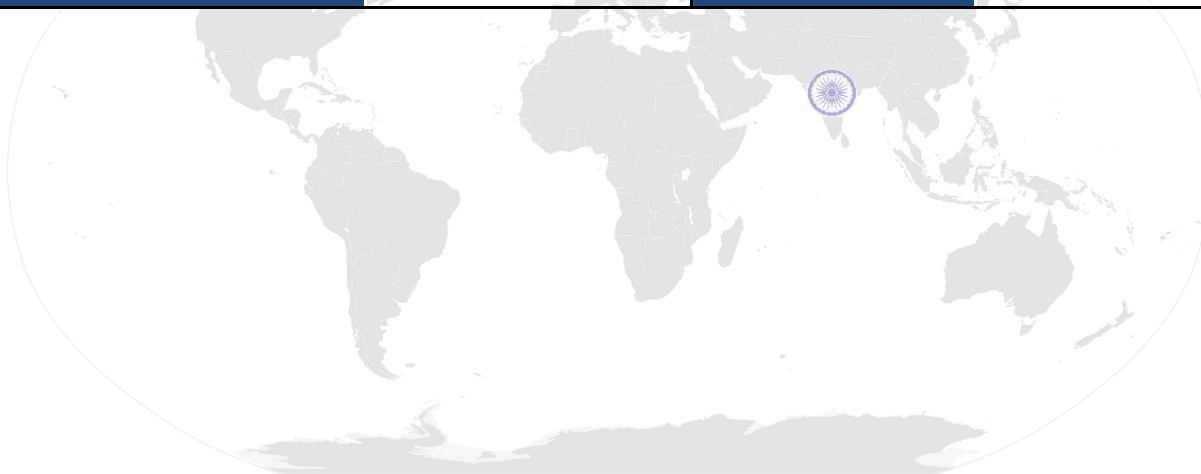


**LFS/N0250 : Carry out reporting and documentation for bioprocessing activities**

	<b>Problem Solving</b>
	NA
	<b>Customer Centricity</b>
	NA

**NOS Version Control**

NOS Code	LFS/N0250		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	15/12/14
Industry Sub-sector	Pharmaceutical and Biopharmaceutical	Last reviewed on	01/08/16
Occupation	Manufacturing	Next review date	01/08/19



LFS/N0250 : Carry out reporting and documentation for bioprocessing activities

# National Occupational Standards



LFS/N0103 : Ensure cleanliness in the work area

## Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Bio Process Engineer to ensure cleanliness in the work area by carrying out housekeeping for respective area.

National Occupational Standard	Unit Code	LFS/N0103
	Unit Title (Task)	Ensure cleanliness in the work area
	Description	This NOS unit is about the Bio Process Engineer to carry out housekeeping activities for respective area
	Scope	This unit/task covers the following: <ul style="list-style-type: none"> <li>• Pre housekeeping activities</li> <li>• Operations</li> <li>• Post housekeeping activities</li> </ul>
	Performance Criteria (PC) w.r.t. the Scope	
	Element	Performance Criteria
	Pre housekeeping activities	To be competent, the user/individual on the job must be able to: <ul style="list-style-type: none"> <li>PC1. inspect the area while taking into account various surfaces</li> <li>PC2. identify the material requirements for cleaning the areas inspected, by considering risk, time, efficiency and type of stain</li> <li>PC3. ensure that the cleaning equipment is in proper working condition</li> <li>PC4. select the suitable alternatives for cleaning the areas in case the appropriate equipment and materials are not available and inform the appropriate person</li> <li>PC5. plan the sequence for cleaning the area to avoid re-soiling clean areas and surfaces</li> <li>PC6. inform the affected people about the cleaning activity</li> <li>PC7. display the appropriate signage for the work being conducted</li> <li>PC8. ensure that there is adequate ventilation for the work being carried out</li> <li>PC9. wear the personal protective equipment required for the cleaning method and materials being used</li> </ul>
	Operations	<ul style="list-style-type: none"> <li>PC10. use the correct cleaning method for the work area, type of soiling and surface</li> <li>PC11. deal with accidental damage, if any, caused while carrying out the work</li> <li>PC12. report to the appropriate person any difficulties in carrying out work</li> <li>PC13. identify and report to the appropriate person any additional cleaning required that is outside one's responsibility or skill</li> </ul>

**LFS/N0103 : Ensure cleanliness in the work area**

<p>Post housekeeping activities</p>	<p>PC14. ensure that there is no oily substance on the floor to avoid slippage</p> <p>PC15. ensure that no scrap material is lying around</p> <p>PC16. maintain and store housekeeping equipment and supplies</p> <p>PC17. follow workplace procedures to deal with any accidental damage caused during the cleaning process</p> <p>PC18. ensure that, on completion of the work, the area is left clean and dry and meets requirements</p> <p>PC19. return the equipment, materials and personal protective equipment that were used to the right places making sure they are clean, safe and securely stored</p> <p>PC20. dispose the waste garnered from the activity in an appropriate manner</p> <p>PC21. dispose of used and un-used solutions according to manufacturer’s instructions, and clean the equipment thoroughly</p> <p>PC22. maintain schedules and records for housekeeping duty</p> <p>PC23. replenish any necessary supplies or consumables</p>
<p><b>Knowledge and Understanding (K)</b></p>	
<p><b>A. Organisational Context</b> (Knowledge of the Company/ Organisation and its processes)</p>	<p>The user/individual on the job needs to know and understand:</p> <p>KA1. levels of hygiene required by storage area and importance of maintaining the same</p> <p>KA2. methodology for storage area inspection with methods and materials required for cleaning variety of surfaces and equipment</p> <p>KA3. the method to check the treated surface and equipment on completion of cleaning</p> <p>KA4. procedures for reporting any unidentified soiling</p> <p>KA5. escalation procedures for soils or stains that could not be removed</p>
<p><b>B. Technical Knowledge</b></p>	<p>The user/individual on the job needs to know and understand:</p> <p>KB1. role of different materials, chemicals and equipment</p>
<p><b>Skills (S)</b></p>	
<p><b>A. Core Skills/ Generic Skills</b></p>	<p><b>Writing Skills</b></p> <p>The user/ individual on the job needs to know and understand how to:</p> <p>SA1. record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail</p> <p><b>Reading and Understanding Skills</b></p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SA2. understand the various coding systems as per company norms</p>

