

# 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

Contact Us:  
New Delhi

E-mail:



## Contents

1. Introduction and Contacts.....P.1
2. Qualifications Pack.....P.2
3. Glossary of Key Terms .....P.4
4. NOS Units.....P.6
5. Annexure: Nomenclature for QP & OS....P.41
6. Assessment Criteria.....P.43

## Introduction

### Qualifications Pack-Quality Control Chemist-Microbiology

**SECTOR:** LIFE SCIENCES

**SUB-SECTOR:** PHARMACEUTICAL AND BIOPHARMACEUTICAL

**OCCUPATION:** QUALITY

**REFERENCE ID:** LFS/Q0308

**ALIGNED TO:** NOS 2004/NIL

**Quality Control Chemist-Microbiology** is responsible for various microbiological analysis of the raw material and finished products in the Quality Control Laboratory. The chemist helps contain the growth of microorganisms and ensure quality checks as per laid down methods and specifications.

**Brief Job Description:**Quality Control Chemist- Microbiology is responsible for inspection of incoming materials, perform research work to support the development of new products, carry out housekeeping and carrying out reporting and documentation to meet quality standards.

**Personal Attributes:** The individual should have knowledge pertaining to functioning of quality control equipment like stability chambers and BOD incubators and adequate training for the competent performance of tests, operation of equipment and basic techniques, e.g. counting of colonies, plate pouring, serial dilutions, etc.

Qualifications Pack For Quality Control Chemist - Microbiology

Job Details

Qualifications Pack Code	LFS/Q0308		
Job Role	Quality Control Chemist-Microbiology		
Credits(NSQF)	TBD	Version number	1.0
Sector	Life Sciences	Drafted on	22/12/14
Sub-sector	Pharmaceutical and Biopharmaceutical	Last reviewed on	25/02/15
Occupation	Quality	Next review date	25/02/16
NSQC Clearance on	20/07/2015		

Job Role	Quality Control Chemist-Microbiology
Role Description	Responsible for various microbiological analysis of the raw material and finished products in the Quality Control Laboratory. The chemist helps contain the growth of microorganisms and ensure quality checks as per laid down methods and specifications
NSQF level	5
Minimum Educational Qualifications	B.Sc in a relevant subject such as biochemistry, biology, chemistry, immunology, biomedical science, biotechnology, microbiology (Preferable)
Maximum Educational Qualifications	Doctorate in a relevant subject such as biochemistry, biology, chemistry, immunology, biomedical science, biotechnology, microbiology (Preferable)
Training (Suggested but not mandatory)	On the job training
Minimum Job Entry Age	20 Years
Experience	0-2 years
Applicable National Occupational Standards (NOS)	<p><b>Compulsory:</b></p> <ol style="list-style-type: none"> <li><a href="#">LFS/N0321:Perform inspection of incoming materials</a></li> <li><a href="#">LFS/N0322: Perform research work to support the development of new products</a></li> <li><a href="#">LFS/N0314: Carry out reporting and documentation to meet quality standards</a></li> <li><a href="#">LFS/N0104: Coordinate with Supervisor and team members</a></li> </ol>

*Qualifications Pack For Quality Control Chemist - Microbiology*

	<ol style="list-style-type: none"> <li>5. <a href="#">LFS/N0103: Ensure cleanliness in the work area</a></li> <li>6. <a href="#">LFS/N0101: Maintain a healthy, safe and secure working environment in the life sciences facility</a></li> <li>7. <a href="#">LFS/N0320: Carry out quality checks in the quality control process</a></li> </ol> <p><b>Optional:</b> N.A.</p>
<b>Performance Criteria</b>	As described in the relevant OS units

Qualifications Pack For Quality Control Chemist - Microbiology

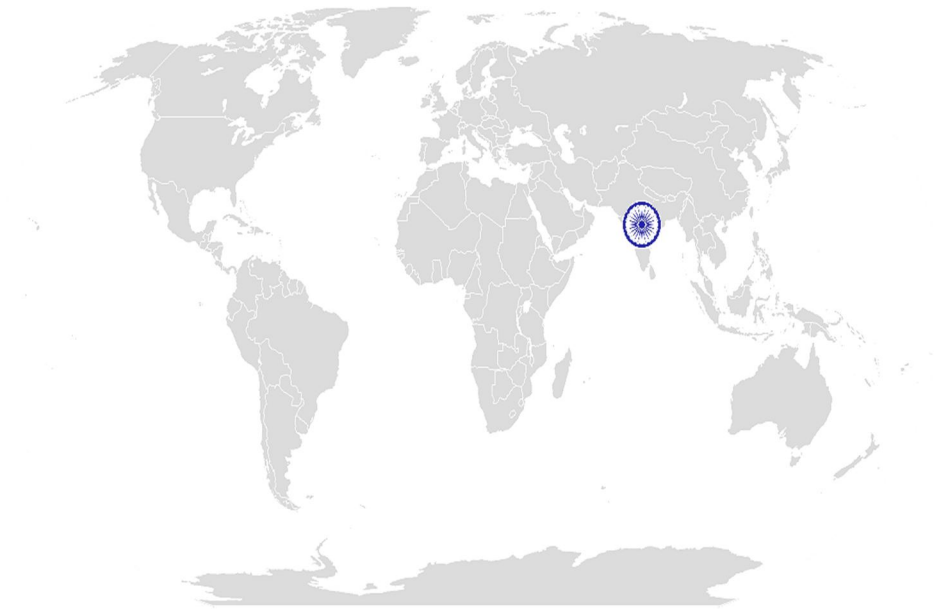
Definitions	Keywords /Terms	Description
	Core Skills/Generic Skills	Core Skills or Generic Skills are a group of skills that are key to learning and working in today's world. These skills are typically needed in any work environment. In the context of the NOS, these include communication related skills 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.	

### Qualifications Pack For Quality Control Chemist - Microbiology

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
ISO	International Organization for Standardization
TS	Technical Specifications
QC	Quality Control
OHSAS	Occupational health and safety management system
OOS	Out of Specifications
OOT	Out of Trend

LFS/N0321:Perform inspection of incoming materials

# National Occupational Standard



## Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Quality Control Chemist-Microbiology to perform inspection of incoming materials.

