QUALIFICATIONS PACK - OCCUPATIONAL STANDARDS FOR LIFE SCIENCES INDUSTRY

Contents

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-Microbiology

SECTOR: LIFE SCIENCES

SUB-SECTOR: PHARMACEUTICAL AND BIOPHARMACEUTICAL

OCCUPATION: QUALITY

REFERENCE ID: LFS/Q0308

ALIGNED TO: NCO 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.

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**	**23/12/15**
Occupation	**Quality**	**Next review date**	**01/04/17**
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)	**Compulsory:** 1. LFS/N0321:Perform inspection of incoming materials 2. LFS/N0322: Perform research work to support the development of new products 3. LFS/N0314: Carry out reporting and documentation to meet quality standards 4. LFS/N0104: Coordinate with Supervisor and team members

	5. LFS/N0103: Ensure cleanliness in the work area 6. LFS/N0101: Maintain a healthy, safe and secure working environment in the life sciences facility **7.** LFS/N0320: Carry out quality checks in the quality control process **Optional:** N.A.
Performance Criteria	As described in the relevant OS units

Definitions

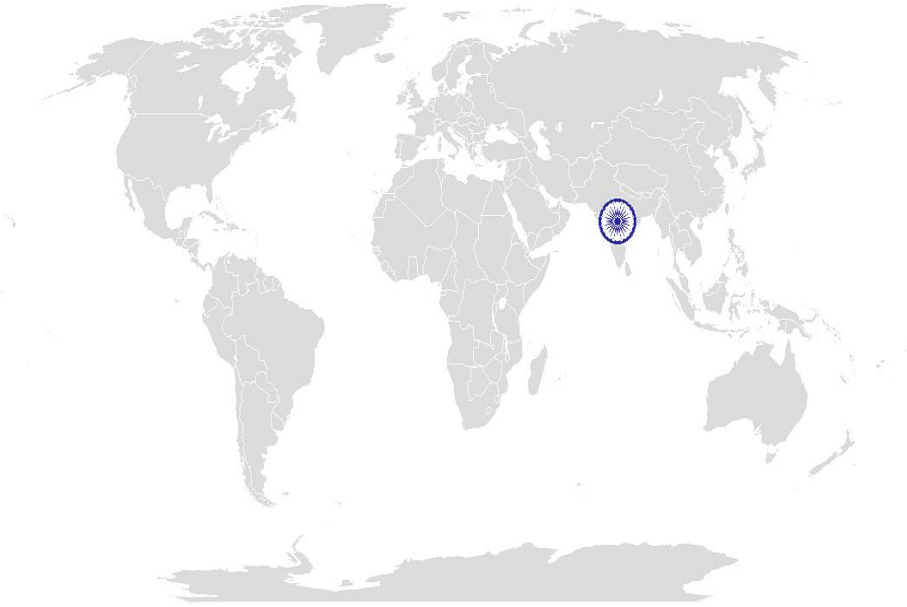
Keywords /Terms	Description
Core Skills/Generic Skills	Core Skills or Generic Skills are a group of skills that are key to learning and working in today's world. These skills are typically needed in any work environment. In the context of the NOS, these include communication related skills that are applicable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

Acronyms

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

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

Unit Code	LFS/N0321
Unit Title (Task)	**Perform inspection of incoming materials**
Description	This OS is about a Quality Control Chemist-Microbiology inspecting the incoming materials
Scope	The unit/ task covers the following: • Inspecting the products for microorganism, if any, and testing the safety and purity of drugs • Undertaking laboratory and sample related activities
Performance Criteria (PC) w.r.t. the Scope	
Element	**Performance Criteria**
Inspection	To be competent, the user/individual on the job must be able to: PC1. observe, monitor and identify microorganisms and their growth/colonies in the sample and conduct tests like LAL tests for detecting endotoxins, etc. 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 PC3. use a variety of identification methods, like molecular testing to test samples PC4. identify the reason for unwanted growth of microorganisms and check for OOT and OOS samples PC5. manage and oversee the laboratory work with respect 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 PC7. identify and classify microorganisms found in specimens collected from humans, plants, animals, or the environment PC8. validate test methodsand undertake calibration exercises PC9. serve as the primary contact for all QC Microbiology related filings and inspections of Regulatory Agencies PC10. undertake culture/media preparation to conduct quality analysis on the samples and maintain standard cultures
Laboratory and sample related activities	PC11. maintain restricted access to the microbiological laboratory as per cGMP and GLP guidelines PC12. minimize the risks of cross-contamination, false-positive and false-negative results PC13. define alert and action limits and maintain positive and negative controls during testing as considered appropriate PC14. fulfil requirements of sterility testing like aseptic conditions PC15. ensure that all reagents (including stock solutions), media, diluents and other suspending fluids are adequately labelled to indicate the identity,

LFS/N0321: Perform inspection of incoming materials

	concentration, storage conditions, preparation date, validated expiry date and/or recommended storage period
Knowledge and Understanding (K)	
A. Organisational Context (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 pharmacoepia
B. Technical Knowledge	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
Skills (S)	
A. Core Skills/ Generic Skills	**Writing Skills**
	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
	Reading Skills
	The user/individual on the job needs to know and understand how to: SA3. interpret documented guidelines/procedures/rules and service level agreements
	Oral Communication (Listening and Speaking Skills)

LFS/N0321: Perform inspection of incoming materials

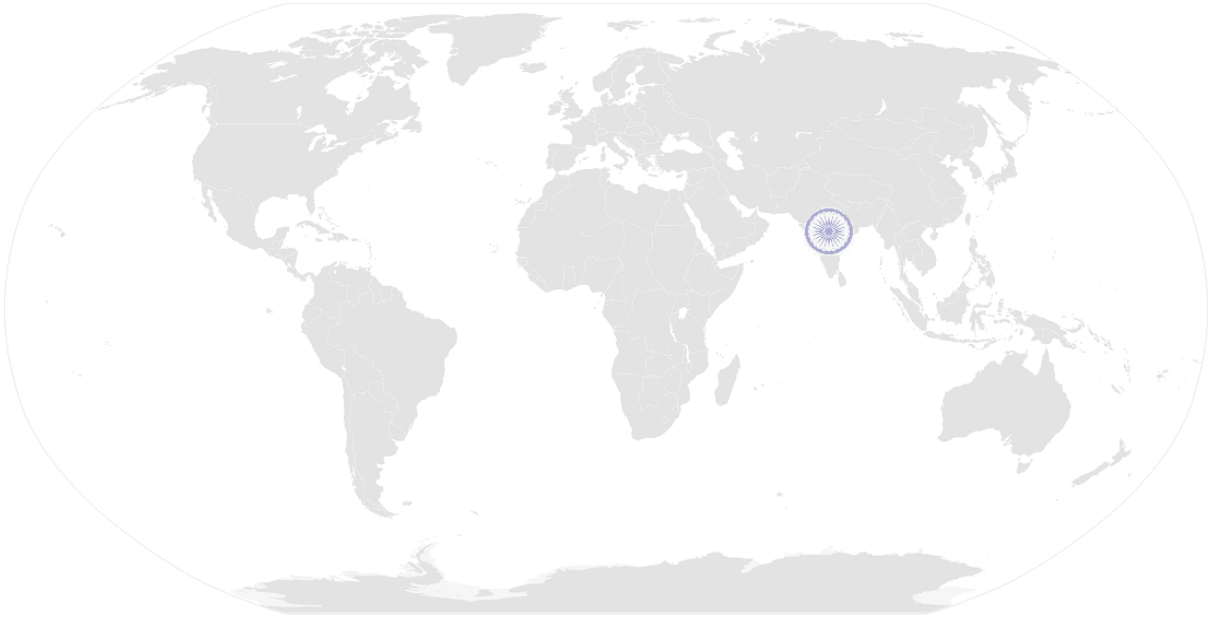
	The user/individual on the job needs to know and understand how to: SA4. interact with people to effectively gather information SA5. listen effectively and orally communicate information accurately SA6. ask for clarification and advice from others
B. Professional Skills	**Decision Making**
	The user/individual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

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	23/12/15
Occupation	Quality	Next review date	01/04/17

National Occupational Standards



Overview

This Occupational Standard describes the knowledge, understanding and skills required of aQuality 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