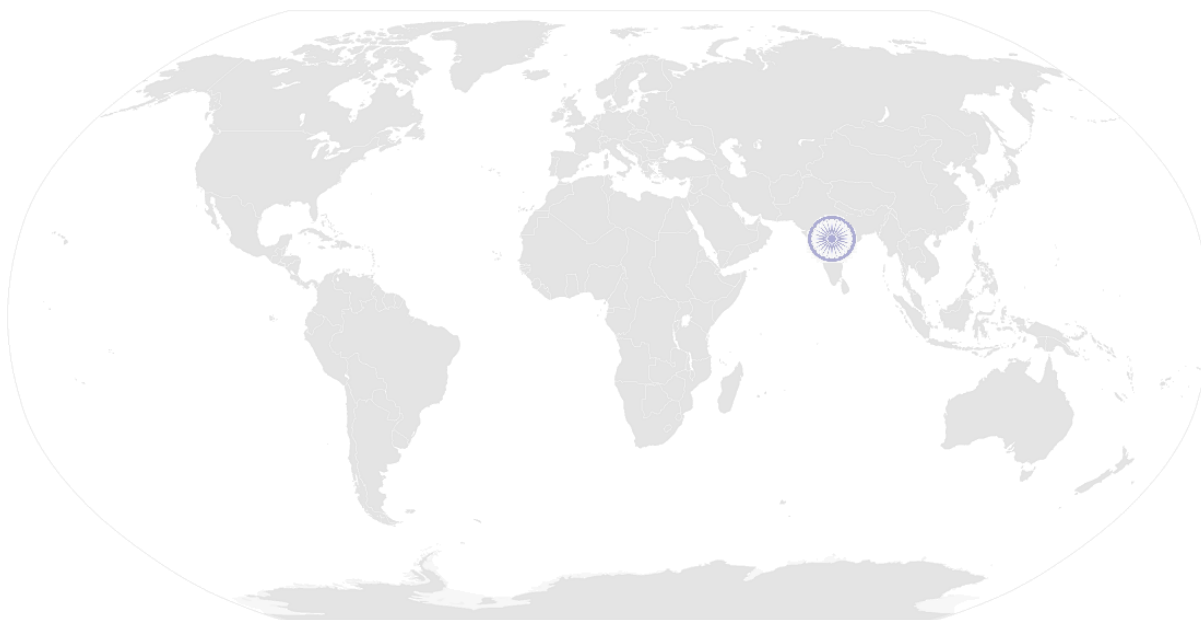
**LFS/N0103 : Ensure cleanliness in the work area**

	<b>Oral Communication (Listening and Speaking skills)</b>
	<p>The user/individual on the job needs to know and understand how to:</p> <p>SA3. communicate with upstream and downstream teams</p> <p>SA4. disclose information only to those who have the right and need to know it.</p>
<b>B. Professional Skills</b>	<b>Critical Thinking</b>
	<p>The user/individual on the job needs to know and understand how to:</p> <p>SB1. suggest improvements(if any) in process based on experience</p>
	<b>Decision Making</b>
	<p>SB2. make decisions to maintain cleanliness in the area of work</p>
	<b>Analytical Thinking</b>
	<b>Problem Solving</b>
	<b>Plan and Organize</b>
	<b>Customer Centricity</b>