**LFS/N0321:Perform inspection of incoming materials**

National Occupational Standard	<b>Unit Code</b>	<b>LFS/N0321</b>
	<b>Unit Title (Task)</b>	<b>Perform inspection of incoming materials</b>
	<b>Description</b>	This OS is about a Quality Control Chemist-Microbiology inspecting the incoming materials
	<b>Scope</b>	<p>The unit/ task covers the following:</p> <ul style="list-style-type: none"> <li>Inspecting the products for microorganism, if any, and testing the safety and purity of drugs</li> <li>Undertaking laboratory and sample related activities</li> </ul>
	<b>Performance Criteria (PC) w.r.t. the Scope</b>	
	<b>Element</b>	<b>Performance Criteria</b>
	Inspection	<p>To be competent, the user/individual on the job must be able to:</p> <p>PC1. observe, monitor and identify microorganisms and their growth/colonies in the sample and conduct tests like LAL tests for detecting endotoxins, etc.</p> <p>PC2. monitor and assess samples from a range of sources like raw material sampling (microbiology), microbiological analysis of water for purified water and raw waterfor MCT/ BET/ Sterility</p> <p>PC3. use a variety of identification methods, like molecular testing to test samples</p> <p>PC4. identify the reason for unwanted growth of microorganisms and check for OOT and OOS samples</p> <p>PC5. manage and oversee the laboratory work with respect to maintaining sterile conditions and work in isolation (wherever needed)</p> <p>PC6. work with specialised computer software to undertake studies and research and train production line staff for sterile conditions, good micro trial operations</p> <p>PC7. identify and classify microorganisms found in specimens collected from humans, plants, animals, or the environment</p> <p>PC8. validate test methodsand undertake calibration exercises</p> <p>PC9. serve as the primary contact for all QC Microbiology related filings and inspections of Regulatory Agencies</p> <p>PC10. undertake culture/media preparation to conduct quality analysis on the samples and maintain standard cultures</p>
	Laboratory and sample related activities	<p>PC11. maintain restricted access to the microbiological laboratory as per cGMP and GLP guidelines</p> <p>PC12. minimize the risks of cross-contamination, false-positive and false-negative results</p> <p>PC13. define alert and action limits and maintain positive and negative controls during testing as considered appropriate</p> <p>PC14. fulfil requirements of sterility testing like aseptic conditions</p> <p>PC15. ensure that all reagents (including stock solutions), media, diluents and other suspending fluids are adequately labelled to indicate the identity,</p>

LFS/N0321: Perform inspection of incoming materials

	concentration, storage conditions, preparation date, validated expiry date and/or recommended storage period
<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:  KA1. different quality management systems (ISO-9000, TS16949, ISO-14001, OHSAS-18000), good laboratory and manufacturing practices KA2. organizational coding system of finished materials, compounds and the company manual KA3. implications of not adhering to quality control procedures KA4. quality and damage checks to be carried out and importance of the same KA5. quality control procedures followed by the company and importance of the same KA6. use and maintenance of bod incubators, laminar air flows, autoclaves, etc. KA7. concepts of pharmacopeia
<b>B. Technical Knowledge</b>	The user/individual on the job needs to know and understand:  KB1. all concepts taught to attain a professional certification in microbiology or equivalent KB2. methods for the competent performance of tests, operation of equipment and basic techniques, e.g. counting of colonies, plate pouring, serial dilutions, etc. KB3. the method and importance of containment of microorganisms within the laboratory facility KB4. GMP, GLP and safety requirements KB5. use of sophisticated scientific/laboratory instruments
<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. make complete and accurate notes of the information and data gathered SA2. use English as a language for writing/documentation
	<b>Reading Skills</b>
	The user/individual on the job needs to know and understand how to:  SA3. interpret documented guidelines/procedures/rules and service level agreements
	<b>Oral Communication (Listening and Speaking Skills)</b>



**LFS/N0321:Perform inspection of incoming materials**

	<p>The user/individual on the job needs to know and understand how to:</p> <p>SA4. interact with people to effectively gather information SA5. listen effectively and orally communicate information accurately SA6. ask for clarification and advice from others</p>
<b>B. Professional Skills</b>	<b>Decision Making</b>
	<p>The user/individual on the job needs to know and understand how to:</p> <p>SB1. make decisions on a suitable course of action or response</p>
	<b>Plan and Organise</b>
	<p>The user/individual on the job needs to know and understand how to:</p> <p>SB2. plan work assigned on a daily basis and provide estimates of time required for each piece of work</p>
	<b>Problem Solving</b>
	<p>The user/individual on the job needs to know and understand how to:</p> <p>SB3. seek clarification on problems from supervisors SB4. use effective problem solving techniques</p>
	<b>Analytical Thinking</b>
	<p>The user/individual on the job needs to know and understand how to:</p> <p>SB5. analyse data and activities SB6. pass on relevant information to members and supervisors SB7. use computer application software to carry investigations</p>
	<b>Critical Thinking</b>
<p>The user/individual on the job needs to know and understand how to:</p> <p>SB8. provide opinions on work in a detailed and constructive way SB9. apply balanced judgments to different approaches</p>	

LFS/N0321:Perform inspection of incoming materials

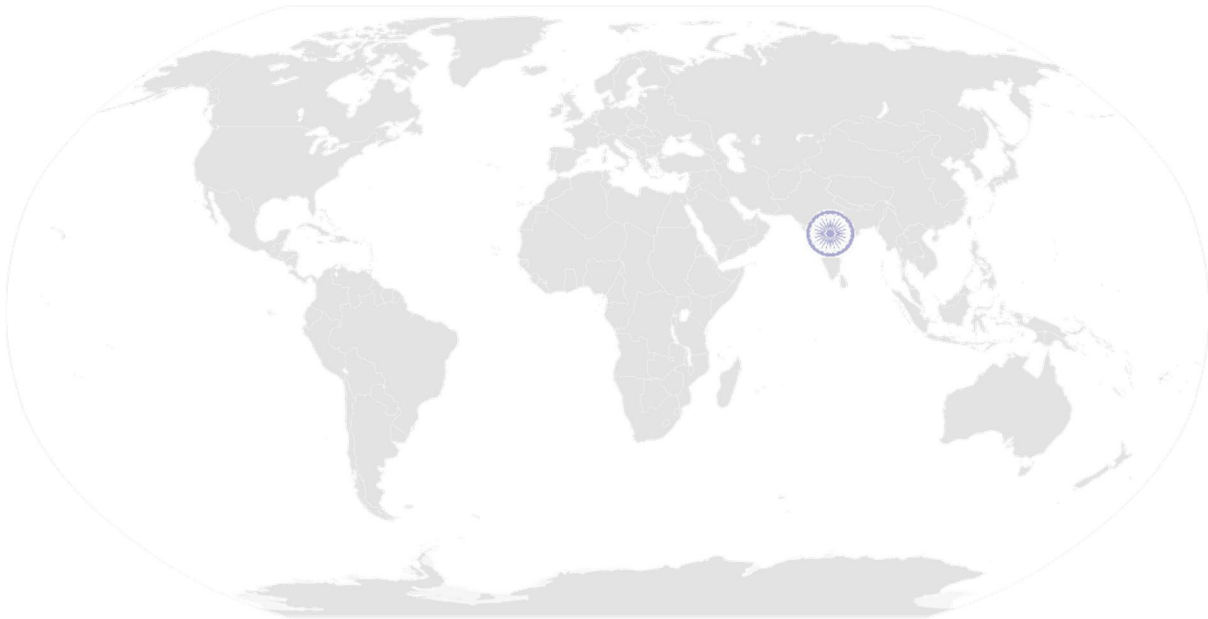
## NOS Version Control

NOS Code	LFS/N0321		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	22/12/14
Industry Sub-sector	Pharmaceuticals and Biopharmaceuticals	Last reviewed on	28/01/15
Occupation	Quality	Next review date	28/01/16