Unit Code	**LFS/N0322**
Unit Title (Task)	**Perform research work to support the development of new products**
Description	This OS unit is about a Quality Control Chemist-Microbiology performing research work to support the development of new products
Scope	The unit/ task covers the following: • Carrying out research and developing new products

Performance Criteria (PC) w.r.t the Scope	
Element	**Performance Criteria**
Research	To be competent, the user/individual on the job must be able to: PC1. grow strains of bacteria in various conditions to understand their reaction PC2. work with technicians, chemists and scientists of other fields to contain the growth of microorganisms PC3. present research findings to scientists, non-scientist executives, engineers, other colleagues, and the public PC4. keep up with new research PC5. attend national and international conferences and other events PC6. work with specialised computer software to undertake studies and research

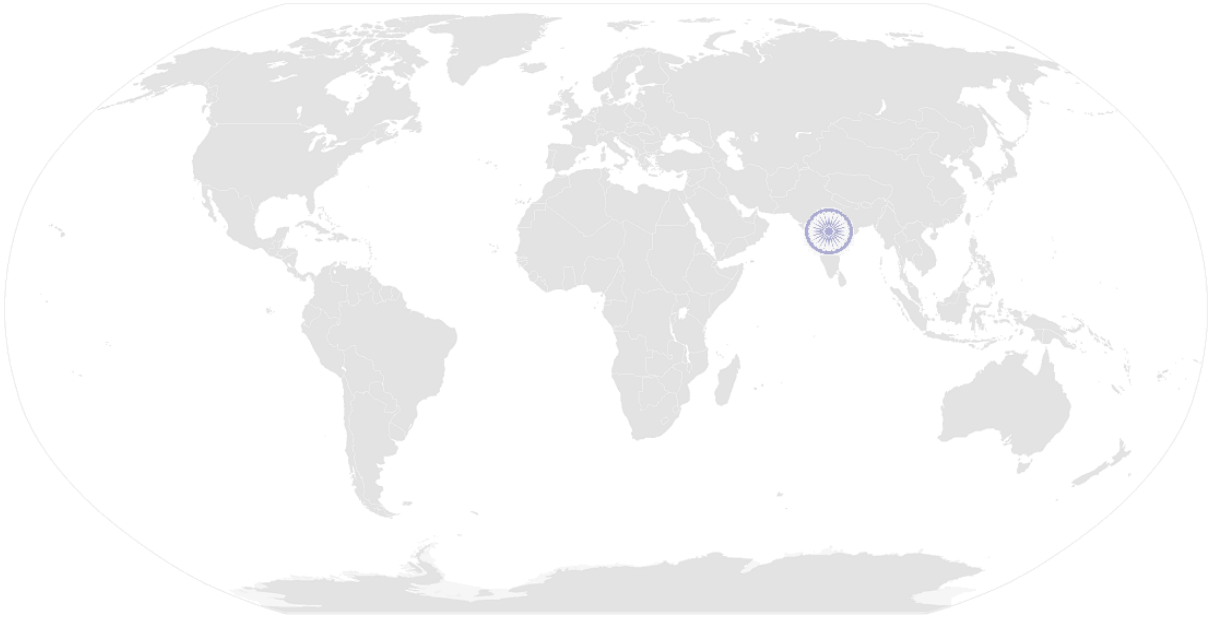
Knowledge and Understanding (K)	
A. Organisational Context (Knowledge of the Company/ Organisation and its processes)	The user/individual on the job needs to know and understand: KA1. importance of identifying non-conforming products KA2. risk and impact of not following defined procedures/work instructions KA3. escalation matrix for reporting identified issues KA4. records to be maintained and the implications of non-maintenance of the same KA5. health, safety and environment guidelines, legislation and regulations as applicable KA6. impact of poor practices on health, safety and environment KA7. impact of various practices on cost, quality, productivity, delivery and safety
B Technical Knowledge	The user/individual on the job needs to know and understand: KB1. various kinds of testing equipment and related test method and purpose of tests KB2. methods of using laboratory equipment like autoclave, laminar airflow, etc. KB3. national/international standard test methods for different compounds KB4. importance of the safe handling of microorganisms KB5. factors that adversely affect integrity of the sample KB6. the use of computer applications/software specific to microbiological processes carried out in the laboratory

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

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

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

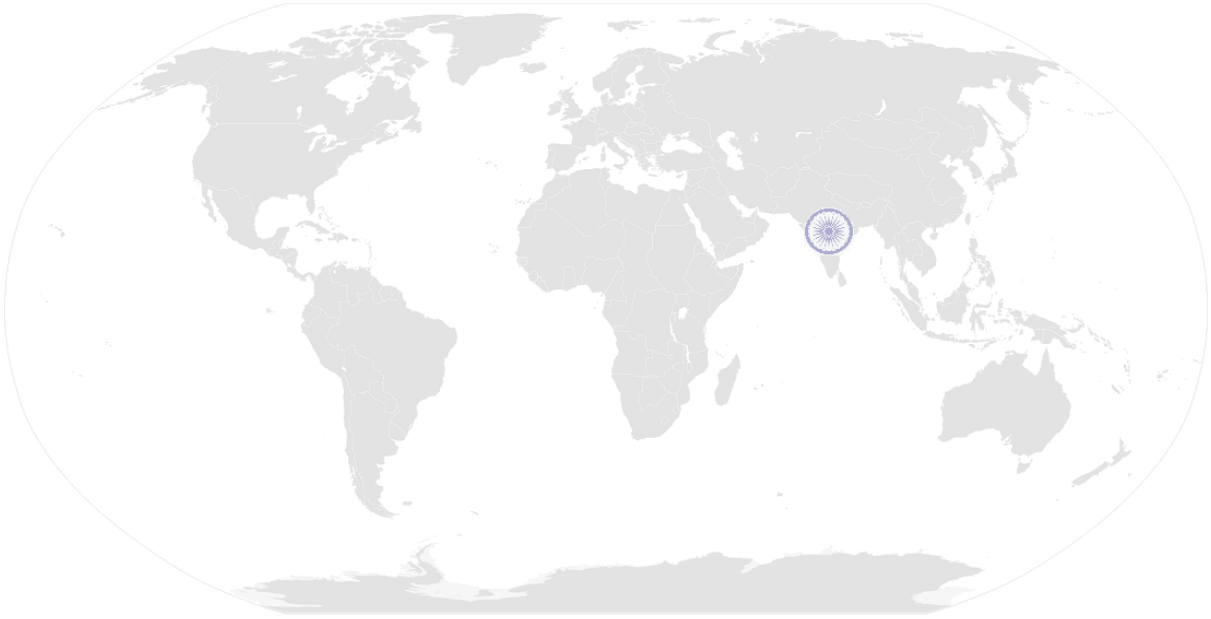
	Critical Thinking
	The user/individual on the job needs to know and understand how to: SB9. suggest improvements(if any) in process based on experience



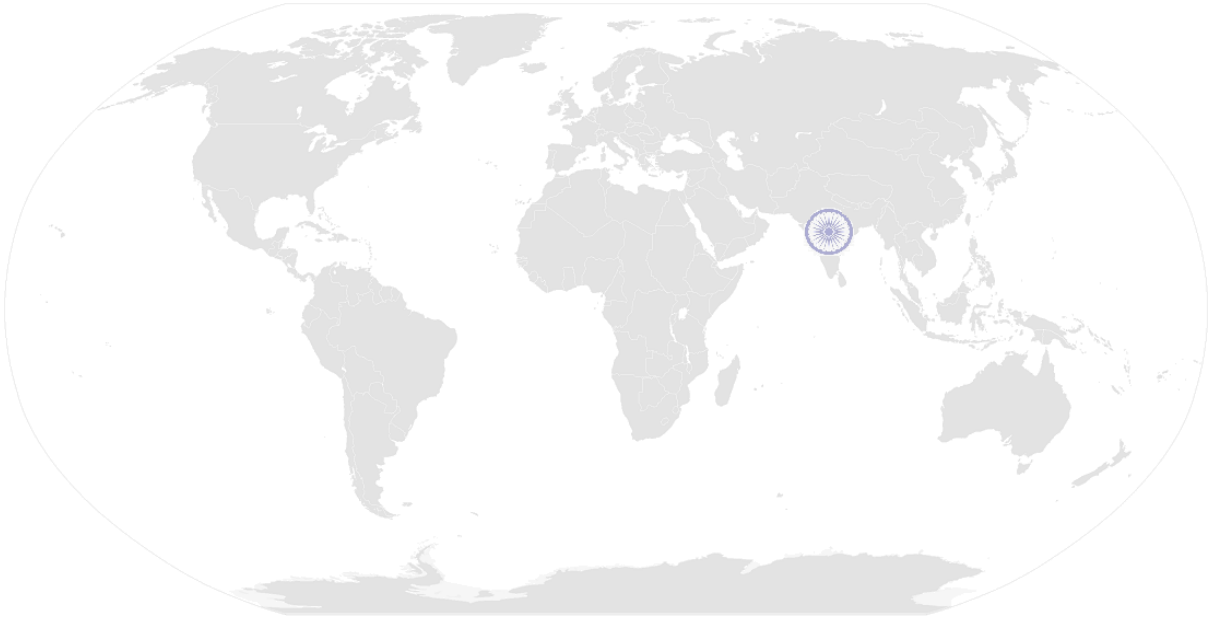
LFS/N0322: Perform research work to support the development of new products