LFS/N0103 : Ensure cleanliness in the work area

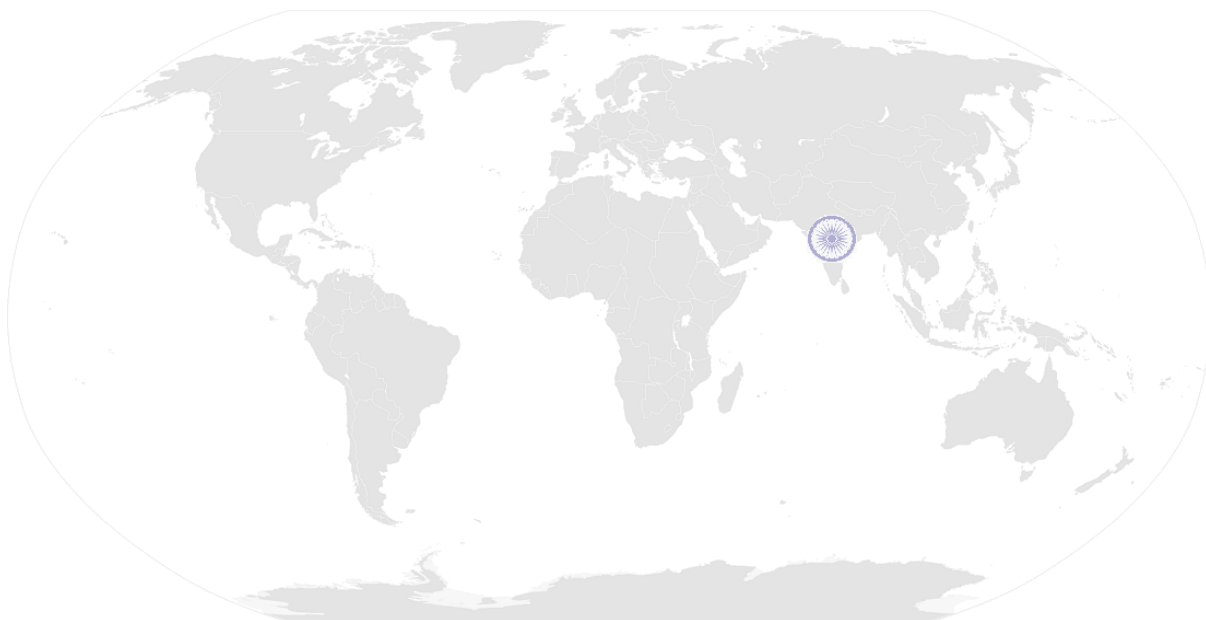
## NOS Version Control

NOS Code	LFS/N0103		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	22/12/14
Industry Sub-sector	Pharmaceuticals and Bio Pharmaceuticals	Last reviewed on	01/08/16
Occupation	Manufacturing, Quality, Supply Chain, R&D	Next review date	01/08/19



LFS/N0251 : Coordinate with manager and team members to carry out bioprocessing activities

# National Occupational Standards



## Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Bio Process Engineer to coordinate with manager and team members to carry out bioprocessing activities.

### LFS/N0251 : Coordinate with manager and team members to carry out bioprocessing activities

National Occupational Standard	<b>Unit Code</b>	<b>LFS/N0251</b>
	<b>Unit Title (Task)</b>	<b>Coordinate with manager and team members to carry out bioprocessing activities</b>
	<b>Description</b>	This NOS is about a Bio Process Engineer coordinating with manager and team members to carry out bioprocessing activities
	<b>Scope</b>	The unit covers the following: <ul style="list-style-type: none"> <li>• Coordination with manager</li> <li>• Coordination with team members</li> </ul>
	<b>Performance Criteria (PC) w.r.t. the Scope</b>	
	<b>Element</b>	<b>Performance Criteria</b>
	Coordination with manager	To be competent, the user/individual on the job must be able to: <ul style="list-style-type: none"> <li>PC1. receive work instructions from reporting manager</li> <li>PC2. communicate to reporting supervisor about process-flow improvements and quality defects received from manufacturing activities</li> <li>PC3. investigate, bring to the manager's attention and suggest possible solutions to problems arising within the department resulting from faulty equipment, dated SOP or human error</li> <li>PC4. communicate any potential hazards or expected process disruptions</li> <li>PC5. provide requisite information, documents, clarifications to manager during actual audits</li> </ul>
	Coordination with team members	<ul style="list-style-type: none"> <li>PC6. collaborate with the manufacturing department in updating manufacturing procedures and policies</li> <li>PC7. work as a team with colleagues and share work as per their own workload and skills</li> <li>PC8. support team members to support internal and external audit activities as per instructions of superiors/supervisor</li> <li>PC9. provide documented shift handovers to the next person in the shift</li> <li>PC10. communicate and discuss work flow related difficulties in order to find solutions with mutual agreement</li> </ul>
	<b>Knowledge and Understanding (K)</b>	
	<b>A. Organisational Context</b> (Knowledge of the Company/ Organisation and its processes)	The user/individual on the job needs to know and understand: <ul style="list-style-type: none"> <li>KA1. escalation matrix for reporting identified issues</li> <li>KA2. importance of complete and accurate documentation</li> <li>KA3. risk and impact of not following defined procedures/work instructions</li> <li>KA4. the reason and impact of the occurrence of problems</li> <li>KA5. measures, steps and possible solutions that have been taken/identified to address the previous problems</li> </ul>



**LFS/N0251 : Coordinate with manager and team members to carry out bioprocessing activities**

<p><b>B. Technical Knowledge</b></p>	<p>The user/individual on the job needs to know and understand:</p> <p>KB1. the organizational systems and requirements relevant to one's role</p> <p>KB2. the boundaries of one's role and responsibilities and that of other team members</p> <p>KB3. method of identifying information by categorizing, estimating, recognizing differences or similarities, and detecting changes in circumstances or events</p> <p>KB4. method of entering, transcribing, recording, storing, or maintaining information in written or electronic/magnetic form</p>
<p><b>Skills (S)</b></p>	
<p><b>A. Core Skills/ Generic Skills</b></p>	<p><b>Writing skills</b></p> <p>The user/ individual on the job needs to know and understand how to:</p> <p>SA1. record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail</p> <p>SA2. maintain proper records as per given format</p> <p>SA3. write reports</p> <p><b>Reading skills</b></p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SA4. read and understand manuals, SOPs, health and safety instructions, memos, reports, job cards, etc.</p> <p>SA5. read images, graphs, diagrams</p> <p>SA6. use and interpret the various coding systems as per company norms</p> <p><b>Oral Communication (Listening and Speaking skills)</b></p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SA7. communicate with upstream and downstream teams</p> <p>SA8. communicate with job owners like sample originating section, supplier etc.</p> <p>SA9. disclose information only to those who have the right and need to know it</p> <p>SA10. communicate confidential and sensitive information discretely to authorized person as per the SOP</p>
<p><b>B. Professional Skills</b></p>	<p><b>Decision making</b></p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SB1. analyse and identify when to report an issue/concern to supervisor and when to deal with a colleague individually, depending on the type of concern</p> <p>SB2. act objectively, rather than impulsively or emotionally when faced with difficult/stressful or emotional situations</p> <p>SB3. resolve any difficulties in relationships with colleagues, or get help from an appropriate person, in a way that preserves goodwill and trust</p> <p><b>Analytical thinking</b></p> <p>The user/individual on the job needs to know and understand how to:</p>