LFS/N0322: Perform research work to support the development of new products

# National Occupational Standards



## Overview

**This Occupational Standard describes the knowledge, understanding and skills required of a Quality Control Chemist-Microbiology to perform research work to support the development of new products**

**LFS/N0322: Perform research work to support the development of new products**

National Occupational Standard	<b>Unit Code</b>	<b>LFS/N0322</b>
	<b>Unit Title (Task)</b>	<b>Perform research work to support the development of new products</b>
	<b>Description</b>	ThisOS unit is about a Quality Control Chemist-Microbiology performing research work to support the development of new products
	<b>Scope</b>	The unit/ task covers the following: <ul style="list-style-type: none"> <li>Carrying out research and developing new products</li> </ul>
	<b>Performance Criteria (PC) w.r.t the Scope</b>	
	<b>Element</b>	<b>Performance Criteria</b>
	Research	To be competent, the user/individual on the job must be able to: <ul style="list-style-type: none"> <li>PC1. grow strains of bacteria in various conditions to understand their reaction</li> <li>PC2. work with technicians, chemists and scientists of other fields to contain the growth of microorganisms</li> <li>PC3. present research findings to scientists, non-scientist executives, engineers, other colleagues, and the public</li> <li>PC4. keep up with new research</li> <li>PC5. attend national and international conferences and other events</li> <li>PC6. work with specialised computer software to undertake studies and research</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. importance of identifying non-conforming products</li> <li>KA2. risk and impact of not following defined procedures/work instructions</li> <li>KA3. escalation matrix for reporting identified issues</li> <li>KA4. records to be maintained and the implications of non-maintenance of the same</li> <li>KA5. health, safety and environment guidelines, legislation and regulations as applicable</li> <li>KA6. impact of poor practices on health, safety and environment</li> <li>KA7. impact of various practices on cost, quality, productivity, delivery and safety</li> </ul>
	<b>B Technical Knowledge</b>	The user/individual on the job needs to know and understand: <ul style="list-style-type: none"> <li>KB1. various kinds of testing equipment and related test method and purpose of tests</li> <li>KB2. methods of using laboratory equipment like autoclave, laminar airflow, etc.</li> <li>KB3. national/international standard test methods for different compounds</li> <li>KB4. importance of the safe handling of microorganisms</li> <li>KB5. factors that adversely affect integrity of the sample</li> <li>KB6. the use of computer applications/software specific to microbiological processes carried out in the laboratory</li> </ul>

**LFS/N0322: Perform research work to support the development of new products**

	<p>KB7. the concepts of tissue culture</p> <p>KB8. biology of microorganisms at both the molecular and cellular level</p>
<b>Skills (S)</b>	
<b>A. Core Skills/ Generic Skills</b>	<p><b>Writing Skills</b></p> <p>The user/ individual on the job needs to know and understand how to:</p> <p>SA1. read, write and speak at least one local language</p> <p>SA2. complete documentation accurately</p>
	<p><b>Reading Skills</b></p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SA3. read information accurately</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>SA4. communicate effectively with team members and supervisors</p> <p>SA5. answer questions effectively</p> <p>SA6. communicate with upstream and downstream teams</p>
<b>B. Professional Skills</b>	<p><b>Decision Making</b></p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SB1. make decisions on a suitable course of action or response</p>
	<p><b>Plan and Organise</b></p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SB2. plan work assigned on a daily basis</p> <p>SB3. provide estimates of time required for each piece of work</p> <p>SB4. manage multiple and varied tasks, and prioritize workload</p>
	<p><b>Analytical Thinking</b></p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SB5. apply statistical analysis methods</p> <p>SB6. pay attention to detail</p>
	<p><b>Problem Solving</b></p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SB7. identify immediate or temporary solutions to resolve delays</p> <p>SB8. comprehend the problem, identify the solution(s) and suggest the best possible solution to the team</p>

**LFS/N0322: Perform research work to support the development of new products**

	<b>Critical 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



LFS/N0322: Perform research work to support the development of new products

## NOS Version Control

NOS Code	LFS/N0322		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	22/12/14
Industry Sub-sector	Pharmaceuticals and Biopharmaceuticals	Last reviewed on	28/01/15
Occupation	Quality	Next review date	28/01/16



LFS/N0314: Carry out reporting and documentation to meet quality standards

# National Occupational Standards



## Overview

**This Occupational Standard describes the knowledge, understanding and skills required of a Quality Control Chemist-Microbiology to carry out reporting and documentation to meet quality standards**



**LFS/N0314: Carry out reporting and documentation to meet quality standards**

National Occupational Standard	<b>Unit Code</b>	<b>LFS/N0314</b>
	<b>Unit Title (Task)</b>	<b>Carry out reporting and documentation to meet quality standards</b>
	<b>Description</b>	This OS unit is about the Quality Control Chemist - Microbiology carrying out reporting and documentation to meet quality standards and ensure that the final documents meet regulatory and compliance requirements
	<b>Scope</b>	The unit/ task covers the following: <ul style="list-style-type: none"> <li>• Reporting of defects/problem/incidents/quality issues/test results</li> <li>• Recording and Documentation</li> <li>• Information Security</li> </ul>
	<b>Performance Criteria (PC) w.r.t. the Scope</b>	
	<b>Element</b>	<b>Performance Criteria</b>
	Reporting	To be competent, the user/individual on the job must be able to: <ul style="list-style-type: none"> <li>PC1. report defects/problem/incidents/quality issues/test results as applicable in a timely manner</li> <li>PC2. report to the appropriate authority as laid down by the company</li> <li>PC3. follow reporting procedures as prescribed by the company</li> <li>PC4. work with production management and quality assurance to provide feedback regarding quality standards and issues</li> <li>PC5. help other R&amp;D lab staff with any other testing required during the developmental work</li> </ul>
	Recording and documentation	<ul style="list-style-type: none"> <li>PC6. identify documentation to be completed relating to one's role</li> <li>PC7. record details accurately in appropriate format</li> <li>PC8. accurately document the results of the inspections and testing</li> <li>PC9. maintain all controlled document files and test records in a timely and accurate manner</li> <li>PC10. ensure that the final document meets regulatory and compliance requirements</li> <li>PC11. make sure documents are available to all appropriate authorities to inspect</li> <li>PC12. evaluate problems and make initial recommendations for possible corrective action to supervise</li> <li>PC13. perform review of records and other documentation for compliance to established procedures and good documentation practices</li> <li>PC14. write and update the inspection procedures, protocols and checklists</li> <li>PC15. prepare inspection reports as per the inspection activity performed</li> </ul>

