

## QUALIFICATIONS PACK - OCCUPATIONAL STANDARDS FOR LIFE SCIENCES INDUSTRY



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### 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-Quality Control Chemist

**SECTOR:** LIFE SCIENCES

**SUB-SECTOR:** PHARMACEUTICAL

**OCCUPATION:** QUALITY

**REFERENCE ID:** LFS/Q1301

**ALIGNED TO:** NCO-2004/ 2113.02

**A Quality Control Chemist** is responsible for conducting qualitative and quantitative analysis to ensure specified quality of the manufactured products

**Brief Job Description: A Quality Control Chemist** prepares and tests samples from all phases of the manufacturing process to ensure that the product quality meets the standards, prepares documents that report test results and is responsible for preserving workplace safety while handling hazardous materials. Also responsible for testing of in-process/input raw materials & packing materials, in-process samples apart from finished products. Also responsible for testing of process validation samples, product stability samples and cleaning validation samples (Rinse samples/Swab samples etc.).

**Personal Attributes:** The individual should have strong analytical technique in chemical testing and instrumental methods of analysis. Good understanding of chemistry and investigational abilities. He/she should have familiarity with guidelines such as GLP, cGMP and principles of Quality Management. The role holder should have attention to detail and excellent organizational skills.

Job Details

<b>Qualifications Pack Code</b>	<b>LFS/Q1301</b>		
<b>Job Role</b>	<b>Quality Control Chemist</b>		
<b>Credits(NSQF)</b>	<b>TBD</b>	<b>Version number</b>	<b>1.0</b>
<b>Sector</b>	<b>Life Sciences</b>	<b>Drafted on</b>	<b>23/06/14</b>
<b>Sub-sector</b>	<b>Pharmaceutical</b>	<b>Last reviewed on</b>	<b>15/05/15</b>
<b>Occupation</b>	<b>Quality</b>	<b>Next review date</b>	<b>01/06/16</b>

<b>Job Role</b>	<b>Quality Control Chemist</b>
<b>Role Description</b>	Responsible for conducting qualitative and quantitative analysis to ensure specified quality of the manufactured products
<b>NSQF level</b>	5
<b>Minimum Educational Qualifications</b>	B. Pharma / B. Sc with Chemistry major subject or Analytical Chemistry (Preferable)
<b>Maximum Educational Qualifications</b>	M. Pharma in Pharmaceutical Analysis or Quality Control & Assurance / M. Sc with Chemistry major subject or Analytical Chemistry (Preferable) Quality-related certification
<b>Training</b> (Suggested but not mandatory)	On the job training
<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/N0301 Perform routine analysis in lab while ensuring compliance with Good Manufacturing Practices(GMP) and Good Laboratory Practices (GLP)</a></li> <li><a href="#">LFS/N0101 Maintain a healthy, safe and secure working environment in the life sciences facility</a></li> <li><a href="#">LFS/N0302 Coordinate with Supervisors and colleagues within and outside the department</a></li> <li><a href="#">LFS/N0103 To ensure cleanliness in the work area</a></li> <li><a href="#">LFS/N0314 To carry out reporting and documentation to meet quality standards</a></li> </ol>

	6. <a href="#">LFS/N0320 To carry out quality checks in the quality control process</a>  <b>Optional:</b> N.A.
<b>Performance Criteria</b>	As described in the relevant OS units

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.	

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.
Vertical	Vertical may exist within a sub-sector representing different domain areas or the client industries served by the industry.
<b>Keywords /Terms</b>	<b>Description</b>
NOS	National Occupational Standard(s)
NSQF	National Skill Qualifications Framework
NCO-2004	National Classification of Occupations-2004
OS	Occupational Standard(s)
QP	Qualifications Pack
QC	Quality Control
SOP	Standard Operating Procedures
GMP	Good Manufacturing Practices
GLP	Good Laboratory Practices
OOS	Out of Specifications
OOT	Out of Trend

Acronyms

LFS/N0301: Perform Routine Analysis in lab while ensuring compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP)

# National Occupational Standard



## Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Quality Control Chemist to perform routine analysis in lab while ensuring compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP)

**LFS/N0301: Perform Routine Analysis in lab while ensuring compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP)**

National Occupational Standard	<b>Unit Code</b>	<b>LFS/N0301</b>
	<b>Unit Title (Task)</b>	<b>Perform routine analysis in lab while ensuring compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP)</b>
	<b>Description</b>	This OS is about a Quality Control Chemist conducting routine analysis in lab to ensure compliance with Good Manufacturing Practices and Good Laboratory Practices
	<b>Scope</b>	The unit/ task covers the following <ul style="list-style-type: none"> <li>• Perform routine checks</li> <li>• Conduct analysis &amp; documentation in lab</li> <li>• Check upkeep of instruments</li> </ul>
	<b>Performance Criteria (PC) w.r.t. the Scope</b>	
	<b>Element</b>	<b>Performance Criteria</b>
	Perform routine checks	To be competent, the user/individual on the job must be able to: <ul style="list-style-type: none"> <li>PC1. perform all the routine quality check activities and validations satisfactorily, including checking for sample authenticity, appropriate storage of chemicals/ reagents, maintaining reaction temperatures</li> <li>PC2. train the line staff effectively to perform quality checks</li> <li>PC3. plan and manage manpower efficiently to undertake the needed work/ quality checks, post receiving samples for testing, recording in the specified documents</li> <li>PC4. ensure that all work meets applicable QA/QC guidelines and approved within procedures</li> <li>PC5. review the data given by analysts and ensure that it is as per the SOP approved within procedures</li> <li>PC6. ensure all activities conducted shall meet the quality standards and norms as specified</li> </ul>
	Conduct analysis & documentation in lab	<ul style="list-style-type: none"> <li>PC7. fill log book, column, reagent, volumetric solution, working standard, reference standard entries, calibration records, etc and prepare reports for document findings and recommendations on time</li> <li>PC8. conduct sampling and analysis on time and as per approved written procedure, along with reagent, reference standard preparation and standardisation</li> <li>PC9. coordinate effectively with personnel in other disciplines to integrate findings and recommendations</li> <li>PC10. identify causes for out-of-spec products and then recommend changes by following CAPA/Change Control Procedures to improve the product's quality</li> <li>PC11. analyse root cause of deviations, OOS/OOT and incidents, take corrective as well preventive actions to avoid future deviations</li> <li>PC12. participate in laboratory investigations and check the validity/ stability of volumetric solutions/pH buffers, standards as part of daily routine and discard expired solutions/standards as per written procedures</li> <li>PC13. regular documentation (online/offline) of all the activities</li> <li>PC14. review and update test methods and procedures as per schedule or when a regulatory requirement arises according to written procedures</li> </ul>

**LFS/N0301: Perform Routine Analysis in lab while ensuring compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP)**