**LFS/N0251 : Coordinate with manager and team members to carry out bioprocessing activities**

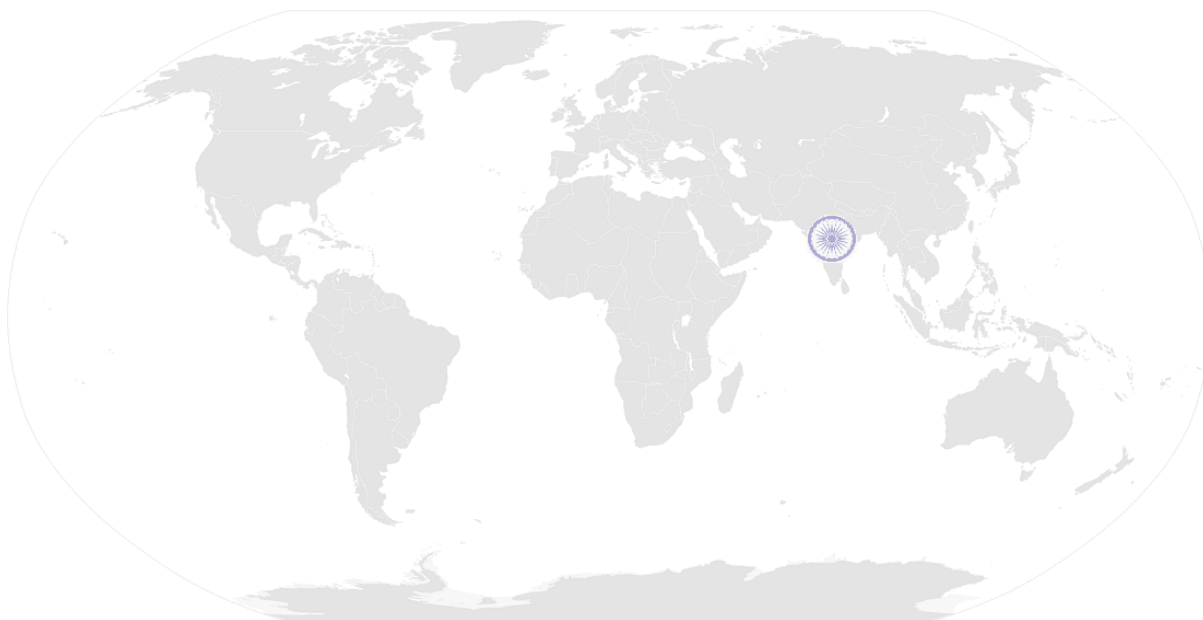
	SB4. analyse and identify improvement work processes by interacting with others and adopting best practices
	SB5. pay attention to detail
	SB6. use computer applications/software for analysis
	<b>Plan and Organize</b>
	The user/individual on the job needs to know and understand how to:
	SB7. multi-task and adapt
	SB8. identify, define and resolve problems using a structured methodology
	SB9. prioritize needs and effectively schedule work
	<b>Critical thinking</b>
	NA
<b>Problem solving</b>	
NA	
<b>Customer Centricity</b>	
NA	



LFS/N0251 : Coordinate with manager and team members to carry out bioprocessing activities