### LFS/N0314: Carry out reporting and documentation to meet quality standards

Information Security	<p>PC16. respond to requests for information in an appropriate manner whilst following organizational procedures</p> <p>PC17. inform the appropriate authority of requests for information received</p>
<b>Knowledge and Understanding (K)</b>	
<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. procedures for reporting any unresolved issues and hazards</p> <p>KA2. reporting incidents where standard operating procedures are not followed</p> <p>KA1. the importance of complete and accurate documentation</p> <p>KA2. proper procedure for selecting the material/product and performing quality checks without affecting the material</p> <p>KA3. characteristics of the product/material</p> <p>KA4. availability and use of monitoring and measuring devices</p>
<p><b>B. Technical Knowledge</b></p>	<p>The user/individual on the job needs to know and understand:</p> <p>KB1. high-end knowledge of quality control laboratory tools like photofluorometer, gas chromatography, HPCL, pH meter, etc.</p> <p>KB2. inspection or test points (control points) in the process and the related procedures and recording requirements</p> <p>KB3. common causes of variation and corrective action required</p> <p>KB4. operational health and safety (OHS) hazards and controls, including limitations of protective clothing and equipment relevant to the work process</p> <p>KB5. procedures and responsibility for reporting production and performance information</p>
<b>Skills (S)</b>	
<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 and concise records as per given format</p>
	<p><b>Reading Skills</b></p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SA3. read notes/comments from supervisors and stakeholders</p> <p>SA4. disclose information only to those who have the right and need to know it</p> <p>SA5. communicate confidential and sensitive information discretely to authorized person as per SOP</p>
	<p><b>Oral Communication (Listening and Speaking skills)</b></p>

**LFS/N0314: Carry out reporting and documentation to meet quality standards**

	The user/individual on the job needs to know and understand how to: SA6. communicate effectively with the team members and supervisors
<b>B. Professional Skills</b>	<b>Decision Making</b>
	The user/individual on the job needs to know and understand how to: SB1. decide whether the quality standards are been met or not
	<b>Plan and Organise</b>
	The user/individual on the job needs to know and understand how to: SB2. plan the quality research work within timeline and budget SB3. planning skills with the ability to multi-task and adapt
	<b>Critical Thinking</b>
	The user/individual on the job needs to know and understand how to: SB4. suggest improvements(if any) in process based on experience
	<b>Problem Solving</b>
	The user/individual on the job needs to know and understand how to: SB5. effectively solve problems while organizing SB6. think through problems, evaluate the possible solution(s) and suggest an optimum /best possible solution(s) SB7. identify immediate or temporary solutions to resolve delays
	<b>Analytical Thinking</b>
	The user/individual on the job needs to know and understand how to: SB8. use of computer/ application software SB9. attention to detail SB10. arithmetic and mechanical aptitude to resolve issues

LFS/N0314: Carry out reporting and documentation to meet quality standards

## NOS Version Control

NOS Code	LFS/N0314		
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	15/05/15
Occupation	Quality	Next review date	01/06/16



LFS/N0104: Coordinate with Supervisor and team members

# National Occupational Standard



## Overview

**This Occupational Standard describes the knowledge, understanding and skills required of a Quality Control Chemist-Microbiology to co-ordinate with manager and team members.**

### LFS/N0104: Coordinate with Supervisor and team members

National Occupational Standard

<b>Unit Code</b>	<b>LFS/N0104</b>
<b>Unit Title (Task)</b>	<b>Coordinate with Supervisor and team members</b>
<b>Description</b>	This OS unit is about the Quality Control Chemist – Microbiology communicating with colleagues and seniors in order to achieve smooth and hazard-free work flow during production
<b>Scope</b>	<p>This unit/task covers the following:</p> <p>Coordinate with supervisor</p> <ul style="list-style-type: none"> <li>• receive work instructions from reporting supervisor</li> <li>• communicate to reporting supervisor about process-flow improvements, production defects received from previous process, repairs and maintenance of equipment as required</li> <li>• provide support to supervisor for carrying out investigations related to complaints, batch failures, OOS/ OOT, incidents etc.</li> <li>• communicate any potential hazards or expected process disruptions</li> <li>• provide requisite information, documents, clarifications to supervisor during actual audits</li> <li>• handover completed work to supervisor</li> </ul> <p>Coordinate with team members</p> <ul style="list-style-type: none"> <li>• work as a team with colleagues and share work as per their or own work load and skills</li> <li>• interview team members and colleagues to collect data to be recorded in log books and batch documents</li> <li>• support/assign personnel/team members to support internal and external audit activities as per instructions of superiors/supervisor</li> <li>• work with colleagues of other departments</li> <li>• communicate and discuss work flow related difficulties in order to find solutions with mutual agreement</li> <li>• provide documented shift handovers to the next person in the shift</li> </ul>
<b>Performance Criteria (PC) w.r.t. the Scope</b>	
<b>Element</b>	<b>Performance Criteria</b>
Coordinate with supervisor	<p>To be competent, the user/individual on the job must be able to:</p> <p>PC1. understand the work output requirements</p> <p>PC2. comply with company policy and rule</p> <p>PC3. proactively inform supervisor on issues requiring intervention</p> <p>PC4. deliver quality work on time and report any anticipated reasons for delays</p>
Coordinate with team members	<p>To be competent, the user/individual on the job must be able to:</p> <p>PC5. put team over individual goals</p> <p>PC6. be able to resolve conflicts</p> <p>PC7. learn how to multi-task relevant activities</p>

**LFS/N0104: Coordinate with Supervisor and team members**

	PC8. impart training to team members/cross-function team members
<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:  KA1. knowledge of process management. KA2. the correct method for carrying out corrective actions outlined for each problem. KA3. escalation matrix for reporting identified issues KA4. implications of not adhering to quality control procedures(pertaining to call audits by quality analysts for the executives). KA5. company's tie-ups with technical bodies
<b>B. Technical Knowledge</b>	The user/individual on the job needs to know and understand:  KB1. domain knowledge pertaining to life sciences industry. KB2. benefits of the product with respect to similar products from other companies KB3. application of basic sciences (chemistry), mathematics KB4. commercial awareness of pharmaceutical products and overall healthcare sector
<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. report/observation writing skills
	<b>Reading Skills</b>
	The user/individual on the job needs to know and understand how to:  SA2. read notes/comments from the supervisor SA3. read job sheets and interpret technical details mentioned in the jobsheet
	<b>Oral Communication (Listening and Speaking skills)</b>
	The user/individual on the job needs to know and understand how to:  SA3. interact with team members to work efficiently
<b>B. Professional Skills</b>	<b>Decision Making</b>
	The user/individual on the job needs to know and understand how to:  SB1. spot and communicate potential areas of disruptions to work process and report the same SB2. when to report to supervisor and when to deal with a colleague individually, depending on the type of concern
	<b>Problem Solving</b>