<p>Check upkeep of instruments</p>	<p>PC15. conduct regular checks for positioning of all equipment and instrument tags, undertake cleaning procedures for instruments post usage</p> <p>PC16. conduct regular checks on equipment and instrument conditions, document calibrations and coordinate with maintenance team for preventive maintenance</p> <p>PC17. ensure precision in instrument calibrations to minimize source of errors</p> <p>PC18. maintain instrument maintenance logs and follow preventive maintenance schedules</p> <p>PC19. investigate out of calibration if any, and impact of previously analysed products as per approved written procedures</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. quality specifications and policy of the company</p> <p>KA2. good documentation practices of the company</p> <p>KA3. composition/requirements of the product manufactured</p> <p>KA4. standard operating procedures of the quality control and assurance unit</p> <p>KA5. legal and regulatory frameworks relevant to the quality control and assurance and further implications of failing to comply with those</p> <p>KA6. quality control methods approved by the company</p> <p>KA7. format of presenting the information captured during quality checks</p> <p>KA8. sample handling procedures used with the organization and what to do with a faulty sample</p> <p>KA9. approved methods of Analysis along with Specifications</p> <p>KA10. handling procedures of hazardous and poisonous substances</p> <p>KA11. thorough understanding of sampling procedures and procedures on how to handle abnormal / faulty sample</p> <p>KA12. procedure of destruction of retail sample</p>
<p><b>B. Technical Knowledge</b></p>	<p>The user/individual on the job needs to know and understand:</p> <p>KB1. thorough understanding and interpretation of pharmacopoeia</p> <p>KB2. relevant regulatory guidelines along with ICH and WHO guidelines</p> <p>KB3. Current Good Manufacturing Practices (GMP) and current Good Laboratory Practices (GLP)</p> <p>KB4. understanding of Electronic Records &amp; Electronic Signatures, Audit Trails, Date and Time Stamps, Data Integrity.</p> <p>KB5. exposure to relevant ERP systems</p> <p>KB6. working of analytical instruments and equipment</p> <p>KB7. nature of reagents &amp; solvents</p> <p>KB8. working knowledge of chemical analysis tests and other test parameters for pH and viscosity tests</p> <p>KB9. operation &amp; cleaning procedure of various equipment used in qc</p> <p>KB10. handling, use and interpretation of data generated on the analytical equipments / instruments used in the Quality Control Laboratory , for atleast one ,but not limited to – Analytical Balanace, pH/Conductivity/TDS meter, Autotitrator (KF/Potentiometric) Melting Point Apparatus, Polarimeter,</p>



**LFS/N0301: Perform Routine Analysis in lab while ensuring compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP)**

	<p>Refractometer, High Performance Liquid Chromatography, Gas Chromatography, Dissolution Testing Apparatus, Disintegrating Test Apparatus, Friability test apparatus, UV-Visible Spectrophotometer, Atomic Absorption Spectrophotometer, Fourier Transfer Infrared Spectrophotometer, maintenance of stability chambers etc</p> <p>KB11. excellent knowledge of karl fischer apparatus, IR moisture balance, digital Vernier caliper, tapped density apparatus, friability test apparatus, TOC Analyzer, photoflurometer, etc</p> <p>KB12. Knowledge of 5S and design of quality control lab to enhance efficiency and effectiveness</p> <p>KB13. sound knowledge of science behind analytical procedures</p> <p>KB14. procedures for dealing with spill management</p> <p>KB15. knowledge of antibodies, acids, oxidizing agents, cytotoxic drugs and keeping their samples safely and avoiding cross contamination</p> <p>KB16. knowledge of worksheets, log books , date and time formats to be followed</p> <p>KB17. expertise on chemical methods of analysis like volumetric analysis, gravimetric analysis, where chemical standards and reagents are used to perform qualitative and quantitative analysis</p> <p>KB18. knowledge of material Safety Data Sheets for each material available in the laboratory as part of Accidental release measure</p> <p>KB19. understand incompatibility of chemicals, hazards and storage procedures, safe storage of chemicals as per Hazard Classification</p> <p>KB20. through understanding of the PPE required and Glove Compatibility with the chemicals</p> <p>KB21. usage and maintenance of fume hood when conducting chemical experiments</p> <p>KB22. safe handling practices of chemicals (for example, Sodium metal should not get in contact with water if it comes it blasts, before opening ammonia solution the bottle should be cooled in a refrigerator to reach temperature of 4°C or it bumps on to face etc.)</p> <p>KB23. be well versed with formats, Change control management, Version Control, Issue &amp; retrieval of documents, management of Standard Operating Procedures, Standard Testing Procedures, Protocols, Equipment Qualification documents, Method Validation Protocols &amp; Reports etc.</p> <p>KB24. importance of primary solutions and secondary/working solutions</p> <p>KB25. experience for interpreting graphs from analytical instruments and tests</p> <p>KB26. knowledge of storage and maintenance of control samples</p> <p>KB27. Knowledge of Quality by design, quality risk management, waste elimination techniques</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. conduct documentation, including online documentation</p> <p>SA2. make legible entries with permanent ink</p> <p>SA3. write detailed reports for investigation</p>

**LFS/N0301: Perform Routine Analysis in lab while ensuring compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP)**

	SA4. pay attention to detail while recording production parameters
	<b>Reading Skills</b>
	The user/individual on the job needs to know and understand how to:  SA5. read important documents, reports and procedures accurately
	<b>Oral Communication (Listening and Speaking skills)</b>
	The user/individual on the job needs to know and understand how to:  SA6. interact with people to effectively gather information SA7. listen effectively and orally communicate information accurately SA8. build and maintain positive and effective relationships with colleagues
	<b>B. Professional Skills</b>
	<b>Decision Making</b>
	The user/individual on the job needs to know and understand how to:  SB1. interpret and analyse information and evaluate results to choose the best solution and solve problems SB2. use individual judgment to determine if test results or processes comply with regulations and approved standards SB3. make team decisions rather than individual decisions
	<b>Plan and Organise</b>
	The user/individual on the job needs to know and understand how to:  SB4. plan the work in a proper manner so that extensive load should not be there. SB5. plan work assigned on a daily basis and provide estimates of time required for each piece of work
	<b>Problem Solving</b>
	The user/individual on the job needs to know and understand how to:  SB6. seek clarification on problems from others/supervisors SB7. use effective problem solving techniques SB8. assess the problem to reach appropriate solution/conclusion
	<b>Analytical Thinking</b>
	The user/individual on the job needs to know and understand how to:  SB9. analyse data and activities SB10. share relevant information with other team members
	<b>Critical Thinking</b>
	The user/individual on the job needs to know and understand how to:  SB11. provide opinions on work in a detailed and constructive way and apply performance feed forward SB12. apply balanced judgments to different approaches SB13. analyse & understand the depth of issue and handle with a proactive approach

LFS/N0301: Perform Routine Analysis in lab while ensuring compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP)