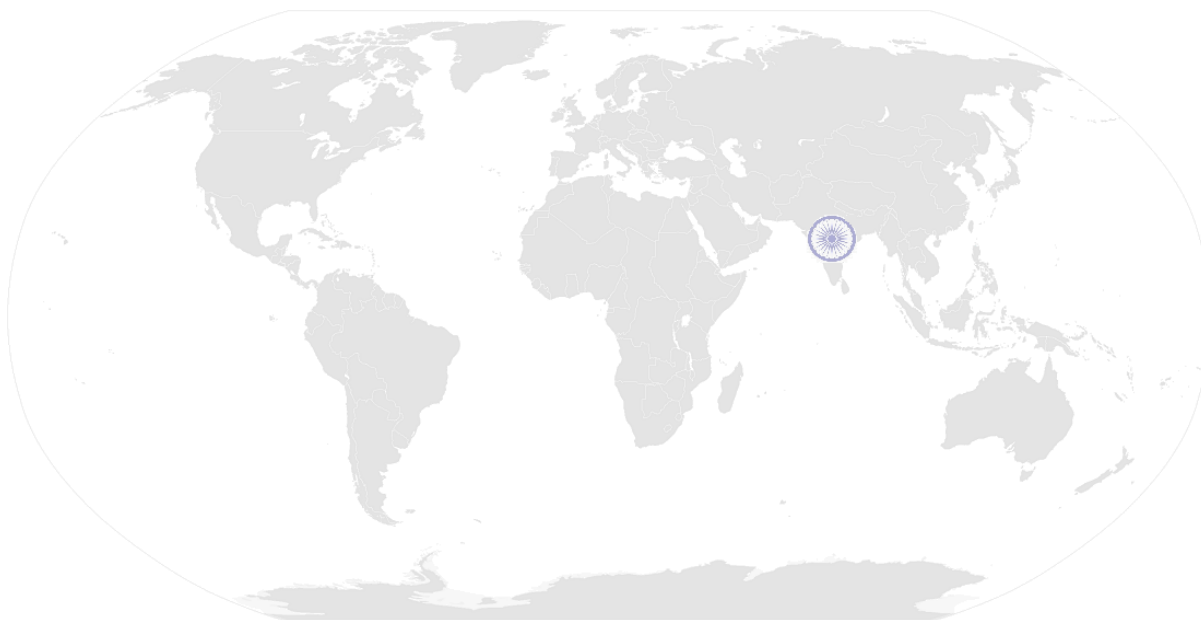
## NOS Version Control

<b>NOS Code</b>	<b>LFS/N0251</b>		
<b>Credits(NSQF)</b>	<b>TBD</b>	<b>Version number</b>	<b>1.0</b>
<b>Industry</b>	<b>Life Sciences</b>	<b>Drafted on</b>	<b>15/12/14</b>
<b>Industry Sub-sector</b>	<b>Pharmaceutical and Biopharmaceutical</b>	<b>Last reviewed on</b>	<b>01/08/16</b>
<b>Occupation</b>	<b>Manufacturing</b>	<b>Next review date</b>	<b>01/08/19</b>



LFS/N0101 : Maintain a healthy, safe and secure working environment in the life sciences facility

# National Occupational Standards



## Overview

**This Occupational Standard is about the knowledge, understanding and skills required by a Bioprocess Engineer to ensure healthy, safe and secure working environment in the life sciences facility.**

**LFS/N0101 : Maintain a healthy, safe and secure working environment in the life sciences facility**

National Occupational Standard	<b>Unit Code</b>	<b>LFS /N0101</b>
	<b>Unit Title (Task)</b>	<b>Maintain a healthy, safe and secure working environment in the life sciences facility</b>
	<b>Description</b>	This NOS unit is about a Bio Process Engineer monitoring the working environment and making sure that it meets the requirements for health, safety and security in the pharmaceutical/contract research/biopharmaceutical facility/ manufacturing/ testing/ analysis/ research laboratory.
	<b>Scope</b>	<p>This unit / task covers the following:</p> <p><b>Ensuring healthy, safe and secure working environment:</b></p> <ul style="list-style-type: none"> <li>• self monitor and adhere to safety principles and standards</li> <li>• ensure behavioural safety by workmen to cGMP and applicable safety standards on the shop floor/ laboratory</li> <li>• report any identified breaches in health, safety, and security policies and procedures to the designated person</li> </ul> <p><b>Managing emergency procedures:</b></p> <ul style="list-style-type: none"> <li>• illness</li> <li>• accidents</li> <li>• fires</li> <li>• other reasons to evacuate the premises</li> <li>• breaches of security</li> </ul>
<b>Performance Criteria (PC) wrt the Scope</b>		
<b>Element</b>	<b>Performance Criteria</b>	
<b>Ensuring healthy, safe and secure working environment</b>	<p>To be competent, the user/individual on the job must be able to:</p> <p>PC1. observe and comply with the company’s current health, safety and security policies and procedures</p> <p>PC2. while carrying out work, use appropriate safety gears like head gear, masks, gloves and other accessories as mentioned in the guidelines</p> <p>PC3. report any identified breaches in health, safety, and security policies and procedures to the designated person</p> <p>PC4. responsible for maintaining discipline at the shop-floor/ production area</p> <p>PC5. identify and correct any hazards that the individual can deal with safely, competently and within the limits of their authority</p> <p>PC6. adhere and comply to storage and handling guidelines for hazardous material</p> <p>PC7. identify and recommend opportunities for improving health, safety, and security to the designated person</p> <p>PC8. complete any health, safety and security activities like safety drills and prepare records legibly and accurately</p>	
<b>Managing emergency procedures</b>	<p>PC9. report any hazards that the individual is not competent to deal with to the relevant person in line with organizational procedures and warn other people who may be affected</p> <p>PC10. follow the company’s emergency procedures promptly, calmly, and efficiently</p>	

**LFS/N0101 : Maintain a healthy, safe and secure working environment in the life sciences facility**

Knowledge and Understanding (K)	
<p><b>A. Organisational Context</b> (Knowledge of the Company/ Organisation and its processes)</p>	<p>The user/ individual on the job needs to know and understand:</p> <p>KA1. legislative requirements and company’s procedures for health, safety and security and individual’s role and responsibilities in relation to this</p> <p>KA2. what is meant by a hazard, including the different types of health and safety hazards that can be found in the workplace</p> <p>KA3. how and when to report hazards</p> <p>KA4. limits of individual responsibility for dealing with hazards</p> <p>KA5. the organization’s emergency procedures for different emergency situations and the importance of following these</p> <p>KA6. the importance of maintaining high standards of health, safety and security</p> <p>KA7. implications that any non-compliance with health, safety and security may have on individuals and the organization</p> <p>KA8. health hazards and its implications if any in the production process</p>
<p><b>B Technical Knowledge</b></p>	<p>The user/ individual on the job needs to know and understand:</p> <p>KB1. different types of breaches in health, safety and security and how and when to report these</p> <p>KB2. evacuation procedures for workers and visitors</p> <p>KB3. how to summon medical assistance and the emergency services, where necessary</p> <p>KB4. how to use the health, safety and accident reporting procedures and the importance of these</p> <p>KB5. different types of occupational health hazards</p> <p>KB6. knowledge of chemical substances, their characteristics and required precaution and safety measures</p>
Skills (S)	
<p><b>A. Core Skills/ Generic Skills</b></p>	<p><b>Writing skills</b></p>
	<p>The user/ individual on the job needs to know and understand how to:</p> <p>SA1. complete accurate, well written work with attention to detail</p>
	<p><b>Reading skills</b></p>
	<p>The user/ individual on the job needs to know and understand how to:</p> <p>SA2. read instructions, guidelines, procedures, rules and service level agreements</p>
	<p><b>Oral Communication (Listening and Speaking skills)</b></p>
	<p>The user/ individual on the job needs to know and understand how to:</p>