**LFS/N0104: Coordinate with Supervisor and team members**

	The user/individual on the job needs to know and understand how to:  SB3. improve work processes by interacting with others and adopting best practices
	<b>Critical Thinking</b>
	The user/individual on the job needs to know and understand how to:  SB4. spot process disruptions and delays and report and communicate with solutions





LFS/N0104: Coordinate with Supervisor and team members

## NOS Version Control

NOS Code	LFS/N0104		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	23/06/14
Industry Sub-sector	Pharmaceuticals and Bio Pharmaceuticals	Last reviewed on	15/05/15
Occupation	Manufacturing, Quality, Supply Chain, R&D	Next review date	01/06/16



LFS/N0103: Ensure cleanliness in the work area

# National Occupational Standard



## Overview

**This Occupational Standard describes the knowledge, understanding and skills required of a Quality Control Chemist-Microbiology to ensure cleanliness in the work area by carrying out housekeeping activities of their respective area**

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

National Occupational Standard

<b>Unit Code</b>	<b>LFS/N0103</b>
<b>Unit Title (Task)</b>	<b>Ensure cleanliness in the work area</b>
<b>Description</b>	This OS unit is about the Quality Control Chemist – Microbiology to carry out housekeeping activities for respective area
<b>Scope</b>	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>
<b>Performance Criteria (PC) w.r.t. the Scope</b>	
<b>Element</b>	<b>Performance Criteria</b>
Pre housekeeping activities	To be competent, the user/individual on the job must be able to: <p>PC1. inspect the area while taking into account various surfaces</p> <p>PC2. identify the material requirements for cleaning the areas inspected, by considering risk, time, efficiency and type of stain</p> <p>PC3. ensure that the cleaning equipment is in proper working condition</p> <p>PC4. select the suitable alternatives for cleaning the areas in case the appropriate equipment and materials are not available and inform the appropriate person</p> <p>PC5. plan the sequence for cleaning the area to avoid re-soiling clean areas and surfaces</p> <p>PC6. inform the affected people about the cleaning activity</p> <p>PC7. display the appropriate signage for the work being conducted</p> <p>PC8. ensure that there is adequate ventilation for the work being carried out</p> <p>PC9. wear the personal protective equipment required for the cleaning method and materials being used</p>
Operations	PC10. use the correct cleaning method for the work area, type of soiling and surface
	PC11. deal with accidental damage, if any, caused while carrying out the work
	PC12. report to the appropriate person any difficulties in carrying out work
	PC13. identify and report to the appropriate person any additional cleaning required that is outside one's responsibility or skill
Post housekeeping activities	PC14. ensure that there is no oily substance on the floor to avoid slippage
	PC15. ensure that no scrap material is lying around
	PC16. maintain and store housekeeping equipment and supplies
	PC17. follow workplace procedures to deal with any accidental damage caused during the cleaning process
	PC18. ensure that, on completion of the work, the area is left clean and dry and meets requirements
	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

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

	<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>
<b>Knowledge and Understanding (K)</b>	
<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>KA5. levels of hygiene required by storage area and importance of maintaining the same</p> <p>KA6. methodology for storage area inspection with methods and materials required for cleaning variety of surfaces and equipment</p> <p>KA7. the method to check the treated surface and equipment on completion of cleaning</p> <p>KA8. procedures for reporting any unidentified soiling</p> <p>KA9. 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>
<b>Skills (S)</b>	
<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>
<p><b>B. Professional Skills</b></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>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> <p><b>Critical Thinking</b></p> <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>

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

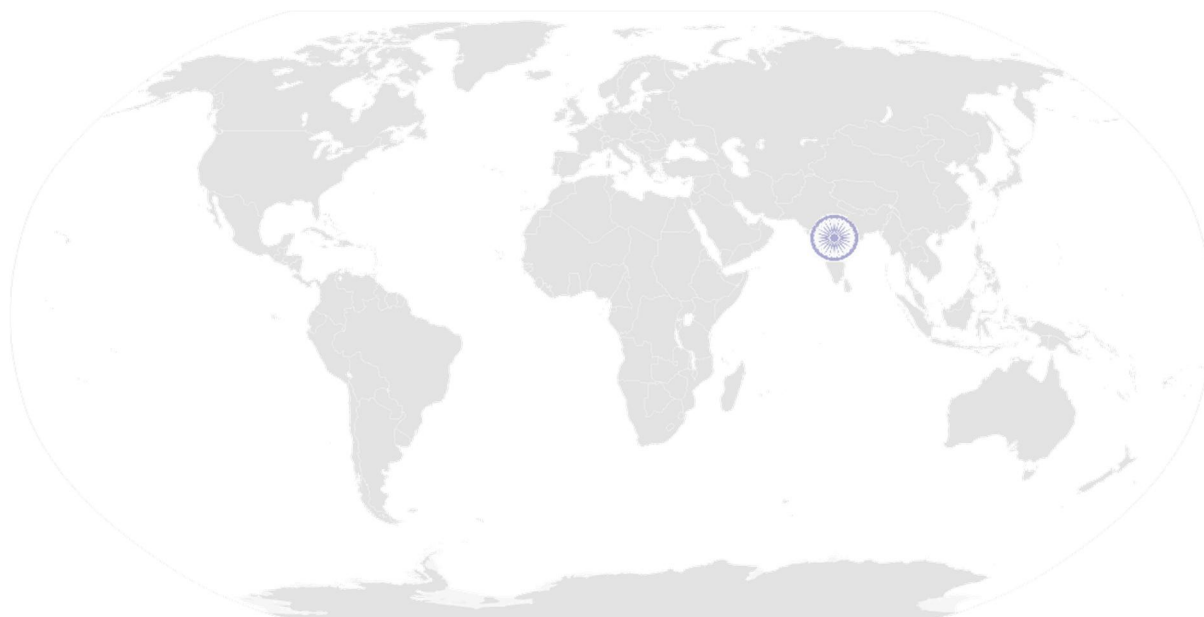
	<b>Decision Making</b>
	SB2. make decisions to maintain cleanliness in the area of work



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	15/05/15
Occupation	Manufacturing, Quality, Supply Chain, R&D	Next review date	01/06/16



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

# National Occupational Standard



## Overview

This Occupational Standard is about the knowledge, understanding and skills required by a Quality Control Chemist-Microbiology 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 Quality Control Chemist - Microbiology 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>PC7. observe and comply with the company's current health, safety and security policies and procedures</p> <p>PC8. while carrying out work, use appropriate safety gears like head gear, masks, gloves and other accessories as mentioned in the guidelines</p> <p>PC9. report any identified breaches in health, safety, and security policies and procedures to the designated person</p> <p>PC10. responsible for maintaining discipline at the shop-floor/ production area</p> <p>PC11. identify and correct any hazards that the individual can deal with safely, competently and within the limits of their authority</p> <p>PC12. adhere and comply to storage and handling guidelines for hazardous material</p> <p>PC13. identify and recommend opportunities for improving health, safety, and security to the designated person</p> <p>PC14. 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**