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	23/12/15
Occupation	Quality	Next review date	01/04/17



National Occupational Standards



Overview

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

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

National Occupational Standard

Unit Code	LFS/N0314
Unit Title (Task)	**Carry out reporting and documentation to meet quality standards**
Description	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
Scope	The unit/ task covers the following: • Reporting of defects/problem/incidents/quality issues/test results • Recording and Documentation • Information Security
Performance Criteria (PC) w.r.t. the Scope	
Element	**Performance Criteria**
Reporting	To be competent, the user/individual on the job must be able to: PC1. report defects/problem/incidents/quality issues/test results as applicable in a timely manner PC2. report to the appropriate authority as laid down by the company PC3. follow reporting procedures as prescribed by the company PC4. work with production management and quality assurance to provide feedback regarding quality standards and issues PC5. help other R&D lab staff with any other testing required during the developmental work
Recording and documentation	PC6. identify documentation to be completed relating to one's role PC7. record details accurately in appropriate format PC8. accurately document the results of the inspections and testing PC9. maintain all controlled document files and test records in a timely and accurate manner PC10. ensure that the final document meets regulatory and compliance requirements PC11. make sure documents are available to all appropriate authorities to inspect PC12. evaluate problems and make initial recommendations for possible corrective action to supervise PC13. perform review of records and other documentation for compliance to established procedures and good documentation practices PC14. write and update the inspection procedures, protocols and checklists PC15. prepare inspection reports as per the inspection activity performed

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

Information Security	PC16. respond to requests for information in an appropriate manner whilst following organizational procedures PC17. inform the appropriate authority of requests for information received
Knowledge and Understanding (K)	
A. Organisational Context (Knowledge of the Company/ Organisation and its processes)	The user/individual on the job needs to know and understand: KA1. procedures for reporting any unresolved issues and hazards KA2. reporting incidents where standard operating procedures are not followed KA1. the importance of complete and accurate documentation KA2. proper procedure for selecting the material/product and performing quality checks without affecting the material KA3. characteristics of the product/material KA4. availability and use of monitoring and measuring devices
B. Technical Knowledge	The user/individual on the job needs to know and understand: KB1. high-end knowledge of quality control laboratory tools like photoflourometer, gas chromatography, HPCL, pH meter, etc. KB2. inspection or test points (control points) in the process and the related procedures and recording requirements KB3. common causes of variation and corrective action required KB4. operational health and safety (OHS) hazards and controls, including limitations of protective clothing and equipment relevant to the work process KB5. procedures and responsibility for reporting production and performance information
Skills (S)	
A. Core Skills/ Generic Skills	**Writing Skills**
	The user/ individual on the job needs to know and understand how to: SA1. record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail SA2. maintain proper and concise records as per given format
	Reading Skills
	The user/individual on the job needs to know and understand how to: SA3. read notes/comments from supervisors and stakeholders SA4. disclose information only to those who have the right and need to know it SA5. communicate confidential and sensitive information discretely to authorized person as per SOP
	Oral Communication (Listening and Speaking skills)

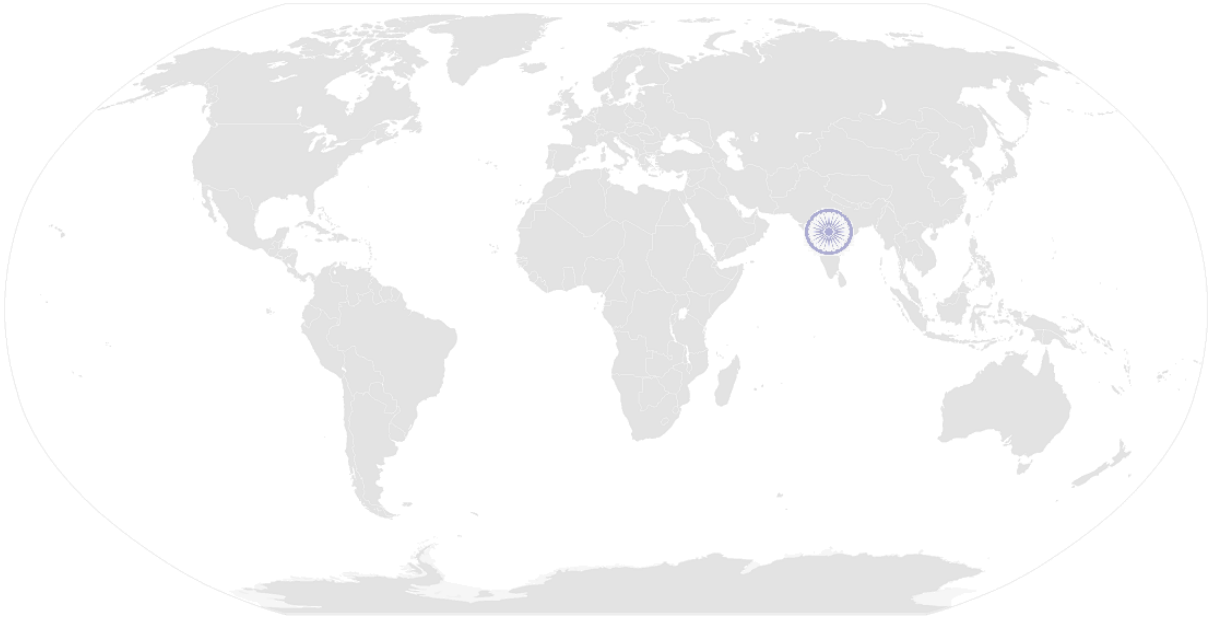
LFS/N0314: Carry out reporting and documentation to meet quality standards

	The user/individual on the job needs to know and understand how to: SA6. communicate effectively with the team members and supervisors
B. Professional Skills	**Decision Making**
	The user/individual on the job needs to know and understand how to: SB1. decide whether the quality standards are been met or not
	Plan and Organise
	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
	Critical Thinking
	The user/individual on the job needs to know and understand how to: SB4. suggest improvements(if any) in process based on experience
	Problem Solving
	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
	Analytical Thinking
	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