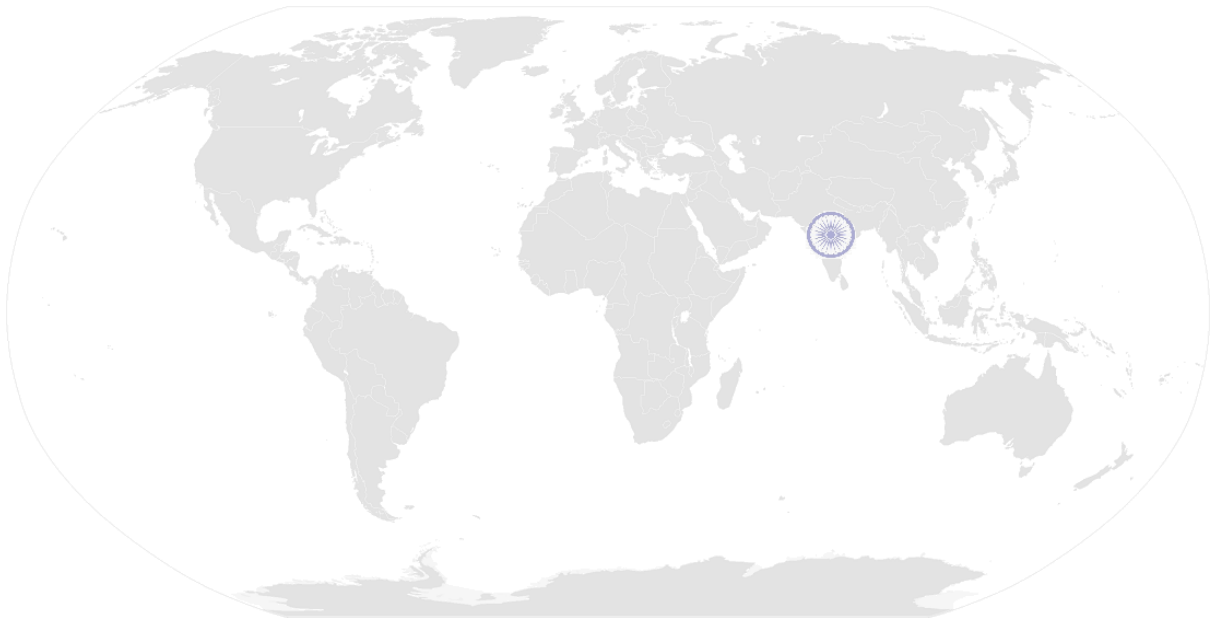
**NOS Version Control**

<b>NOS Code</b>	<b>LFS/N0301</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>23/06/14</b>
<b>Industry Sub-sector</b>	<b>Pharmaceuticals</b>	<b>Last reviewed on</b>	<b>15/05/15</b>
<b>Occupation</b>	<b>Quality</b>	<b>Next review date</b>	<b>01/06/16</b>



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 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 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**

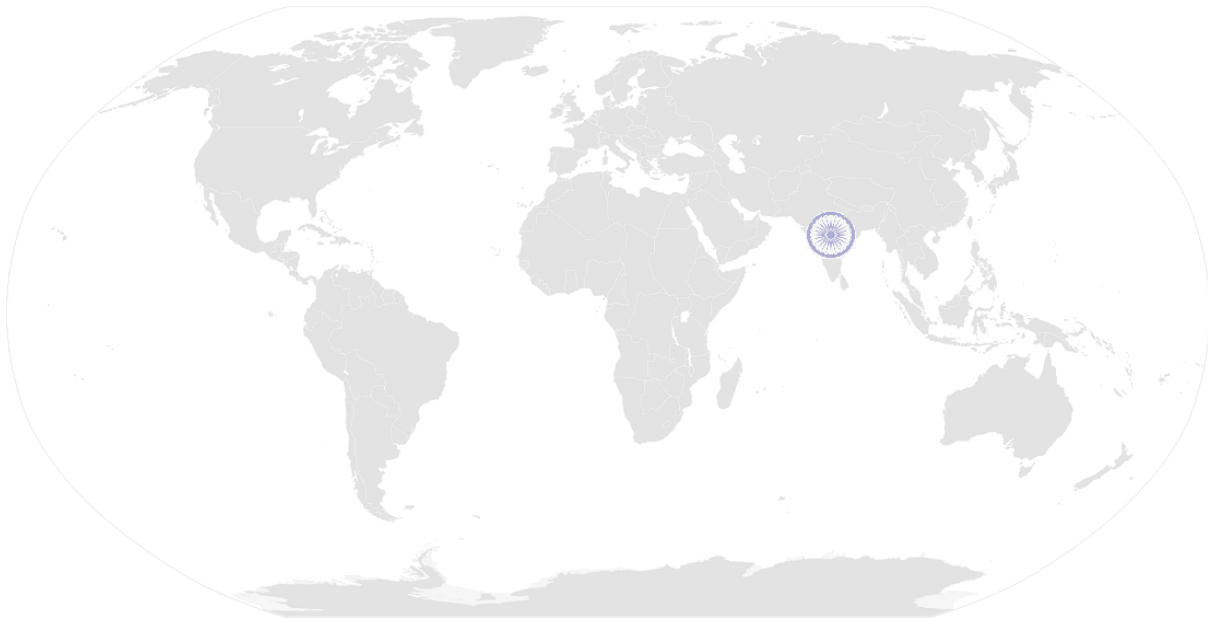
Knowledge and Understanding (K)	
<p><b>A. Organisational Context</b> (Knowledge of the Company/ Organisation and its processes)</p>	<p>The user/ individual on the job needs to know and understand:</p> <p>KA1. legislative requirements and company’s procedures for health, safety and security and individual’s 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	

LFS/N0101: Maintain a healthy, safe and secure working environment in the Life Sciences Facility  
**NOS Version Control**

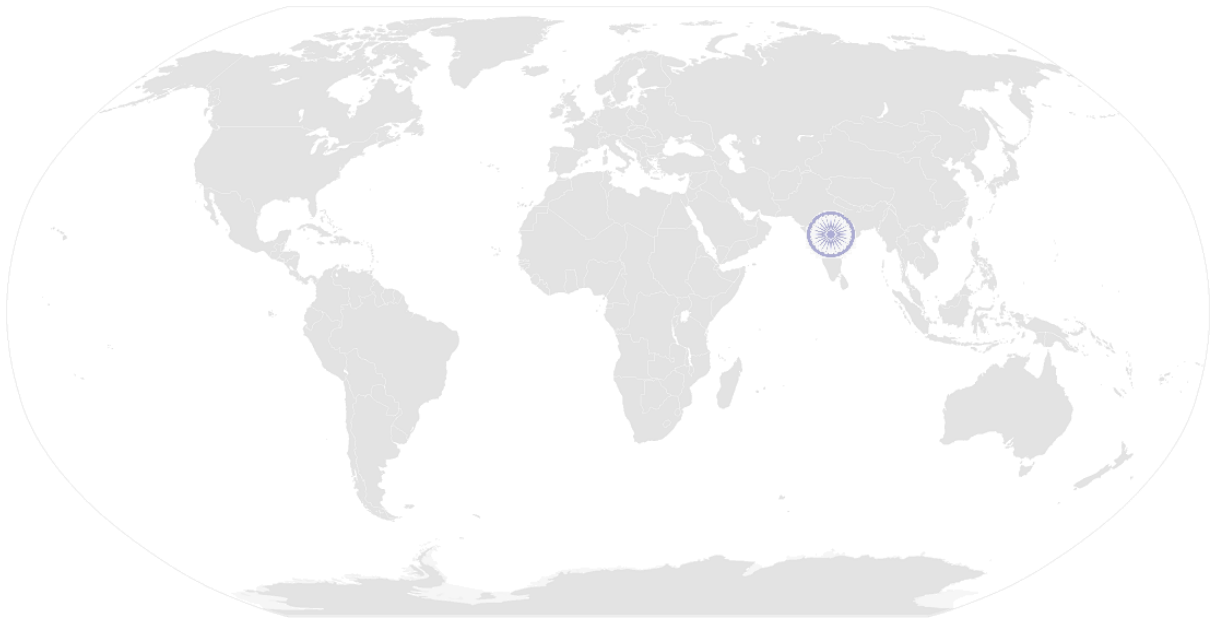
<b>NOS Code</b>	<b>LFS/N0101</b>		
<b>Credits(NSQF)</b>	<b>TBD</b>	<b>Version number</b>	<b>1.0</b>
<b>Industry</b>	<b>Life Sciences</b>	<b>Drafted on</b>	<b>26/06/14</b>
<b>Industry Sub-sector</b>	<b>Pharmaceuticals and Bio Pharmaceuticals</b>	<b>Last reviewed on</b>	<b>15/05/15</b>
<b>Occupation</b>	<b>Manufacturing, Quality, Supply Chain, R&amp;D</b>	<b>Next review date</b>	<b>01/06/16</b>