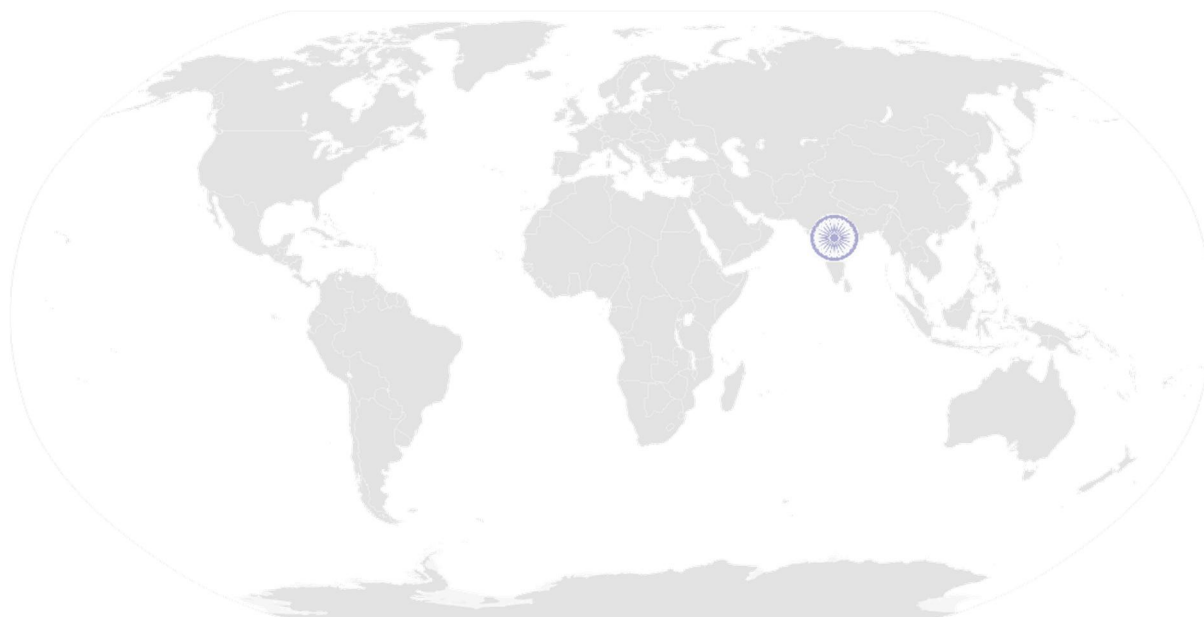
Knowledge and Understanding (K)	
<p><b>B. Organisational Context</b> (Knowledge of the Company/ Organisation and its processes)</p>	<p>The user/ individual on the job needs to know and understand:</p> <p>KA8. legislative requirements and company's procedures for health, safety and security and individual's role and responsibilities in relation to this</p> <p>KA9. what is meant by a hazard, including the different types of health and safety hazards that can be found in the workplace</p> <p>KA10. how and when to report hazards</p> <p>KA11. limits of individual responsibility for dealing with hazards</p> <p>KA12. the organization's emergency procedures for different emergency situations and the importance of following these</p> <p>KA13. the importance of maintaining high standards of health, safety and security</p> <p>KA14. implications that any non-compliance with health, safety and security may have on individuals and the organization</p> <p>KA15. 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>KB9. different types of breaches in health, safety and security and how and when to report these</p> <p>KB10. evacuation procedures for workers and visitors</p> <p>KB11. how to summon medical assistance and the emergency services, where necessary</p> <p>KB12. how to use the health, safety and accident reporting procedures and the importance of these</p> <p>KB13. different types of occupational health hazards</p> <p>KB14. knowledge of chemical substances, their characteristics and required precaution and safety measures</p>
Skills (S)	
<p><b>C. 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>SA7. 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>SA8. 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**

	SA9. listen effectively and orally communicate information accurately
<b>D. Professional Skills</b>	<b>Decision making</b>
	The user/ individual on the job needs to know and understand how to:
	SB10. 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:
	SB11. 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:
	SB12. apply problem solving approaches in different situations
	<b>Analytical thinking</b>
	The user/ individual on the job needs to know and understand how to:
	SB13. analyse data and activities
	<b>Critical thinking</b>
	The user/ individual on the job needs to know and understand how to:
SB14. apply balanced judgments to different situations	

**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	15/05/15
Occupation	Manufacturing, Quality, Supply Chain, R&D	Next review date	01/06/16



LFS/N0320: Carry out quality checks in the quality control process.

# National Occupational Standard



## Overview

This Occupational Standard describes the knowledge, understanding and skills required of a Quality Control Chemist-Microbiology to carry out quality checks in the quality control process.

**LFS/N0320: Carry out quality checks in the quality control process.**

National Occupational Standard

<b>Unit Code</b>	<b>LFS/N0320</b>
<b>Unit Title (Task)</b>	<b>Carry out quality checks in the quality control process</b>
<b>Description</b>	This OS unit is about the Quality Control Chemist - Microbiology carrying out quality checks in the quality control process
<b>Scope</b>	The unit/ task covers the following: <ul style="list-style-type: none"> <li>Carrying out quality checks to identify problems in inspection</li> <li>Analysis</li> </ul>
<b>Performance Criteria (PC) w.r.t. the Scope</b>	
<b>Element</b>	<b>Performance Criteria</b>
Inspection	To be competent, the user/individual on the job must be able to: <p>PC1. ensure that total range of checks are regularly and consistently performed</p> <p>PC2. use appropriate measuring instruments, equipment, tools, accessories etc. ,as required</p> <p>PC3. ensure the status and accuracy of instruments used for measurement</p>
Analysis	<p>PC4. identify non-conformities to quality assurance standards</p> <p>PC5. identify potential causes of non-conformities to quality assurance standards</p> <p>PC6. identify impact on final product due to non-conformance to company standards</p> <p>PC7. evaluating the need for action to ensure that problems do not recur</p> <p>PC8. suggest corrective action to address problem</p> <p>PC9. review effectiveness of corrective action</p>
<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: <p>KA1. the method to check the treated surface and equipment on completion of cleaning</p> <p>KA2. procedures for reporting any unidentified soiling</p> <p>KA3. escalation procedures for soils or stains that could not be removed</p> <p>KA4. reporting incidents where standard operating procedures are not followed</p> <p>KA5. the importance of complete and accurate documentation</p> <p>KA6. the importance of quality control procedures</p> <p>KA7. proper procedure for selecting the material/product and performing quality checks without affecting the material</p> <p>KA8. characteristics of the product/material</p> <p>KA9. availability and use of monitoring and measuring devices</p> <p>KA10. implications of inaccurate measuring and testing instruments and equipment</p>