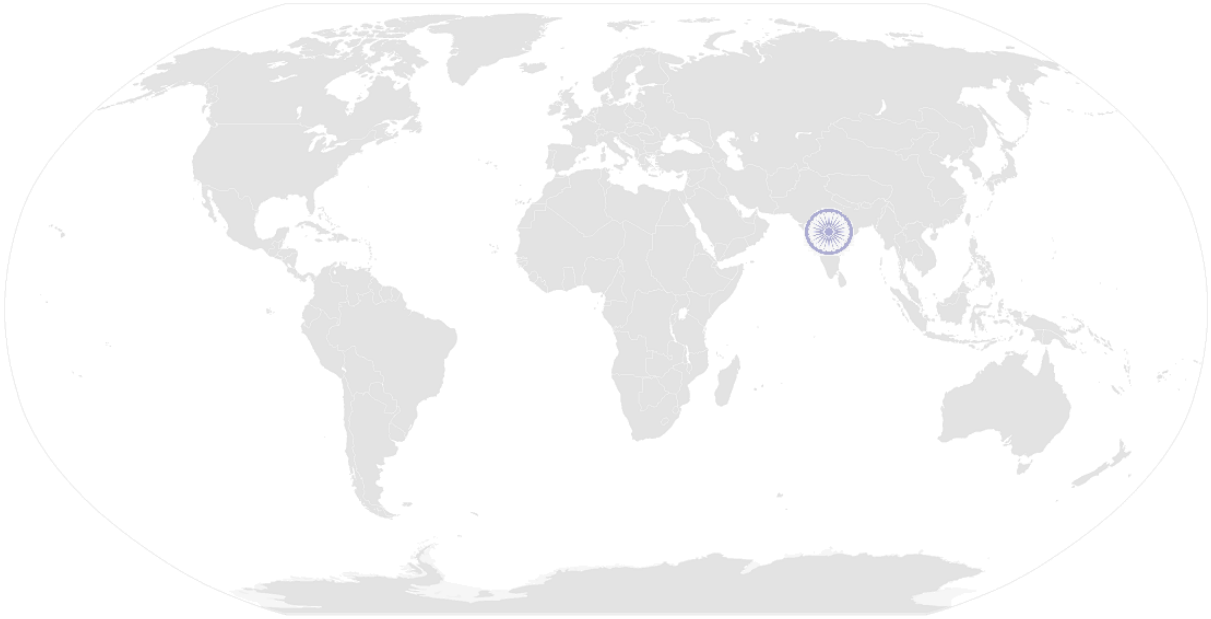
LFS/N0314: Carry out reporting and documentation to meet quality standards

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



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

Unit Code	**LFS/N0104**
Unit Title (Task)	**Coordinate with Supervisor and team members**
Description	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
Scope	This unit/task covers the following: Coordinate with supervisor • receive work instructions from reporting supervisor • communicate to reporting supervisor about process-flow improvements, production defects received from previous process, repairs and maintenance of equipment as required • provide support to supervisor for carrying out investigations related to complaints, batch failures, OOS/ OOT, incidents etc. • communicate any potential hazards or expected process disruptions • provide requisite information, documents, clarifications to supervisor during actual audits • handover completed work to supervisor Coordinate with team members • work as a team with colleagues and share work as per their or own work load and skills • interview team members and colleagues to collect data to be recorded in log books and batch documents • support/assign personnel/team members to support internal and external audit activities as per instructions of superiors/supervisor • work with colleagues of other departments • communicate and discuss work flow related difficulties in order to find solutions with mutual agreement • provide documented shift handovers to the next person in the shift

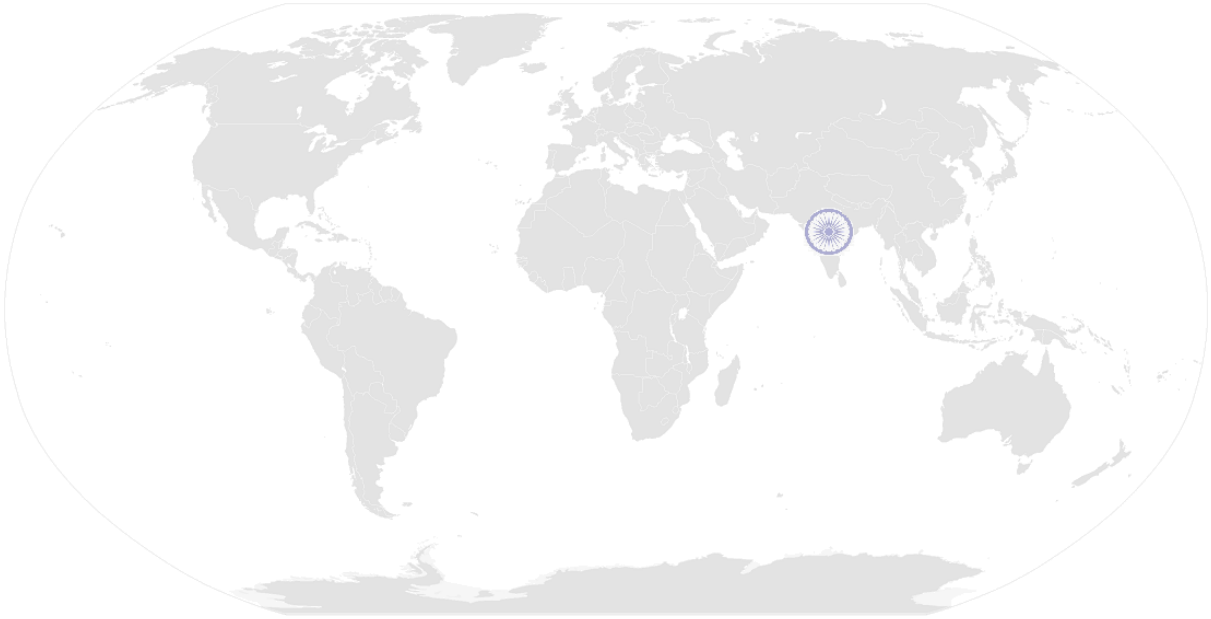
Performance Criteria (PC) w.r.t. the Scope	
Element	**Performance Criteria**
Coordinate with supervisor	To be competent, the user/individual on the job must be able to: PC1. understand the work output requirements PC2. comply with company policy and rule PC3. proactively inform supervisor on issues requiring intervention PC4. deliver quality work on time and report any anticipated reasons for delays
Coordinate with team members	To be competent, the user/individual on the job must be able to: PC5. put team over individual goals PC6. be able to resolve conflicts PC7. learn how to multi-task relevant activities

LFS/N0104: Coordinate with Supervisor and team members

	PC8. impart training to team members/cross-function team members
Knowledge and Understanding (K)	
A. Organisational Context (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. Technical Knowledge	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
Skills (S)	
A. Core Skills/ Generic Skills	**Writing Skills**
	The user/ individual on the job needs to know and understand how to: SA1. report/observation writing skills
	Reading Skills
	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 job-sheet
	Oral Communication (Listening and Speaking skills)
	The user/individual on the job needs to know and understand how to: SA3. interact with team members to work efficiently
B. Professional Skills	**Decision Making**
	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
	Problem Solving

LFS/N0104: Coordinate with Supervisor and team members

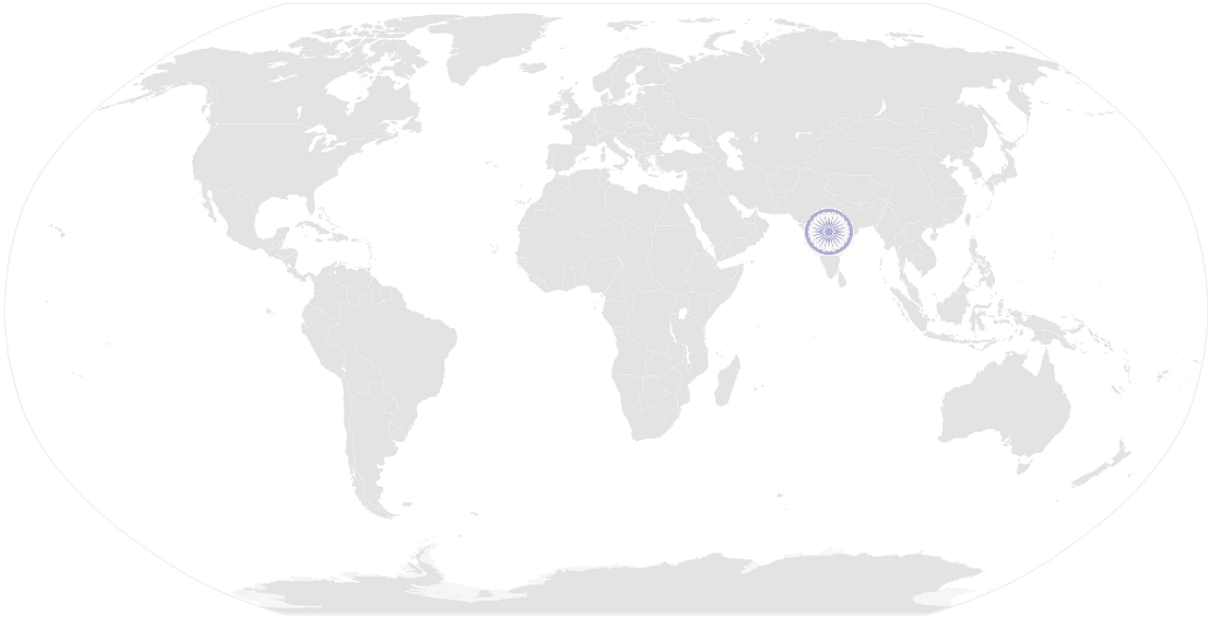
	The user/individual on the job needs to know and understand how to: SB3. improve work processes by interacting with others and adopting best practices
	Critical Thinking
	The user/individual on the job needs to know and understand how to: SB4. spot process disruptions and delays and report and communicate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