LFS/N0302: Coordinate with Supervisors and colleagues within and outside the department

# National Occupational Standard



## Overview

This Occupational Standard describes the knowledge, understanding and skills required of a Quality Control Chemist to work as a team member and multi-task in order to achieve production on schedule and meeting the quality requirements.

**LFS/N0302: Coordinate with Supervisors and colleagues within and outside the department**

National Occupational Standard	<b>Unit Code</b>	<b>LFS/N0302</b>
	<b>Unit Title (Task)</b>	<b>Coordinate with Supervisors and colleagues within and outside the department</b>
	<b>Description</b>	This NOS unit is about the Quality Control Chemist coordinating with supervisors and colleagues within and outside the department
	<b>Scope</b>	The unit/ task covers the following: <ul style="list-style-type: none"> <li>• Supervisors</li> <li>• Team management</li> </ul>
	<b>Performance Criteria (PC) w.r.t. the Scope</b>	
	<b>Element</b>	<b>Performance Criteria</b>
	Coordination with Supervisor	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 supervisor</li> <li>PC2. communicate to reporting supervisor about process-flow improvements, production defects received from previous process, repairs and maintenance of equipment as required</li> <li>PC3. communicate deviations in the production process to reporting supervisor</li> <li>PC4. communicate any potential hazards or expected process disruptions</li> <li>PC5. handover completed work to supervisor</li> </ul>
	Team Management	<ul style="list-style-type: none"> <li>PC6. work as a team with colleagues and share work as per their or own work load and skills</li> <li>PC7. work and support colleagues of other departments</li> <li>PC8. train line or reporting staff if needed</li> <li>PC9. communicate and discuss work flow related difficulties in order to find solutions with mutual agreement</li> <li>PC10. explain what information means and how it can be used to team members</li> <li>PC11. document all the control steps undertaken or recommended to be followed as per the standards</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. company's policies on: preferred language of communication, reporting and escalation policy, quality delivery standards, and personnel management</li> <li>KA2. reporting structure</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. communicate effectively</li> <li>KB2. build team coordination</li> </ul>	

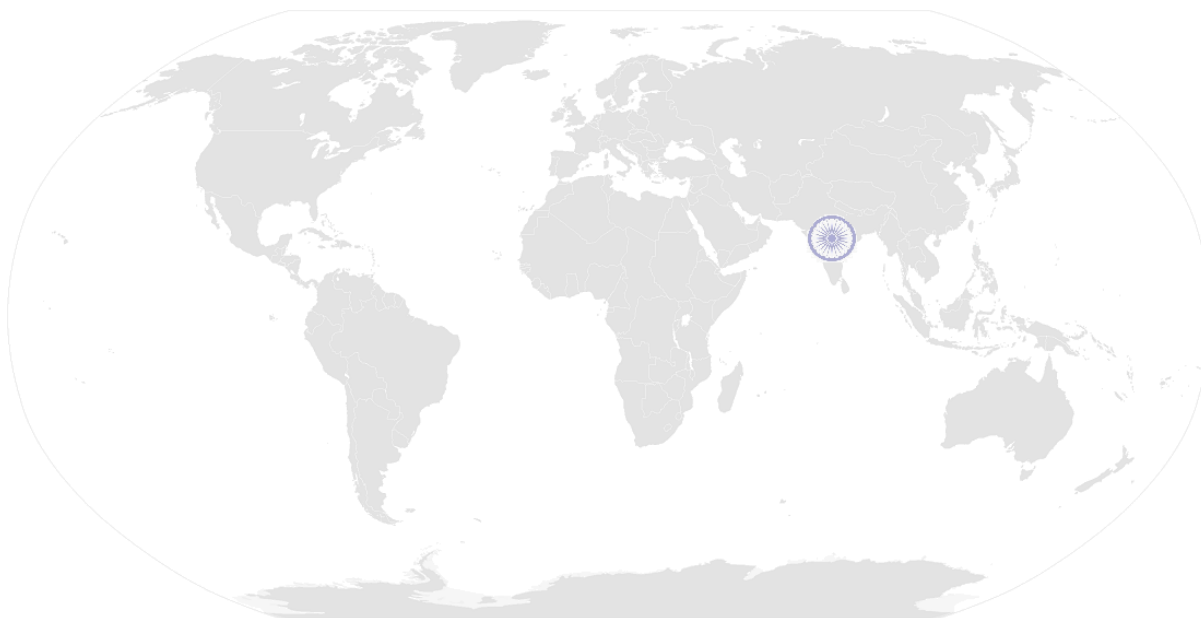
**LFS/N0302: Coordinate with Supervisors and colleagues within and outside the department**

Skills (S)	
<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. read job sheets and interpret technical details mentioned in the jobsheet
	<b>Reading skills</b>
	The user/individual on the job needs to know and understand how to:  SA2. read notes/comments from the supervisor
<b>B. Professional Skills</b>	<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 SA4. communicate with colleagues and supervisor to maintain an effective and smooth interpersonal relationship
	<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>Critical Thinking</b>
	The user/individual on the job needs to know and understand how to:  SB3. spot process disruptions and delays and report and communicate with solutions SB4. improve work processes by interacting with others and adopting best practices

LFS/N0302: Coordinate with Supervisors and colleagues within and outside the department

