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

Contact Us:
Life Sciences Sector Skill Development Council
13, Palam Marg, 3rd Floor, Vasant Vihar, New Delhi, 110057
Phone No.: +91 11 41042407/408
E-mail: info@lsssdc.in

Introduction

Qualifications Pack- Validation Supervisor

SECTOR: LIFE SCIENCES

SUB-SECTOR: PHARMACEUTICAL AND BIOPHARMACEUTICAL

OCCUPATION:QUALITY

REFERENCE ID: LFS/Q0305

ALIGNED TO: NCO-2004/NIL

Validation Supervisor is responsible for implementation of validation strategy to ensure that the validation deliverables meet the quality standards and requirements of company policies and government regulations.

Brief Job Description: Responsible for performing and overseeing the qualification and validation of manufacturing processes, cleaning procedures, equipment and media fills. Validation activities include writing and executing protocols that comply with plant and regulatory requirements.

Personal Attributes: The individual should have good knowledge of standard documentation procedures, rules, regulations and statutory requirements in carrying out validation activities. The individual must demonstrate attention to detail and proactive behaviour.

Qualifications Pack Code	**LFS/Q0305**		
Job Role	**Validation Supervisor**		
Credits(NSQF)	**TBD**	**Version number**	**1.0**
Sector	**Life Sciences**	**Drafted on**	**15/12/14**
Sub-sector	**Pharmaceutical and Biopharmaceutical**	**Last reviewed on**	**25/02/15**
Occupation	**Quality**	**Next review date**	**01/06/17**
NSQC Clearance on	**20/07/2015**		

Job Role	**Validation Supervisor**
Role Description	Responsible for implementation of validation strategy to ensure that the validation deliverables meet the quality standards and requirements of company policies and government regulations.
NSQF level	4
Minimum Educational Qualifications	D.Pharma/ Diploma / B.Sc in in a scientific or engineering related field
Maximum Educational Qualifications	B.Pharma/ M.Sc in a scientific or engineering related field / B.Tech in chemical engineering
Training (Suggested but not mandatory)	0-2 years, On the job training required for graduates
Minimum Job Entry Age	20 Years
Experience	1-3 years, On the job training required for Diploma Holders
Applicable National Occupational Standards (NOS)	**Compulsory:** 1. LFS/N0312: Monitor and conduct cleaning, process and equipment validation activities during the manufacturing process. 2. LFS/N0313: Provide guidance to workmen on validation issues and documentation.

Job Details

	3. LFS/N0104: Coordinate with Supervisor and team members.
	4. LFS/N0314: Carry out reporting and documentation to meet quality standards 5. LFS/N0101: Maintain a healthy, safe and secure working environment **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.
Vertical	Vertical may exist within a sub-sector representing different domain areas or the client industries served by the industry.

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
GMP	Good Manufacturing Practices
SOP	Standard Operating Procedures
ISO	International Organization for Standardization
TS	Technical Specification(s)
OHSAS	Occupational Health & Safety Management System

LFS/N0312 : **Monitor and conduct cleaning, process and equipment validation activities during the manufacturing process**

National Occupational Standard

Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Validation Supervisor to monitor and conduct cleaning, process and equipment validation activities during the manufacturing process.

LFS/N0312 : Monitor and conduct cleaning, process and equipment validation activities during the manufacturing process

National Occupational Standard

Unit Code	**LFS/N0312**
Unit Title (Task)	**Monitor and conduct cleaning, process and equipment validation activities during the manufacturing process**
Description	This NOS is about a Validation Supervisor performing the required activities to monitor and conduct cleaning, process and equipment validation activities during the manufacturing process
Scope	The unit/ task covers the following: • Assisting in implementation of validation and GMP-related activities • Ensure implementation of validation procedures and appropriate documentation • Providing technical support and guidance • Carrying out tests as per laid down method and specification
Performance Criteria (PC) w.r.t. the Scope	
Element	**Performance Criteria**
Implementation of validation and GMP-related activities	To be competent, the user/individual on the job must be able to: PC1. ensure and assist in the implementation of the overall validation program for systems, facilities, equipment, manufacturing processes and cleaning activities PC2. Ensures support in preparation of validation protocols, inspection maps and timely review and approval of validation protocols/summary reports, master plans and SOPs PC3. support in compilation of deviations, change controls and report the defect trends
Implementation of validation procedures and appropriate documentation	PC4. setup appropriate equipment or apparatus for testing PC5. calibrate the testing equipment periodically as per the SOP PC6. identify defective equipment/apparatus, materials and processes and corrective steps to be taken PC7. release or hold the production for further inspection as per findings PC8. ensure that disposal of waste and left over tested material is carried on safely as per the SOP PC9. ensure the disposal of all materials used in the experiment safely as per health and safety management system of the company
Technical support and guidance	PC10. monitor and adjust the processes to achieve required quality outcomes and support teams during tech transfers PC11. take corrective action in response to typical faults and inconsistencies PC12. troubleshoot/investigate validation related deviations PC13. ensure that all safety measures are in place PC14. review and approve facility equipment and software changes PC15. Take up the results of the findings with the appropriate authority
Carrying out tests as per laid down	PC16. conduct sampling tests to ensure the use of quality procedures as per approved/standard protocols PC17. ensure that sampling is done as per the process flow sheet with control points mentioned in protocols