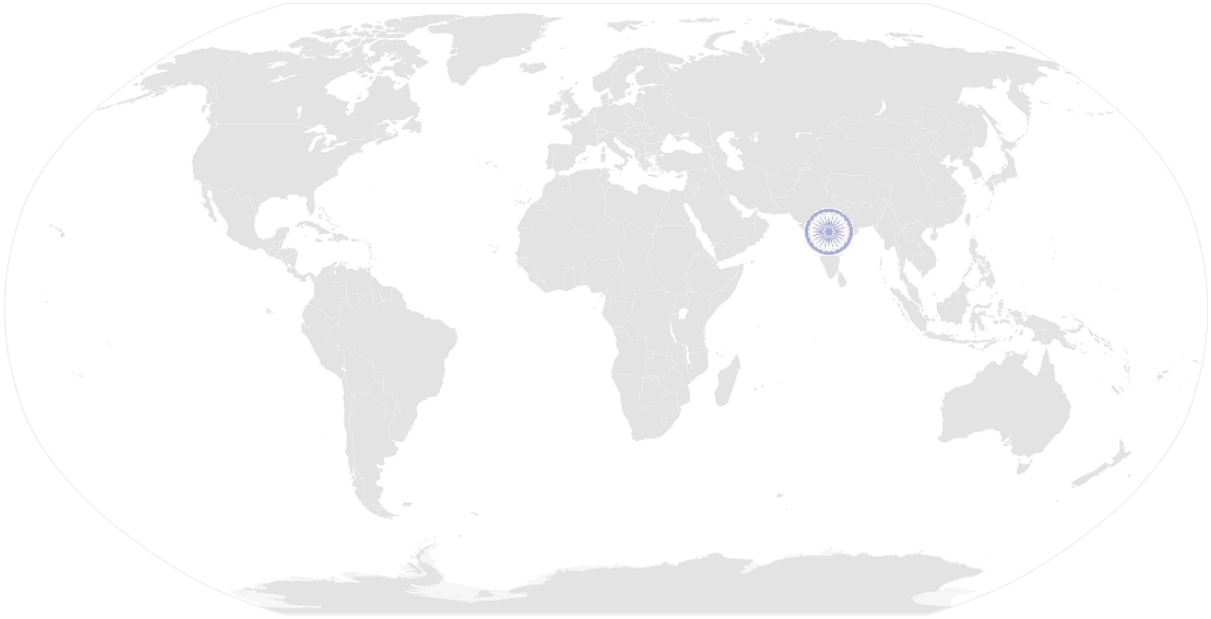
LFS/N0104: Coordinate with Supervisor and team members

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



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

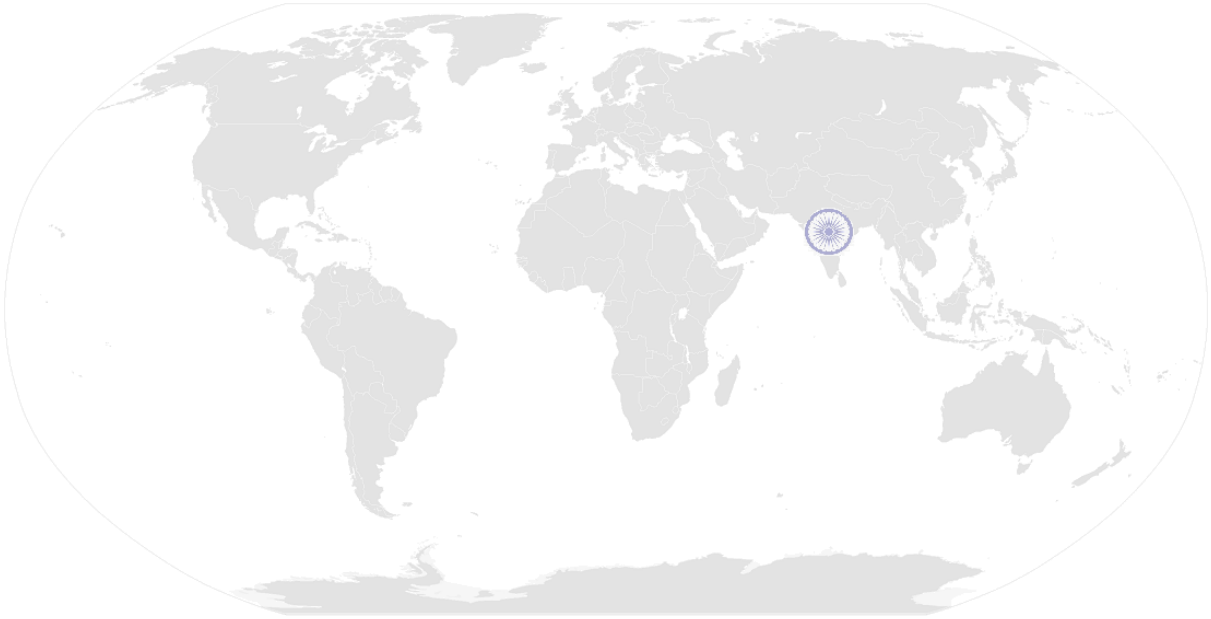
National Occupational Standard

Unit Code	**LFS/N0103**
Unit Title (Task)	**Ensure cleanliness in the work area**
Description	This OS unit is about the Quality Control Chemist – Microbiology to carry out housekeeping activities for respective area
Scope	This unit/task covers the following: • Pre housekeeping activities • Operations • Post housekeeping activities
Performance Criteria (PC) w.r.t. the Scope	
Element	**Performance Criteria**
Pre housekeeping activities	To be competent, the user/individual on the job must be able to: PC1. inspect the area while taking into account various surfaces PC2. identify the material requirements for cleaning the areas inspected, by considering risk, time, efficiency and type of stain PC3. ensure that the cleaning equipment is in proper working condition PC4. select the suitable alternatives for cleaning the areas in case the appropriate equipment and materials are not available and inform the appropriate person PC5. plan the sequence for cleaning the area to avoid re-soiling clean areas and surfaces PC6. inform the affected people about the cleaning activity PC7. display the appropriate signage for the work being conducted PC8. ensure that there is adequate ventilation for the work being carried out PC9. wear the personal protective equipment required for the cleaning method and materials being used
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

	PC20. dispose the waste garnered from the activity in an appropriate manner PC21. dispose of used and un-used solutions according to manufacturer's instructions, and clean the equipment thoroughly PC22. maintain schedules and records for housekeeping duty PC23. replenish any necessary supplies or consumables
Knowledge and Understanding (K)	
A. Organisational Context (Knowledge of the Company/ Organisation and its processes)	The user/individual on the job needs to know and understand: KA5. levels of hygiene required by storage area and importance of maintaining the same KA6. methodology for storage area inspection with methods and materials required for cleaning variety of surfaces and equipment KA7. the method to check the treated surface and equipment on completion of cleaning KA8. procedures for reporting any unidentified soiling KA9. escalation procedures for soils or stains that could not be removed
B. Technical Knowledge	The user/individual on the job needs to know and understand: KB1. role of different materials, chemicals and equipment
Skills (S)	
A. Core Skills/ Generic Skills	**Writing Skills**
	The user/ individual on the job needs to know and understand how to: SA1. record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail
	Reading and Understanding Skills
	The user/individual on the job needs to know and understand how to: SA2. understand the various coding systems as per company norms
	Oral Communication (Listening and Speaking skills)
	The user/individual on the job needs to know and understand how to: SA3. communicate with upstream and downstream teams SA4. disclose information only to those who have the right and need to know it.
B. Professional Skills	**Critical Thinking**
	The user/individual on the job needs to know and understand how to: SB1. suggest improvements(if any) in process based on experience