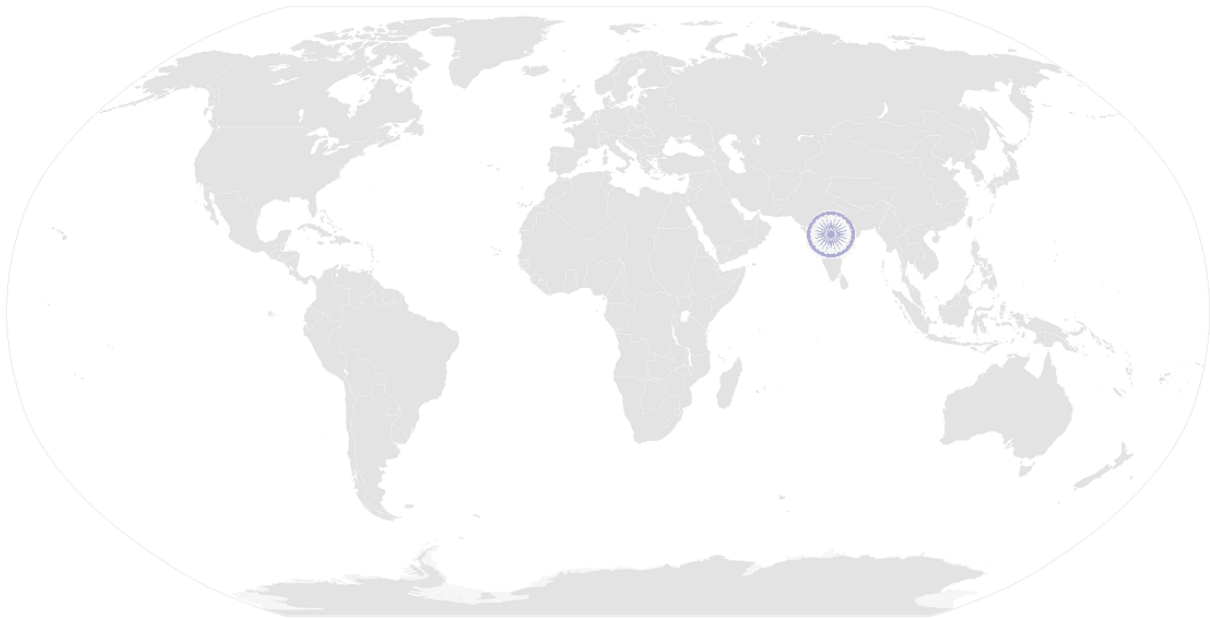
**NOS Version Control**

<b>NOS Code</b>	<b>LFS/N0302</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>23/06/14</b>
<b>Industry Sub-sector</b>	<b>Pharmaceuticals and Bio Pharmaceuticals</b>	<b>Last reviewed on</b>	<b>15/05/15</b>
<b>Occupation</b>	<b>Quality</b>	<b>Next review date</b>	<b>01/06/16</b>



LFS/N0103: To 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 to ensure cleanliness in the work area by carrying out housekeeping for respective area**

**LFS/N0103: To ensure cleanliness in the work area**

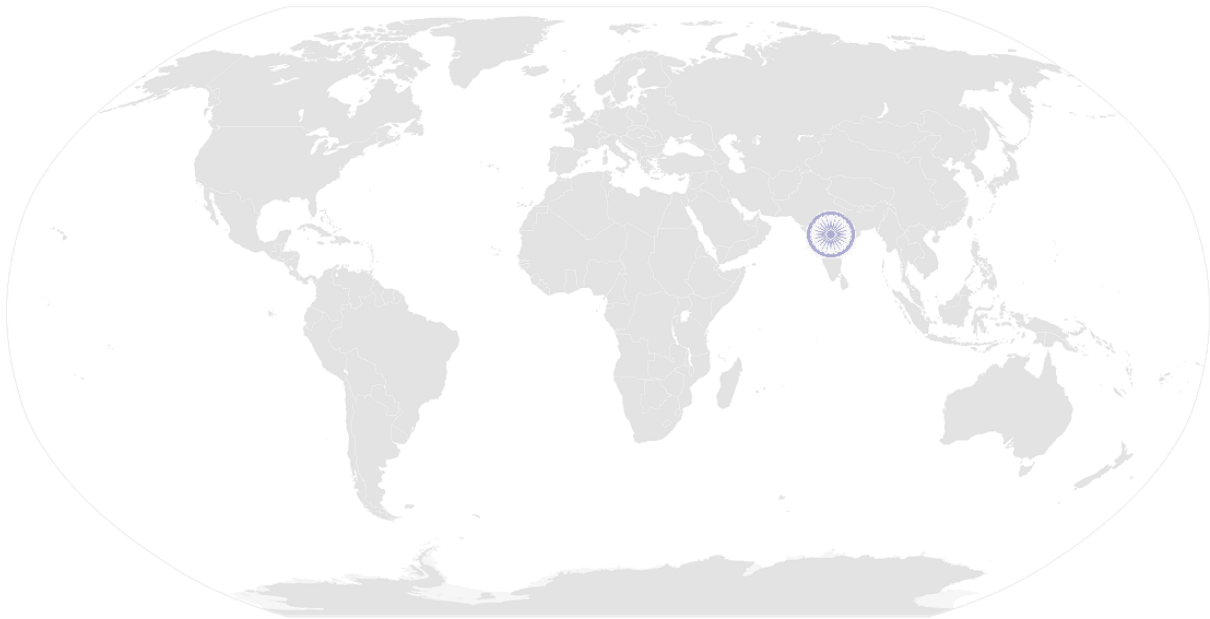
National Occupational Standard	<b>Unit Code</b>	<b>LFS/N0103</b>
	<b>Unit Title (Task)</b>	<b>To ensure cleanliness in the work area</b>
	<b>Description</b>	This OS unit is about the Quality Control Chemist to carry out housekeeping activities for respective area
	<b>Scope</b>	<p>This unit/task covers the following:</p> <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	<p>To be competent, the user/individual on the job must be able to:</p> <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	<p>PC10. use the correct cleaning method for the work area, type of soiling and surface</p> <p>PC11. deal with accidental damage, if any, caused while carrying out the work</p> <p>PC12. report to the appropriate person any difficulties in carrying out work</p> <p>PC13. identify and report to the appropriate person any additional cleaning required that is outside one's responsibility or skill</p>
	Post housekeeping activities	<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>

**LFS/N0103: To ensure cleanliness in the work area**

	<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>
<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. 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>
<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>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>

**LFS/N0103: To ensure cleanliness in the work area**

<b>B. Professional Skills</b>	The user/individual on the job needs to know and understand how to:  SB1. suggest improvements(if any) in process based on experience
	<b>Decision Making</b>
	SB2. make decisions to maintain cleanliness in the area of work