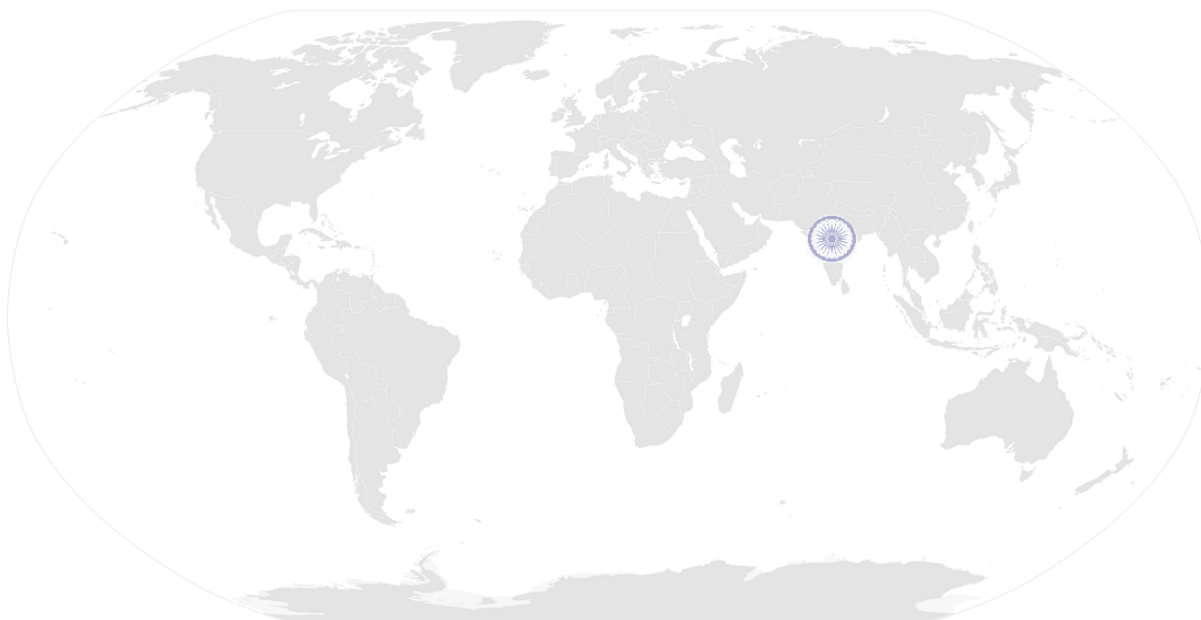
**LFS/N0101 : Maintain a healthy, safe and secure working environment in the life sciences facility**

	SA3. listen effectively and orally communicate information accurately
<b>B. Professional Skills</b>	<b>Decision making</b>
	The user/ individual on the job needs to know and understand how to:
	SB1. make decisions on suitable courses of action
	<b>Plan and Organise</b>
	The user/ individual on the job needs to know and understand how to:
	SB2. plan and organize work to meet health, safety and security requirements
	<b>Problem solving</b>
	The user/ individual on the job needs to know and understand how to:
	SB3. apply problem solving approaches in different situations
	<b>Analytical thinking</b>
	The user/ individual on the job needs to know and understand how to:
	SB4. analyse data and activities
<b>Critical thinking</b>	
The user/ individual on the job needs to know and understand how to:	
SB5. apply balanced judgments to different situations	
<b>Customer Centricity</b>	
NA	

LFS/N0101 : Maintain a healthy, safe and secure working environment in the life sciences facility

## NOS Version Control

NOS Code	LFS/N0101		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	26/06/14
Industry Sub-sector	Pharmaceuticals and Bio Pharmaceuticals	Last reviewed on	01/08/16
Occupation	Manufacturing, Quality, Supply Chain, R&D	Next review date	01/08/19





Qualifications Pack – Bio Process Engineer

Annexure

Nomenclature for QP and NOS

**Qualifications Pack**

9 characters

LFS / Q 0101



**Occupational Standard**

An example of NOS with 'N'

9 characters

LFS / N 0101



*Qualifications Pack for Bio Process Engineer*

The following acronyms/codes have been used in the nomenclature above:

Sub-Sector	Range of Occupation Numbers
Pharmaceutical and Biopharmaceutical and Contract Research	01-10
Pharmaceutical	11-20
Biopharmaceutical	21-30
Contract Research	31-40

Sequence	Description	Example
Three letters	Industry name	LFS
Slash	/	/
Next letter	Whether QP or NOS	Q/N
Next two numbers	Occupation code	01
Next two numbers	OS number	01