LFS/N0103: Ensure cleanliness in the work area

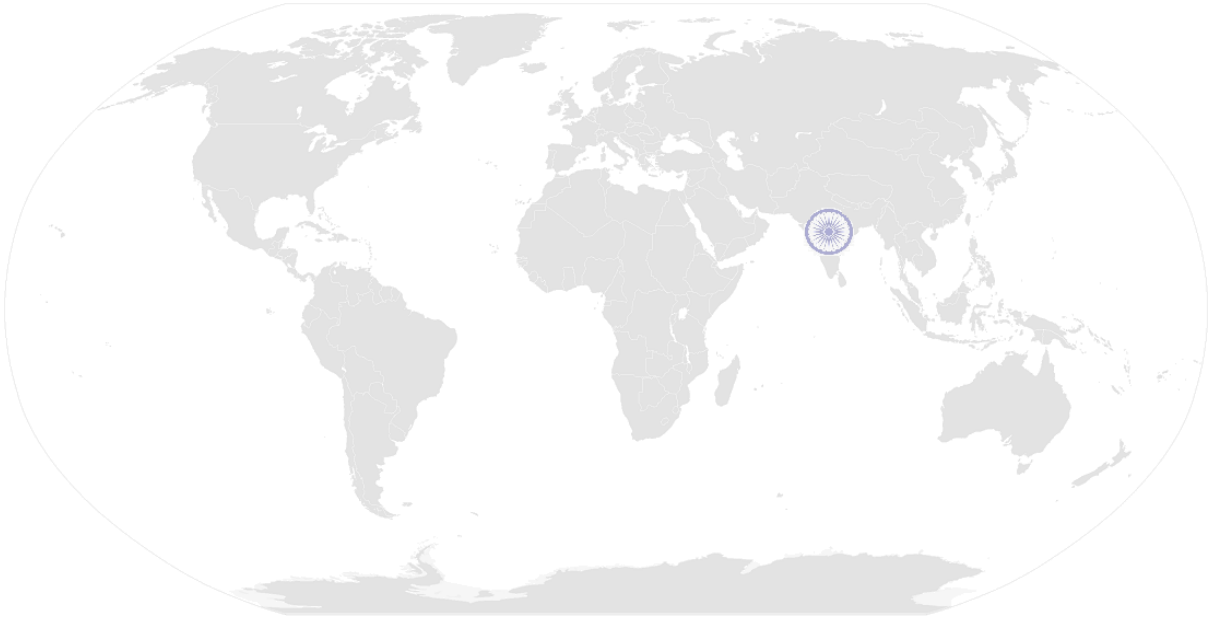
	Decision Making
	SB2. make decisions to maintain cleanliness in the area of work



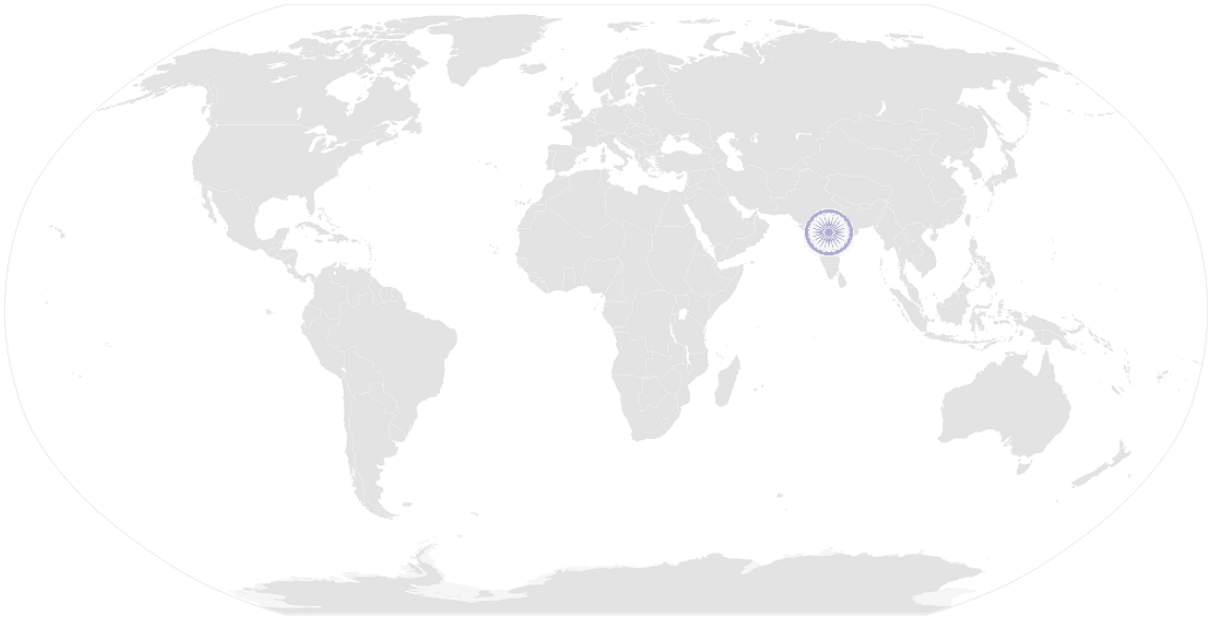
LFS/N0103: **Ensure cleanliness in the work area**

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



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

Unit Code	LFS /N0101
Unit Title (Task)	**Maintain a healthy, safe and secure working environment in the life sciences facility**
Description	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.
Scope	This unit / task covers the following: **Ensuring healthy, safe and secure working environment:** • self monitor and adhere to safety principles and standards • ensure behavioural safety by workmen to cGMP and applicable safety standards on the shop floor/ laboratory • report any identified breaches in health, safety, and security policies and procedures to the designated person **Managing emergency procedures**: • illness • accidents • fires • other reasons to evacuate the premises • breaches of security

Performance Criteria (PC) wrt the Scope	
Element	**Performance Criteria**
Ensuring healthy, safe and secure working environment	To be competent, the user/individual on the job must be able to: PC7. observe and comply with the company's current health, safety and security policies and procedures PC8. while carrying out work, use appropriate safety gears like head gear, masks, gloves and other accessories as mentioned in the guidelines PC9. report any identified breaches in health, safety, and security policies and procedures to the designated person PC10. responsible for maintaining discipline at the shop-floor/ production area PC11. identify and correct any hazards that the individual can deal with safely, competently and within the limits of their authority PC12. adhere and comply to storage and handling guidelines for hazardous material PC13. identify and recommend opportunities for improving health, safety, and security to the designated person PC14. complete any health, safety and security activities like safety drills and prepare records legibly and accurately
Managing emergency procedures	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

	PC10. follow the company's emergency procedures promptly, calmly, and efficiently
Knowledge and Understanding (K)	
B. Organisational Context (Knowledge of the Company/ Organisation and its processes)	The user/ individual on the job needs to know and understand: KA8. legislative requirements and company's procedures for health, safety and security and individual's role and responsibilities in relation to this KA9. what is meant by a hazard, including the different types of health and safety hazards that can be found in the workplace KA10. how and when to report hazards KA11. limits of individual responsibility for dealing with hazards KA12. the organization's emergency procedures for different emergency situations and the importance of following these KA13. the importance of maintaining high standards of health, safety and security KA14. implications that any non-compliance with health, safety and security may have on individuals and the organization KA15. health hazards and its implications if any in the production process
B Technical Knowledge	The user/ individual on the job needs to know and understand: KB9. different types of breaches in health, safety and security and how and when to report these KB10. evacuation procedures for workers and visitors KB11. how to summon medical assistance and the emergency services, where necessary KB12. how to use the health, safety and accident reporting procedures and the importance of these KB13. different types of occupational health hazards KB14. knowledge of chemical substances, their characteristics and required precaution and safety measures
Skills (S)	
C. Core Skills/ Generic Skills	**Writing skills**
	The user/ individual on the job needs to know and understand how to: SA7. complete accurate, well written work with attention to detail
	Reading skills
	The user/ individual on the job needs to know and understand how to: SA8. read instructions, guidelines, procedures, rules and service level agreements