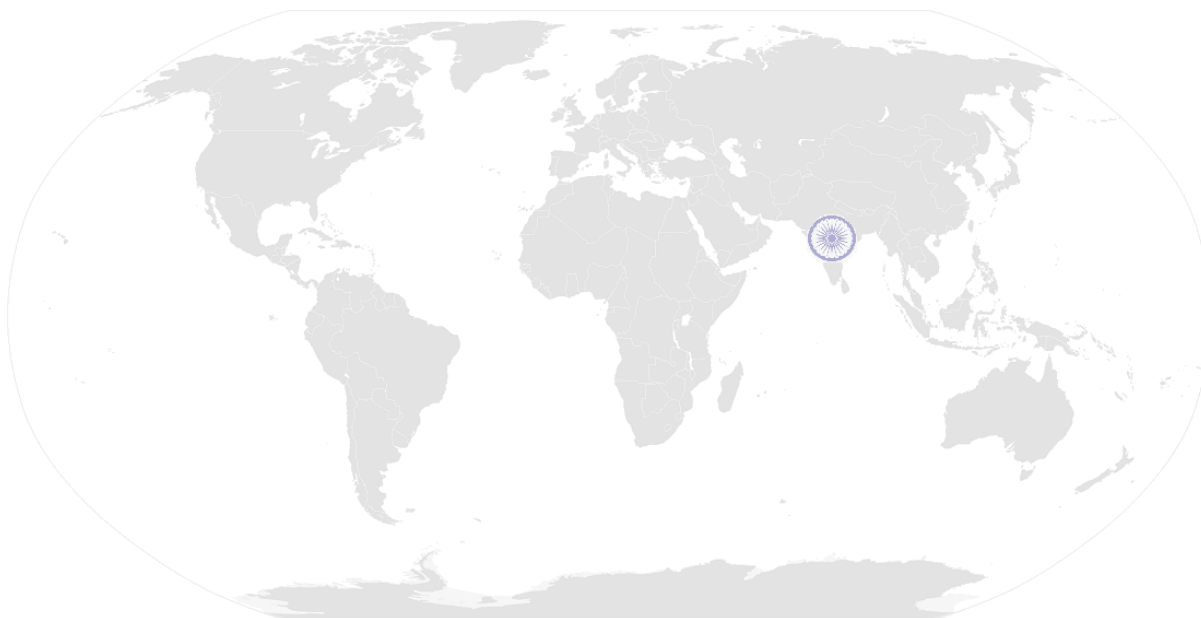




LFS/N0103: To ensure cleanliness in the work area

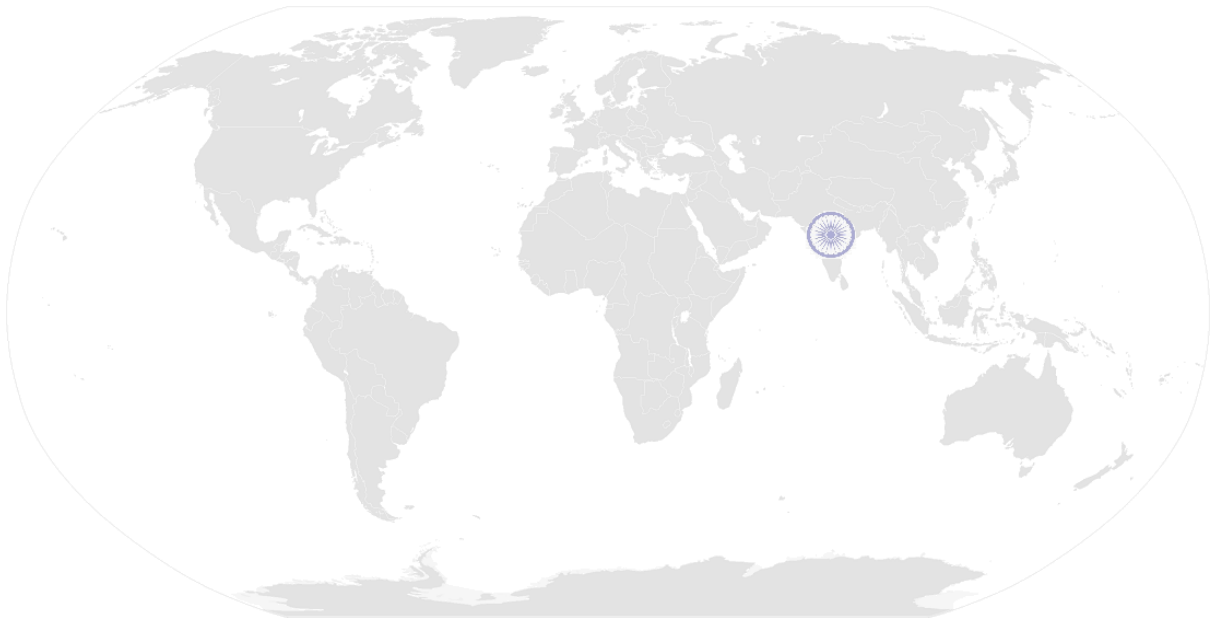
## NOS Version Control

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/N0314: To carry out reporting and documentation to meet quality standards

# National Occupational Standard



## Overview

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

**LFS/N0314: To 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>To carry out reporting and documentation to meet quality standards</b>
	<b>Description</b>	This OS unit is about the Quality Control Chemist 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: To 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>KA6. the importance of complete and accurate documentation</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><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>

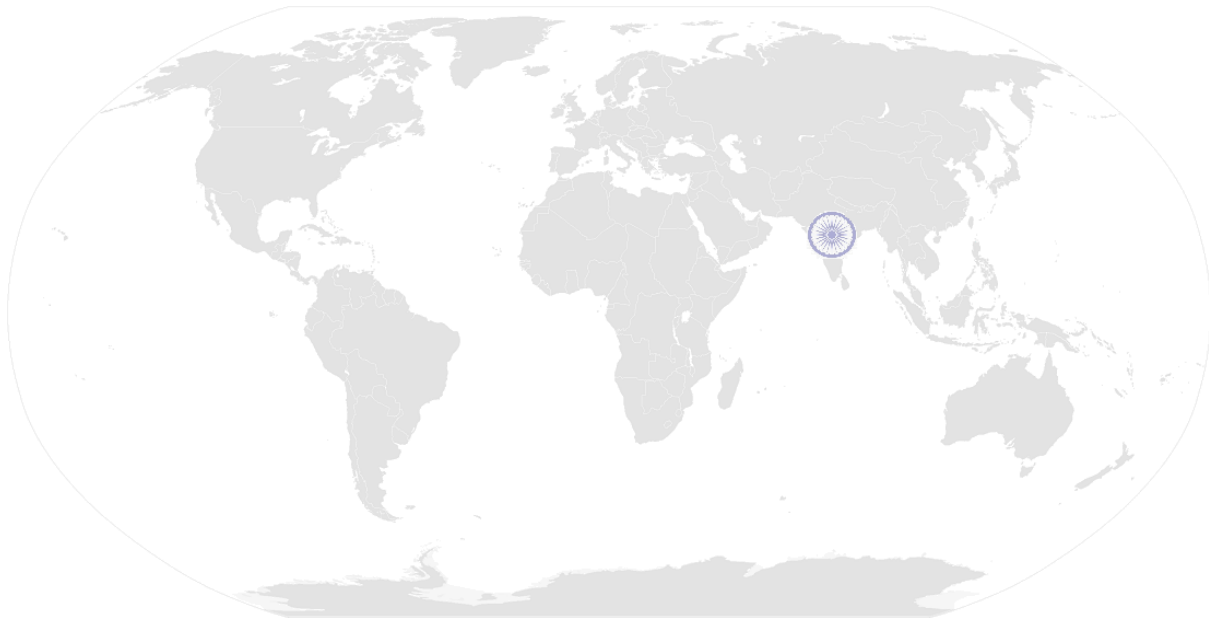
**LFS/N0314: To carry out reporting and documentation to meet quality standards**