Qualifications Pack for Bio Process Engineer

**CRITERIA FOR ASSESSMENT OF TRAINEES**

**Job Role** Bio Process Engineer/Technician

**Qualification Pack** LFS/Q0219

**Sector Skill Council** Life Sciences Sector Skill Development Council

**Guidelines for Assessment:**

1. Criteria for assessment for each Qualification Pack will be created by the Sector Skill Council. Each Performance Criteria (PC) will be assigned marks proportional to its importance in NOS. SSC will also lay down proportion of marks for Theory and Skills Practical for each PC.
2. The assessment for the theory part will be based on knowledge bank of questions created by the SSC.
3. Individual assessment agencies will create *unique question papers for theory part for each candidate at each examination/training center* (as per assessment criteria below)
4. Individual assessment agencies will create *unique evaluations for skill practical for every student at each examination/training center* based on this criteria
5. To pass the Qualification Pack, every trainee should score a minimum of 70% in every NOS
6. In case of successfully passing only certain number of NOS's, the trainee is eligible to take subsequent assessment on the balance NOS's to pass the Qualification Pack.

				Marks Allocation	
Assessment Outcome	Assessment Criteria of Outcome	Total Marks (700)	Out Of	Theory	Skills Practical
LFS/N0247 (Provide operational support for daily manufacturing activities)	PC1. provide technical support for the evaluation of raw material to ensure manufacturing processes are robust, safe and adequate	100	6	2	4
	PC2. assist improvements in raw material testing regimes to ensure the critical functional attributes are evaluated		3	1	2
	PC3. provide support to Manufacturing to meet production demands		6	2	4
	PC4. operate small-scale cell culture areas and systems by operating cleaning, set up, and maintaining batch reefered fermenters; inoculating and maintaining spinner seed cultures using aseptic techniques, maintaining cellbanks; and performing general seed lab operation		9	3	6

*Qualifications Pack for Bio Process Engineer*

PC5. operate large scale column chromatography systems	3	1	2
PC6. comply with safety requirements, GMP, SOP and manufacturing	6	2	4
PC7. assist in use of automation to perform production operations	3	1	2
PC8. participate in continuous operational improvement in the manufacturing process	4	2	2
PC9. apply the concepts in commercial-scale drug substance manufacturing	3	1	2
PC10. anticipate potential problems and takes preventative action	3	1	2
PC11. provide day-to-day bioprocess engineering support to upstream / downstream manufacturing operations.	6	2	4
PC12. support and participate in commissioning and start-up activities of biotech unit operations and equipment.	6	2	4
PC13. initiate and implement facility and equipment upgrades to improve plant productivity and throughput.	6	2	4
PC14. facilitate the introduction of new products with associated new unit operations and equipment and ensure the bio-processing at the site stays current with emerging processing and equipment innovations.	6	2	4
PC15. assemble and prepare equipment for production	4	2	2
PC16. prepare solutions for the production process	4	2	2
PC17. trouble shoot equipment and process problems	4	2	2
PC18. operate systems that clean and sterilize tanks and filtration systems	6	2	4

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	PC19. operate fermenters, centrifuges, other harvest systems and protein purifications units		6	2	4
	PC20. interact with internal and external business partners to remain updated on emerging technologies to best position the operations team with a competitive advantage in delivering products of the highest quality at the lowest cost		3	1	2
	PC21. develop recommendations for improvements to existing commercial-scale manufacturing processes to ensure reliability, robustness, and regulatory compliance		3	1	2
	Total		100	36	64
LFS/N0248 (Support research and development capabilities)	PC1. establish process development scale-up to extend the company's research and development capabilities	100	10	4	6
	PC2. optimize growth and productivity parameters of suspension cell lines and assist, as needed, in the hands-on experiments to define these variables		10	4	6
	PC3. conduct research, along with life scientists, chemists, and medical scientists, on the engineering aspects of the biological systems of humans and animals.		16	6	10
	PC4. diagnose and interpret bioelectric data, using signal processing techniques.		10	4	6
	PC5. design and develop medical diagnostic and clinical instrumentation, equipment, and procedures, using the principles of engineering and bio behavioural sciences.		14	6	8
	PC6. develop models or computer simulations of human bio behavioural systems to obtain data		14	6	8

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	for measuring or controlling life processes.				
	PC7. assist in design, development, and evaluation of biological and health systems and products, such as artificial organs, prostheses, instrumentation, medical information systems, and health management and care delivery systems		14	6	8
	PC8. participate in the creation, development and design of the organization's novel technologies by interfacing with vector design, downstream and analytical teams		6	2	4
	PC9. research new materials to be used for products, such as implanted artificial organs		6	2	4
	Total		100	40	60
LFS/N0249 (Develop and execute technical transfer plans, process transfer and validation protocols)	PC1. contribute technical support to develop and execute technical transfer plans (including transfer of existing products or new products under development), which includes preparation of process transfer protocols, process validation protocols, and supporting regulatory documents	100	24	8	16
	PC2. provide technical guidance to R&D cell-line development and media optimization functions to ensure manufacturing suitability and regulatory compliance of proposed strategies while maximizing process yields and/or reducing cost of goods		20	8	12
	PC3. serve as technical support on capital projects related to manufacturing processes and equipment, and as a bioprocessing functional area subject matter expert on the internal mammalian cell culture manufacturing		20	8	12
	PC4. assist in design and execution of test protocols to optimize unit operations		20	8	12