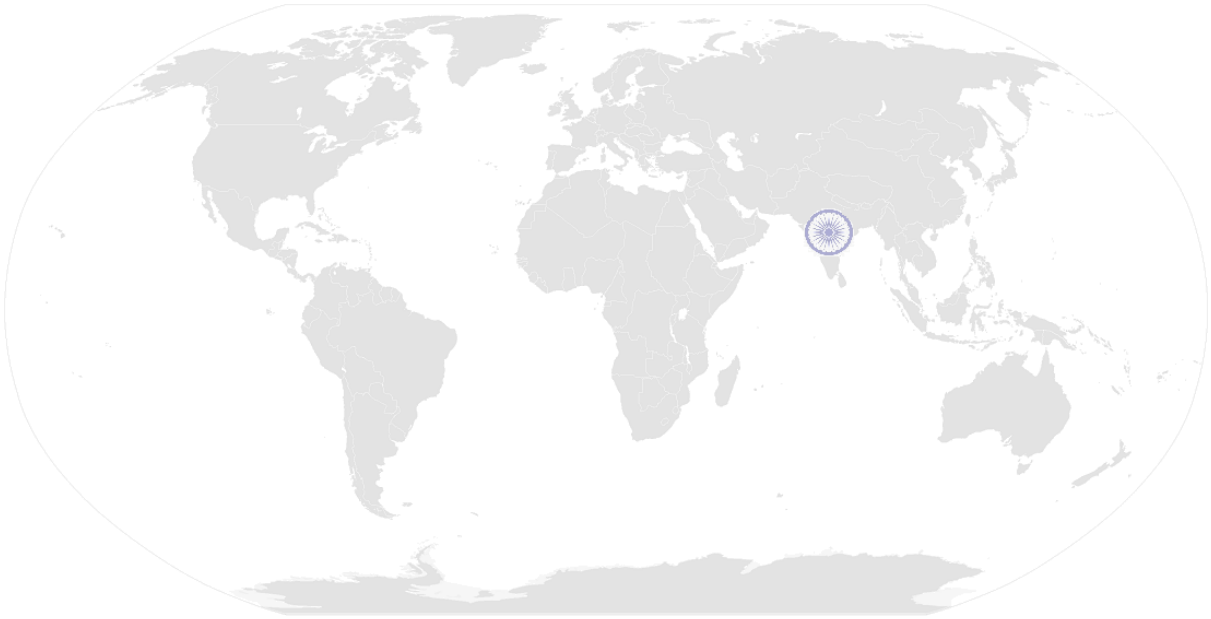
LFS/N0101: Maintain a healthy, safe and secure working environment in the life sciences facility

	Oral Communication (Listening and Speaking skills)
	The user/ individual on the job needs to know and understand how to: SA9. listen effectively and orally communicate information accurately
D. Professional Skills	**Decision making**
	The user/ individual on the job needs to know and understand how to: SB10. make decisions on suitable courses of action
	Plan and Organise
	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
	Problem solving
	The user/ individual on the job needs to know and understand how to: SB12. apply problem solving approaches in different situations
	Analytical thinking
	The user/ individual on the job needs to know and understand how to: SB13. analyse data and activities
	Critical thinking
	The user/ individual on the job needs to know and understand how to: SB14. apply balanced judgments to different situations

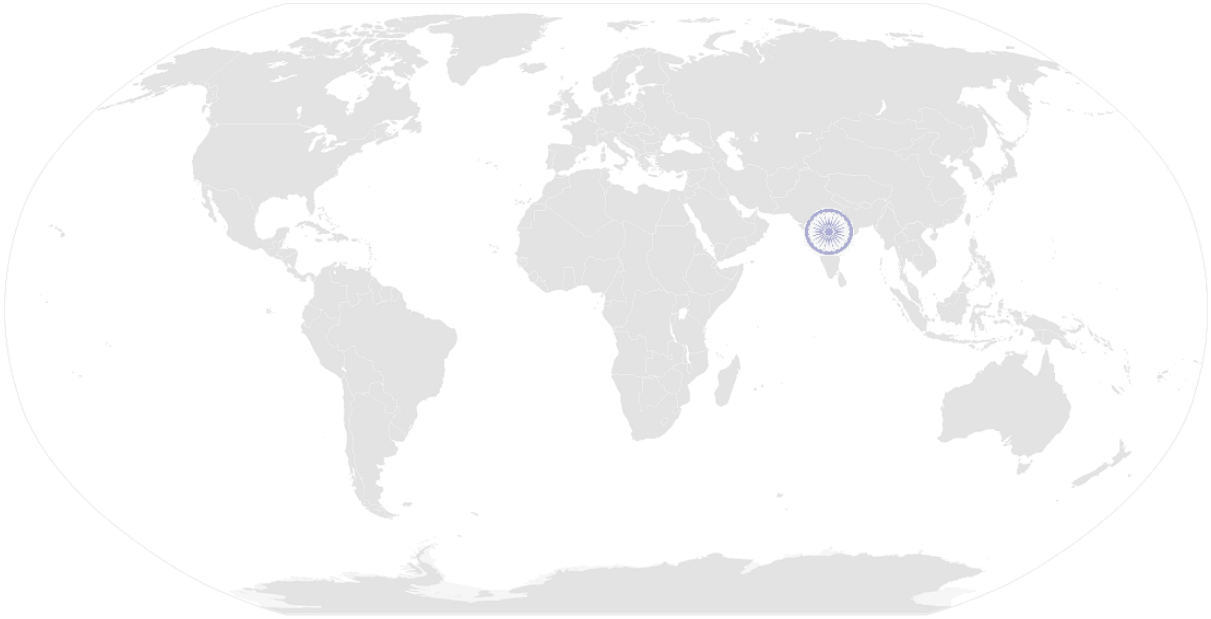
LFS/N0101: **Maintain a healthy, safe and secure working environment in the life sciences facility**

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



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

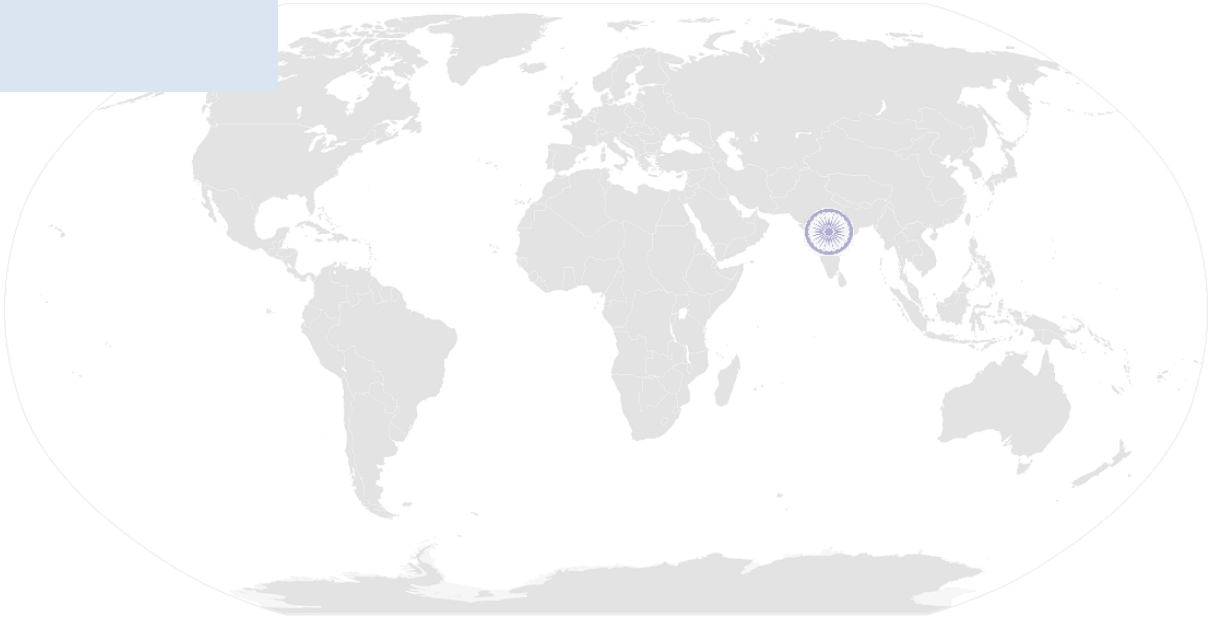
Unit Code	**LFS/N0320**
Unit Title (Task)	**Carry out quality checks in the quality control process**
Description	This OS unit is about the Quality Control Chemist - Microbiology carrying out quality checks in the quality control process
Scope	The unit/ task covers the following: • Carrying out quality checks to identify problems in inspection • Analysis
Performance Criteria (PC) w.r.t. the Scope	
Element	**Performance Criteria**
Inspection	To be competent, the user/individual on the job must be able to: PC1. ensure that total range of checks are regularly and consistently performed PC2. use appropriate measuring instruments, equipment, tools, accessories etc. ,as required PC3. ensure the status and accuracy of instruments used for measurement
Analysis	PC4. identify non-conformities to quality assurance standards PC5. identify potential causes of non-conformities to quality assurance standards PC6. identify impact on final product due to non-conformance to company standards PC7. evaluating the need for action to ensure that problems do not recur PC8. suggest corrective action to address problem PC9. review effectiveness of corrective action
Knowledge and Understanding (K)	
A. Organisational Context (Knowledge of the Company/ Organisation and its processes)	The user/individual on the job needs to know and understand: KA1. the method to check the treated surface and equipment on completion of cleaning KA2. procedures for reporting any unidentified soiling KA3. escalation procedures for soils or stains that could not be removed KA4. reporting incidents where standard operating procedures are not followed KA5. the importance of complete and accurate documentation KA6. the importance of quality control procedures KA7. proper procedure for selecting the material/product and performing quality checks without affecting the material KA8. characteristics of the product/material KA9. availability and use of monitoring and measuring devices KA10. implications of inaccurate measuring and testing instruments and equipment