	<p>The user/individual on the job needs to know and understand how to:</p> <p>SA6. communicate effectively with the team members and supervisors</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. decide whether the quality standards are been met or not</p>
	<b>Plan and Organise</b>
	<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 SB3. planning skills with the ability to multi-task and adapt</p>
	<b>Critical Thinking</b>
	<p>The user/individual on the job needs to know and understand how to:</p> <p>SB4. suggest improvements(if any) in process based on experience</p>
	<b>Problem Solving</b>
	<p>The user/individual on the job needs to know and understand how to:</p> <p>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</p>
	<b>Analytical Thinking</b>
	<p>The user/individual on the job needs to know and understand how to:</p> <p>SB8. use of computer/ application software SB9. attention to detail SB10. arithmetic and mechanical aptitude to resolve issues</p>

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

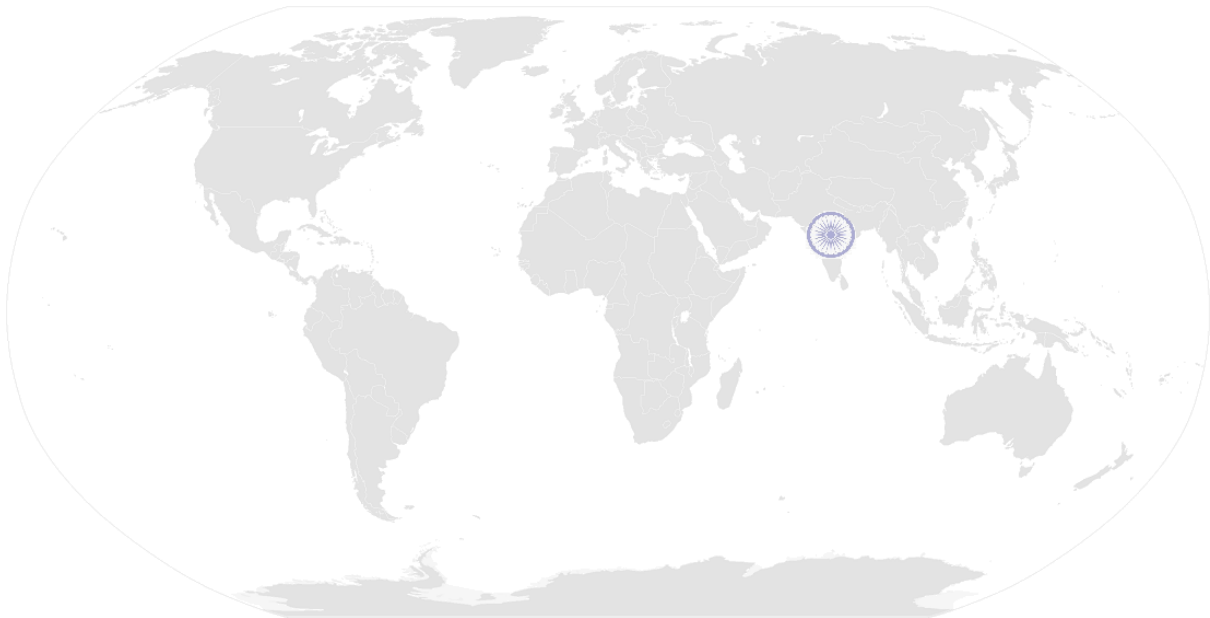
**NOS Version Control**

<b>NOS Code</b>	<b>LFS/N0314</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>22/12/14</b>
<b>Industry Sub-sector</b>	<b>Pharmaceuticals and Bio Pharmaceuticals</b>	<b>Last reviewed on</b>	<b>15/05/15</b>
<b>Occupation</b>	<b>Quality</b>	<b>Next review date</b>	<b>01/06/16</b>



LFS/N0320: To 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 to carry out quality checks in the quality control process.

**LFS/N0320: To 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>To carry out quality checks in the quality control process</b>
<b>Description</b>	This OS unit is about the Quality Control Chemist 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>

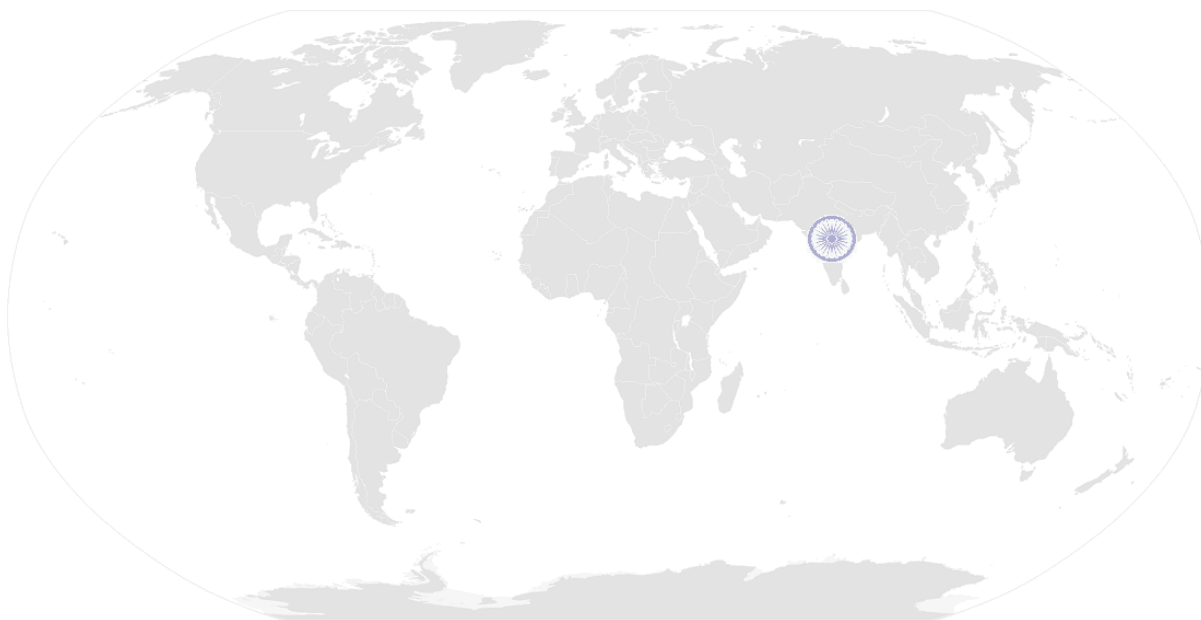


**LFS/N0320: To carry out quality checks in the quality control process**

<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: To carry out quality checks in the quality control process**