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	PC5. assist in processing data to manufacturing performance management meetings to establish and monitor process metrics, extract key learnings		16	6	10
	Total		100	38	62
LFS/N0250 (Carry out reporting and documentation for bioprocessing activities)	PC1. support the team in technical transfer of data, processes and technical specifications to CMOs for the implementation of large-scale manufacturing operations for clinical and commercial development of targeted products	100	12	6	6
	PC2. follow reporting procedures as prescribed by the company		10	4	6
	PC3. identify and report defects/ anomalies to the appropriate authority		12	6	6
	PC4. prepare comprehensive summaries of bioprocessing information and other documents necessary for regulatory submission		16	6	10
	PC5. maintain, update and archive study related files and documents		8	4	4
	PC6. identify documentation to be completed relating to one's role		6	2	4
	PC7. record details accurately in the appropriate format		6	2	4
	PC8. ensure that the final document meets regulatory and compliance requirements		10	4	6
	PC9. perform review of records and other documentation for compliance to established procedures and good documentation practices		10	4	6
	PC10. respond to requests for information in an appropriate manner whilst following organizational procedures		6	3	3
	PC11. inform the appropriate authority of requests for information received		4	2	2
	Total		100	43	57

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LFS/N0103 (Ensure cleanliness in the work area)	PC1. inspect the area while taking into account various surfaces	100	4	2	2
	PC2. identify the material requirements for cleaning the areas inspected, by considering risk, time, efficiency and type of stain		5	2	3
	PC3. ensure that the cleaning equipment is in proper working condition		5	2	3
	PC4. select the suitable alternatives for cleaning the areas in case the appropriate equipment and materials are not available and inform the appropriate person		4	2	2
	PC5. plan the sequence for cleaning the area to avoid re-soiling clean areas and surfaces		4	1	3
	PC6. inform the affected people about the cleaning activity		4	2	2
	PC7. display the appropriate signage for the work being conducted		4	2	2
	PC8. ensure that there is adequate ventilation for the work being carried out		5	2	3
	PC9. wear the personal protective equipment required for the cleaning method and materials being used		4	2	2
	PC10. use the correct cleaning method for the work area, type of soiling and surface		4	2	2
	PC11. deal with accidental damage, if any, caused while carrying out the work		4	1	3
	PC12. report to the appropriate person any difficulties in carrying out your work		4	2	2
	PC13. identify and report to the appropriate person any additional cleaning required that is outside one's responsibility or skill		4	2	2
	PC14. ensure that there is no oily substance on the floor to avoid slippage		4	2	2
	PC15. ensure that no scrap material is lying around		4	2	2



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	PC16. maintain and store housekeeping equipment and supplies		4	2	2
	PC17. follow workplace procedures to deal with any accidental damage caused during the cleaning process		4	2	2
	PC18. ensure that, on completion of the work, the area is left clean and dry and meets requirements		4	2	2
	PC19. return the equipment, materials and personal protective equipment that were used to the right places making sure they are clean, safe and securely stored		5	2	3
	PC20. dispose the waste garnered from the activity in an appropriate manner		5	2	3
	PC21. dispose of used and un-used solutions according to manufacturer's instructions, and clean the equipment thoroughly		5	2	3
	PC22. maintain schedules and records for housekeeping duty		5	2	3
	PC23. replenish any necessary supplies or consumables		5	2	3
	Total		100	44	56
LFS/N0251 (Coordinate with manager and team members to carry out bioprocessing activities)	PC1. receive work instructions from reporting manager	100	6	2	4
	PC2. communicate to reporting supervisor about process-flow improvements, quality defects received from manufacturing activities		18	8	10
	PC3. investigate, bring to the manager's attention and suggest possible solutions to problems arising within the department resulting from faulty equipment, dated SOP or human error		18	8	10
	PC4. communicate any potential hazards or expected process disruptions		15	5	10
	PC5. provide requisite information, documents, clarifications to manager during actual audits		10	4	6
	PC6. collaborate with the manufacturing department in		10	4	6

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	updating manufacturing procedures and policies				
	PC7. work as a team with colleagues and share work as per their own workload and skills		3	1	2
	PC8. support team members to support internal and external audit activities as per instructions of superiors/supervisor		8	4	4
	PC9. provide documented shift handovers to the next person in the shift		6	2	4
	PC10. communicate and discuss work flow related difficulties in order to find solutions with mutual agreement		6	2	4
	<b>Total</b>		<b>100</b>	<b>40</b>	<b>60</b>
LFS/N0101 (Maintain a healthy, safe and secure working environment in the life sciences facility)	PC1. observe and comply with the company's current health, safety and security policies and procedures	100	5	5	10
	PC2. while carrying out work, use appropriate safety gears like head gear, masks, gloves and other accessories as mentioned in the guidelines		5	5	10
	PC3. report any identified breaches in health, safety, and security policies and procedures to the designated person		5	5	10
	PC4. responsible for maintaining discipline at the shop-floor/ production area		5	5	10
	PC5. identify and correct any hazards that the individual can deal with safely, competently and within the limits of their authority		5	5	10
	PC6. adhere and comply to storage and handling guidelines for hazardous material		5	5	10
	PC7. identify and recommend opportunities for improving health, safety, and security to the designated person		5	5	10
	PC8. complete any health, safety and security records legibly and accurately		4	6	10

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	PC9. report any hazards that the individual is not competent to deal with to the relevant person in line with organizational procedures and warn other people who may be affected		4	6	10
	PC10. follow the company's emergency procedures promptly, calmly, and efficiently		5	5	10
	Total	100	48	52	100