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

B. Technical Knowledge	The user/individual on the job needs to know and understand: KB1. importance of maintaining master sample KB2. statistical analysis of test data, techniques and concepts of statistical quality control and statistical process control KB3. knowledge pertaining to functioning of quality control equipment like stability chambers and BOD incubators KB4. high-end operational knowledge of quality lab tools like HPLC, gas chromatography, photoflourometer, etc.
Skills (S)	
A .Core Skills/ Generic Skills	**Writing Skills**
	The user/ individual on the job needs to know and understand how to: SA1. record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail SA2. maintain proper and concise records as per given format
	Reading Skills
	The user/individual on the job needs to know and understand how to: SA3. read images, graphs, diagrams SA4. understand the various coding systems as per company norms
	Oral Communication (Listening and Speaking skills)
	The user/individual on the job needs to know and understand how to: SA5. communicate effectively with the team members and supervisors
B. Professional Skills	**Decision Making**
	The user/individual on the job needs to know and understand how to: SB1. decide whether the quality standards are been met or not and take decisions appropriately
	Plan and Organise
	The user/individual on the job needs to know and understand how to: SB2. plan the quality research work within timeline and budget SB3. ensure timelines are met and delegate tasks as per individual competencies
	Analytical Thinking
	The user/individual on the job needs to know and understand how to: SB4. use of computer/ application software SB5. attention to detail
	Problem Solving

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

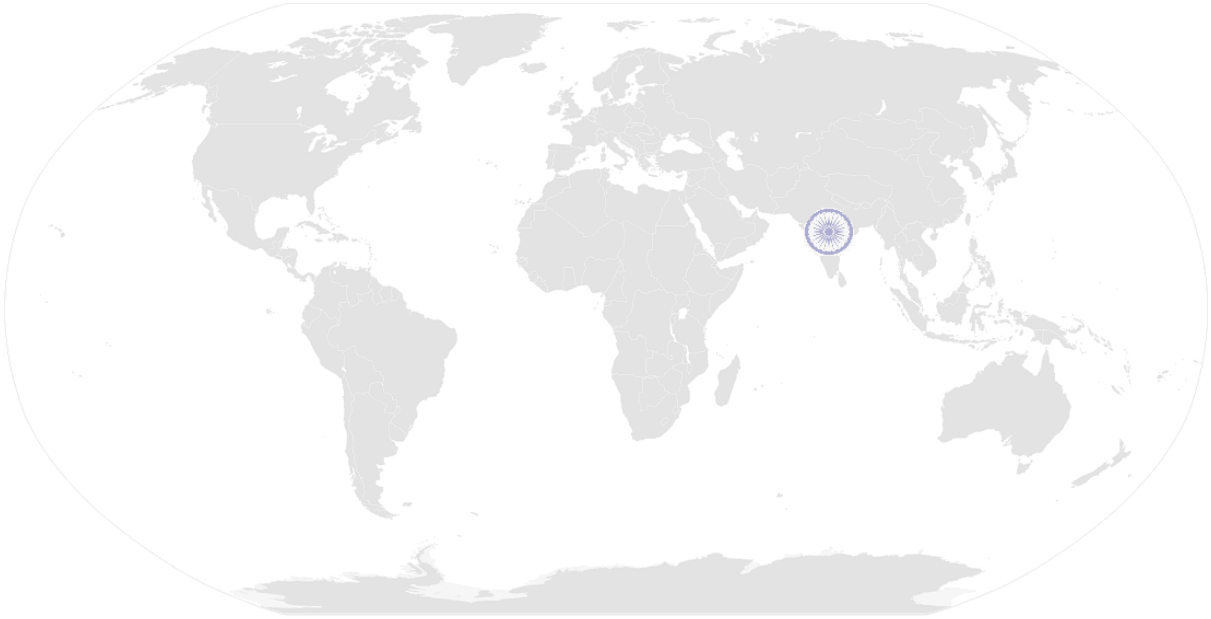
	The user/individual on the job needs to know and understand how to: SB6. effectively solve problems while organizing SB7. think through problems, evaluate the possible solution(s) and suggest an optimum /best possible solution(s) SB8. identify immediate or temporary solutions to resolve delays
	Critical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



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



Annexure

Nomenclature for QP and NOS

Qualification Packs

9 characters

LFS/ Q 0101

LFS

Q denoting Qualification Pack

QP Number (2 numbers)

Occupation (2 numbers)

Occupational Standard

An example of NOS with 'N'

9 characters

LFS/ N 0101

LFS

N denoting National Occupational Standard

OS Number (2 numbers)

Occupation (2 numbers)

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 **Q**P or **N**OS	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/Q0308
Sector Skill Council Life Sciences Sector Skill Development Council

Guidelines for Assessment:

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

				Marks Allocation	
Assessment Outcome	**Assessment Criteria of outcome**	**Total Marks (700)**	**Out of**	**Theory**	**Skills Practical**
1. 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 to maintaining sterile conditions and work in isolation (wherever needed)		6	3	3
	PC6. work with specialized computer software to undertake studies and research and train production line staff for sterile conditions, good micro trial operations		6	3	3
	PC7. identify and classify microorganisms found in specimens collected from humans, plants, animals, or the environment		8	4	4

	PC8. validate test methods and undertake calibration exercises		5	2	3
	PC9. serve as the primary contact for all QC Microbiology related filings and inspections of Regulatory Agencies		7	2	5
	PC10. undertake culture/media preparation to conduct quality analysis on the samples and maintain standard cultures		10	5	5
	PC11. maintain restricted access to the microbiological laboratory as per cGMP and GLP guidelines		8	3	5
	PC12. minimize the risks of cross-contamination, false-positive and false-negative results		6	3	3
	PC13. define alert and action limits and maintain positive and negative controls during testing as considered appropriate		2	1	1
	PC14. fulfil requirements of sterility testing like aseptic conditions		6	3	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 expiry date and/or recommended storage period		6	3	3
		Total	100	44	56
2. 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 specialized computer software to undertake studies and research		20	10	10
		Total	100	45	55
3. 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		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	100	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
4. 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
	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
5. LFS/N0103 Ensure cleanliness in the work	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		5	2	3

area	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	1	3
	PC6. Inform the affected people about the cleaning activity		4	2	2
	PC7. display the appropriate signage for the work being conducted		4	2	2
	PC8. ensure that there is adequate ventilation for the work being carried out		5	2	3
	PC9. wear the personal protective equipment required for the cleaning method and materials being used		4	2	2
	PC10. use the correct cleaning method for the work area, type of soiling and surface		4	2	2
	PC11. deal with accidental damage, if any, caused while carrying out the work		4	1	3
	PC12. report to the appropriate person any difficulties in carrying out 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
	PC23. replenish any necessary supplies or consumables		5	2	3
		Total	100	44	56
6. 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 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
7. 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