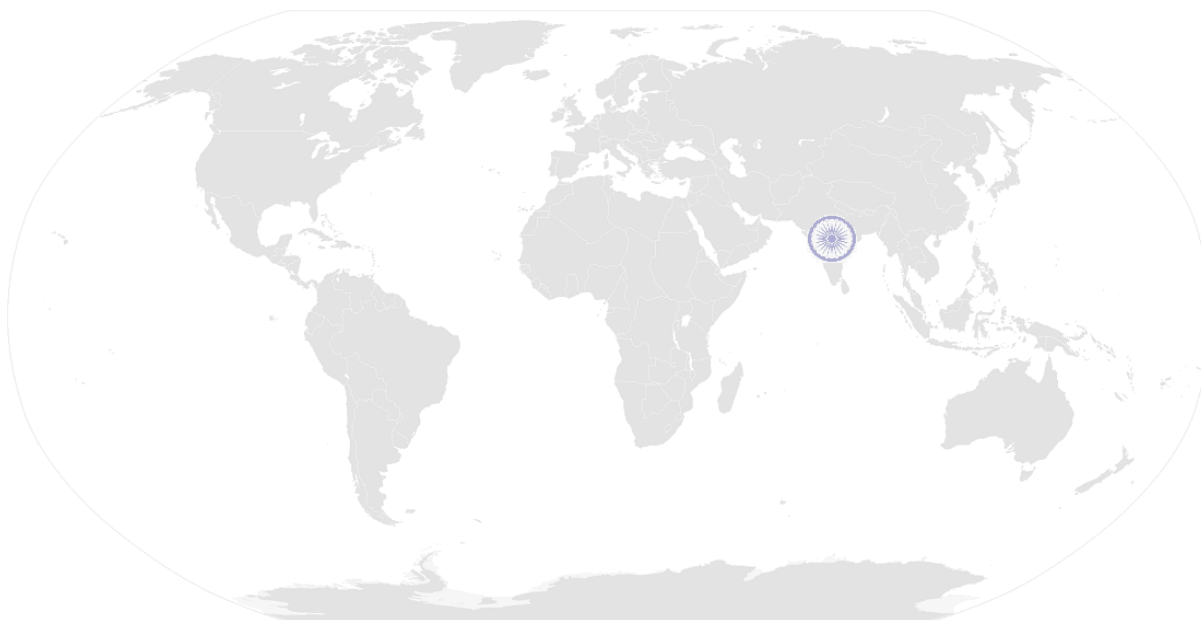
	<p>The user/individual on the job needs to know and understand how to:</p> <p>SB6. effectively solve problems while organizing</p> <p>SB7. think through problems, evaluate the possible solution(s) and suggest an optimum /best possible solution(s)</p> <p>SB8. identify immediate or temporary solutions 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: To 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

Annexure

**Nomenclature for QP and NOS**

**Qualification Pack**

*9 characters*

**LFS / Q 0101**

LFS



QP Number (2 numbers)

Q denoting Qualification Pack

Occupation (2 numbers)

**Occupational Standard**

An example of NOS with 'N'

*9 characters*

**LFS / N 0101**

LFS



OS Number (2 numbers)

N denoting National Occupational Standard

Occupation (2 numbers)

*Qualification Pack - Quality Control Chemist*

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

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

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

Qualification Pack - Quality Control Chemist

**Job Role** Quality Control Chemist

**Qualification Pack** LFS/Q1301

**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 (600)	Out Of	Theory	Skills Practical
LFS/N0301 (Perform routine analysis in lab while ensuring compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP))	PC1. perform all the routine quality check activities and validations satisfactorily, including checking for sample authenticity, appropriate storage of chemicals/ reagents, maintaining reaction temperatures	100	3	1	2
	PC2. train the line staff effectively to perform quality checks		5	2	3
	PC3. plan and manage manpower efficiently to undertake the needed work/ quality checks, post receiving samples for testing, recording in the specified documents		6	3	3
	PC4. ensure that all work meets applicable QA/QC guidelines and approved within procedures		10	5	5
	PC5. review the data given by analysts and ensure that it is as per the SOP approved within procedures		10	5	5

Qualification Pack - Quality Control Chemist

PC6. ensure all activities conducted shall meet the quality standards and norms as specified	10	5	5
PC7. review and update test methods and procedures according to SOP approved within procedures as per schedule or when a regulatory requirement arises according to written procedures	6	3	3
PC8. fill log book, column, reagent, volumetric solution, working standard, reference standard entries, calibration records, etc and prepare reports for document findings and recommendations on time	6	2	4
PC9. conduct sampling and analysis on time and as per approved written procedure, along with reagent, reference standard preparation and standardisation	10	5	5
PC10. coordinate effectively with personnel in other disciplines to integrate findings and recommendations	4	2	2
PC11. analyse root cause of deviations, OOS/OOT and incidents, take corrective as well preventive actions to avoid future deviations	4	2	2
PC12. analyse root cause of deviations, OOS/OOT and take corrective actions	4	1	3
PC13. participate in laboratory investigations and check the validity/ stability of volumetric solutions/pH buffers, standards as part of daily routine and discard expired solutions/standards as per written procedures	4	2	2
PC14. regular documentation (online/offline) of all the activities	2	1	1
PC15. conduct regular checks for positioning of all equipment and	4	2	2

Qualification Pack - Quality Control Chemist

	instrument tags and undertake cleaning procedures for instruments post usage				
	PC16. conduct regular checks on equipment and instrument conditions, document calibrations and coordinate with maintenance team for preventive maintenance		4	2	2
	PC17. precision in instrument calibrations as per specified and approved schedule to minimize source of errors		4	2	2
	PC18. maintain instrument maintenance logs and follow preventive maintenance schedules		2	1	1
	PC19. investigate out of calibration if any, and impact of previously analysed products as per approved written procedures		2	1	1
	<b>Total</b>		<b>100</b>	<b>47</b>	<b>53</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	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



Qualification Pack - Quality Control Chemist

	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 activities like safety drills and prepare 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
	Total		100	48	52
LFS/N0302 (Coordinate with Supervisors and colleagues within and outside the department)	PC1. receive work instructions from reporting supervisor	100	10	5	5
	PC2. communicate to reporting supervisor about process-flow improvements, production defects received from previous process, repairs and maintenance of equipment as required		10	5	5
	PC3. communicate deviations in the production process to reporting supervisor		10	5	5
	PC4. communicate any potential hazards or expected process disruptions		10	4	6
	PC5. handover completed work to supervisor		10	5	5
	PC6. work as a team with colleagues and share work as per their or own work load and skills		8	4	4
	PC7. work and support colleagues of other departments		8	3	5
	PC8. train line or reporting staff if needed		10	5	5
	PC9. communicate and discuss work flow related difficulties in order to find solutions with mutual agreement		8	4	4

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	PC10. explain what information means and how it can be used to team members		8	4	4
	PC11. document all the control steps undertaken or recommended to be followed as per the standards		8	4	4
	Total		100	48	52
LFS/N0320 (To 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
LFS/N0314 (To 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

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	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
	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
	Total		100	45	55
LFS/N0103 (To 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		5	2	3

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areas inspected, by considering risk, time, efficiency and type of stain			
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
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

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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	46	54