**LFS/N0320: Carry out quality checks in the quality control process.**

<p><b>B. Technical Knowledge</b></p>	<p>The user/individual on the job needs to know and understand:</p> <p>KB1. importance of maintaining master sample</p> <p>KB2. statistical analysis of test data, techniques and concepts of statistical quality control and statistical process control</p> <p>KB3. knowledge pertaining to functioning of quality control equipment like stability chambers and BOD incubators</p> <p>KB4. high-end operational knowledge of quality lab tools like HPLC, gas chromatography, photoflourometer, etc.</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 and concise records as per given format</p> <p><b>Reading Skills</b></p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SA3. read images, graphs, diagrams</p> <p>SA4. understand 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>SA5. communicate effectively with the team members and supervisors</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. decide whether the quality standards are been met or not and take decisions appropriately</p> <p><b>Plan and Organise</b></p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SB2. plan the quality research work within timeline and budget</p> <p>SB3. ensure timelines are met and delegate tasks as per individual competencies</p> <p><b>Analytical Thinking</b></p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SB4. use of computer/ application software</p> <p>SB5. attention to detail</p> <p><b>Problem Solving</b></p>

**LFS/N0320: Carry out quality checks in the quality control process.**

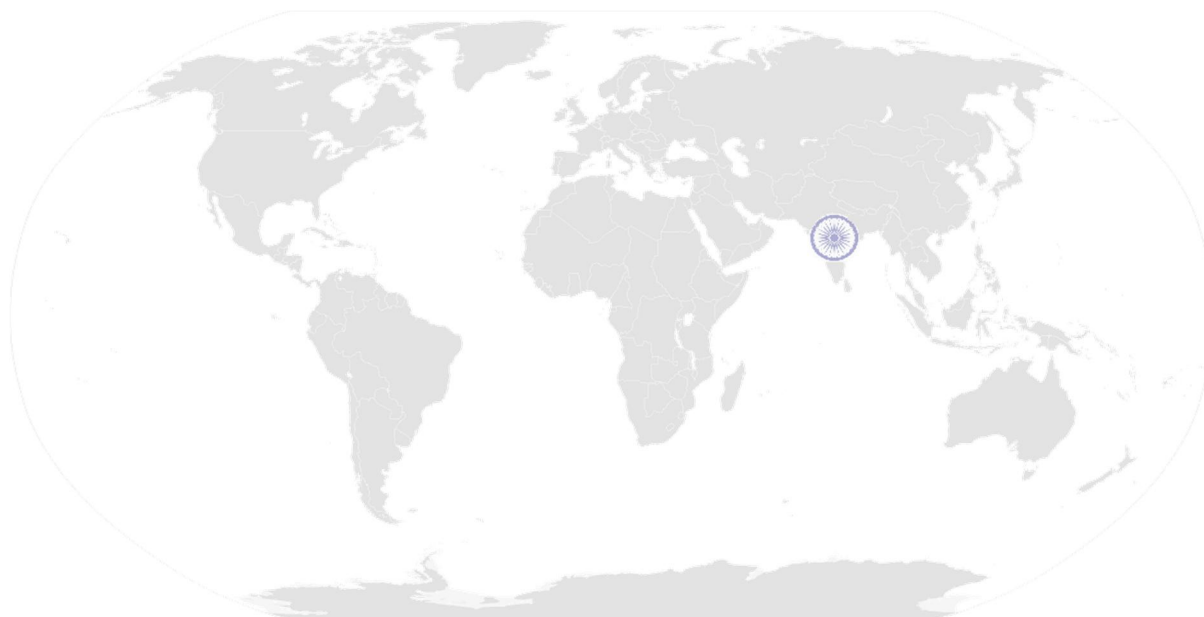
	<p>The user/individual on the job needs to know and understand how to:</p> <p>SB6. effectively solve problems while organizing</p> <p>SB7. think through problems, evaluate the possible solution(s) and suggest an optimum /best possible solution(s)</p> <p>SB8. identify immediate or temporary solutions to resolve delays</p>
	<p><b>Critical Thinking</b></p>
	<p>The user/individual on the job needs to know and understand how to:</p> <p>SB9. suggest improvements(if any) in process based on experience</p>



LFS/N0320: Carry out quality checks in the quality control process.

### NOS Version Control

NOS Code	LFS/N0320		
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	15/05/15
Occupation	Quality	Next review date	01/06/16



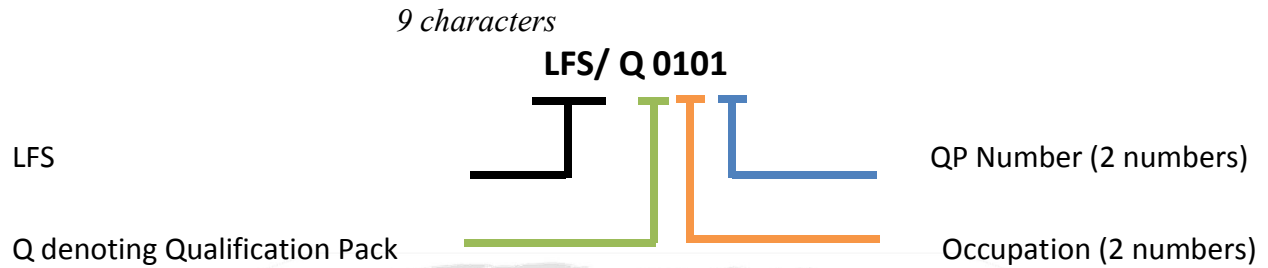


Qualification Pack - Quality Control Chemist -Microbiology

Annexure

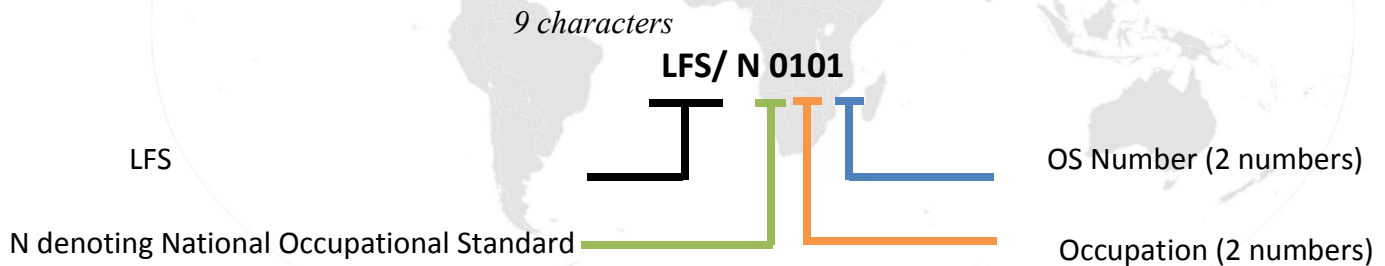
Nomenclature for QP and NOS

**Qualification Packs**



**Occupational Standard**

An example of NOS with 'N'



Qualification Pack - Quality Control Chemist -Microbiology

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

Qualification Pack - Quality Control Chemist - Microbiology

**CRITERIA FOR ASSESSMENT OF TRAINEES**


**Job Role** Quality Control Chemist - Microbiology

**Qualification Pack** LFS/Q0213

**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			
		Total Marks (700)	Out Of 	Theory	Practical
LFS/N0321 (Perform inspection of incoming materials)	PC1.observe, monitor and identify microorganisms and their growth/colonies in the sample and conduct tests like LAL tests for detecting endotoxins, etc.	100	8	3	5
	PC2.monitor and assess samples from a range of sources like raw material sampling (microbiology), microbiological analysis of water for purified water and raw water for MCT/ BET/ Sterility		8	3	5
	PC3.use a variety of identification methods, like molecular testing to test samples		8	3	5
	PC4. identify the reason for unwanted growth of microorganisms and check for OOT and OOS samples		6	3	3
	PC5.manage and oversee the laboratory work with respect		6	3	3

Qualification Pack - Quality Control Chemist -Microbiology

	to maintaining sterile conditions and work in isolation (wherever needed)			
	PC6.work with specialised computer software to undertake studies and research and train production line staff for sterile conditions, good micro trial operations		6	3
	PC7.identify and classify microorganisms found in specimens collected from humans, plants, animals, or the environment		8	4
	PC8.validate test methods and undertake calibration exercises		5	2
	PC9. serve as the primary contact for all QC Microbiology related filings and inspections of Regulatory Agencies		7	2
	PC10.undertake culture/media preparation to conduct quality analysis on the samples and maintain standard cultures		10	5
	PC11. maintain restricted access to the microbiological laboratory as per cGMP and GLP guidelines		8	3
	PC12.minimize the risks of cross-contamination, false-positive and false-negative results		6	3
	PC13.define alert and action limits and maintain positive and negative controls during testing as considered appropriate		2	1
	PC14.fulfil requirements of sterility testing like aseptic conditions		6	3
	PC15.ensure that all reagents (including stock solutions), media, diluents and other suspending fluids are adequately labelled to indicate the identity, concentration, storage conditions, preparation date, validated		6	3

Qualification Pack - Quality Control Chemist -Microbiology

	expiry date and/or recommended storage period				
	Total		100	44	56
LFS/N0322 (Perform research work to support the development of new products)	PC1.grow strains of bacteria in various conditions to understand their reaction	100	15	5	10
	PC2.work with technicians, chemists and scientists of other fields to contain the growth of microorganisms		15	5	10
	PC3.present research findings to scientists, non-scientist executives, engineers, other colleagues, and the public		20	10	10
	PC4.keep up with new research		15	10	5
	PC5.attend national and international conferences and other events		15	5	10
	PC6.work with specialised computer software to undertake studies and research		20	10	10
	Total		100	45	55
LFS/N0314 (Carry out reporting and documentation to meet quality standards)	PC1.report defects/problem/incidents/quality issues/test results as applicable in a timely manner	100	10	5	5
	PC2.report to the appropriate authority as laid down by the company		3	1	2
	PC3.follow reporting procedures as prescribed by the company		4	2	2
	PC4.work with production management and quality assurance to provide feedback regarding quality standards and issues		4	2	2
	PC5.help other R&D lab staff with any other testing required during the developmental work		4	2	2
	PC6.identify documentation to be completed relating to one's role		7	3	4

Qualification Pack - Quality Control Chemist -Microbiology

	PC7.record details accurately in appropriate format		6	3	3
	PC8.accurately document the results of the inspections and testing		8	4	4
	PC9.maintain all controlled document files and test records in a timely and accurate manner		10	5	5
	PC10.ensure that the final document meets regulatory and compliance requirements		7	2	5
	PC11.make sure documents are available to all appropriate authorities to inspect		5	2	3
	PC12.evaluate problems and make initial recommendations for possible corrective action to supervise		4	2	2
	PC13.perform review of records and other documentation for compliance to established procedures and good documentation practices		8	4	4
	PC14.write and update the inspection procedures, protocols and checklists		6	2	4
	PC15.prepare inspection reports as per the inspection activity performed		6	2	4
	PC16.respond to requests for information in an appropriate manner whilst following organizational procedures		4	2	2
	PC17.inform the appropriate authority of requests for information received		4	2	2
	<b>Total</b>		<b>100</b>	<b>45</b>	<b>55</b>
LFS/N0104 (Coordinate with Supervisor and team members)	PC1. understand the work output requirements	100	20	10	10
	PC2. comply with company policy and rule		18	8	10
	PC3. proactively inform supervisor on issues requiring intervention		13	5	8

Qualification Pack - Quality Control Chemist -Microbiology

	PC4. deliver quality work on time and report any anticipated reasons for delays		11	5	6
	PC5. put team over individual goals		8	4	4
	PC6. be able to resolve conflicts		8	4	4
	PC7. learn how to multi-task relevant activities		8	4	4
	PC8. impart training to team members/cross-function team members		14	6	8
		Total	100	46	54
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	2	2
	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

Qualification Pack - Quality Control Chemist -Microbiology

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	2	2
PC12.report to the appropriate person any difficulties in carrying out 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
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



Qualification Pack - Quality Control Chemist -Microbiology

	PC23.replenish any necessary supplies or consumables		5	2	3
	Total		100	46	54
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	10	5	5
	PC2. while carrying out work, use appropriate safety gears like head gear, masks, gloves and other accessories as mentioned in the guidelines		10	5	5
	PC3. report any identified breaches in health, safety, and security policies and procedures to the designated person		10	5	5
	PC4. responsible for maintaining discipline at the shop-floor/ production area		10	5	5
	PC5. identify and correct any hazards that the individual can deal with safely, competently and within the limits of their authority		10	5	5
	PC6. adhere and comply to storage and handling guidelines for hazardous material		10	5	5
	PC7. identify and recommend opportunities for improving health, safety, and security to the designated person		10	5	5
	PC8. complete any health, safety and security records legibly and accurately		10	4	6
	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		10	4	6
	PC10. follow the company's emergency procedures promptly, calmly, and efficiently		10	5	5

Qualification Pack - Quality Control Chemist -Microbiology

	Total		100	48	52
LFS/N0320 (Carry out quality checks in the quality control process)	PC1. ensure that total range of checks are regularly and consistently performed	100	16	8	8
	PC2.use appropriate measuring instruments, equipment, tools, accessories etc. ,as required		13	5	8
	PC3.ensure the status and accuracy of instruments used for measurement		10	5	5
	PC4.identify non-conformities to quality assurance standards		13	5	8
	PC5.identify potential causes of non-conformities to quality assurance standards		13	5	8
	PC6.identify impact on final product due to non-conformance to company standards		16	8	8
	PC7.evaluating the need for action to ensure that problems do not recur		6	3	3
	PC8.suggest corrective action to address problem		7	3	4
	PC9.review effectiveness of corrective action		6	3	3
	Total		100	45	55
					100