LFS/N0312 : **Monitor and conduct cleaning, process and equipment validation activities during the manufacturing process**

method and specification	PC18. Identify the sample by labeling/numbering as per the SOP PC19. ensure that sample quality is same as mentioned in protocol for test/analysis PC20. Identify defect/problem
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. organizational coding system of finished materials, compounds and the company manual KA2. different quality management systems (ISO-9000,ISO-14001,OHSAS-18000) and good laboratory and manufacturing practices. KA3. quality systems and procedures KA4. types of documentation used in the organization, importance of maintaining the same and different methods of recording information. KA5. impact of various practices on cost, quality, productivity ,delivery and safety KA6. procedures for reporting any unresolved issues and hazards KA7. method of reporting incidents where standard operating procedures are not followed KA8. the importance of complete and accurate documentation KA9. proper procedure for selecting the material/product and performing quality checks without affecting the material KA10. characteristics of the product/material KA11. availability and use of monitoring and measuring devices KA12. implications of inaccurate measuring and testing equipment KA13. implications (impact on internal/external customers)of defective products, materials or components. KA14. the method of reporting any anomalies (materials/processes out of specification) to the appropriate authority
B. Technical Knowledge	The user/individual on the job needs to know and understand: KB1. basics of chemistry, principles of the process, measuring units and method of performing simple chemical calculation KB2. high level concepts of microbiology, analytical chemistry and biotechnology KB3. basic mathematical concepts KB4. different standard reference materials KB5. quality systems and validated procedures KB6. application of statistical, risk assessment, experimental design and process improvement tools KB7. implementation of validation protocols KB8. Validation concepts, current and emerging trends. KB9. pharmaceutical GMPs and regulatory requirements (both national and

LFS/N0312 : **Monitor and conduct cleaning, process and equipment validation activities during the manufacturing process**

	international) KB10. quality characteristics to be achieved by the process KB11. quality requirements of materials and effect of variation on process performance KB12. operating requirements, parameters and corrective action required where operation is outside specified operating parameters KB13. the inspection or test points(control points) in the process and the related procedures and recording requirements KB14. common causes of variation and corrective action required KB15. requirements of different shutdowns as appropriate to the process and workplace production requirements, including emergency and routine shutdowns and procedures to follow in the event of a power outage KB16. procedures and responsibility for reporting production and performance information KB17. environmental issues and controls relevant to the process, including waste/rework collection and handling procedures related to the process KB18. how to carry out statistical analysis of test data KB19. how to obtain andinterpretrecords,charts,specifications,equipmentmanuals,history/technical support reports and other documents KB20. Use of basic computer applications/software.
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 the given format
	Reading Skills
	The user/individual on the job needs to know and understand how to: SA3. read and understand manuals, SOPs, health and safety instructions, memos, reports, job cards etc. SA4. read images, graphs, diagrams SA5. use and interpret 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: SA6. communicate confidential and sensitive information discretely to authorized person as per the SOP SA7. maintain confidentiality of information and data.

LFS/N0312 : **Monitor and conduct cleaning, process and equipment validation activities during the manufacturing process**

B. Professional Skills	**Analytical Thinking**
	The user/individual on the job needs to know and understand how to: SB1. pay attention to detail SB2. use basic computer applications/software SB3. apply statistics to data SB4. apply knowledge of chemistry/ microbiology and biotechnology wherever required SB5. use logic and reasoning to identify the strengths and weaknesses of each of the members in the team SB6. combine pieces of information to form general rules or conclusions
	Problem Solving
	The user/individual on the job needs to know and understand how to: SB7. identify, define and resolve problems using a structured methodology SB8. use the right mathematical methods or formulas to solve a problem SB9. apply general rules to specific problems to produce answers that make sense
	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
	Plan and Organise
	The user/individual on the job needs to know and understand how to: SB10. take responsibility for completing one's own work assignment. SB11. take initiative to enhance/learn skills in one's area of work.
	Decision Making
	Not Applicable
	Customer Centricity
	Not Applicable

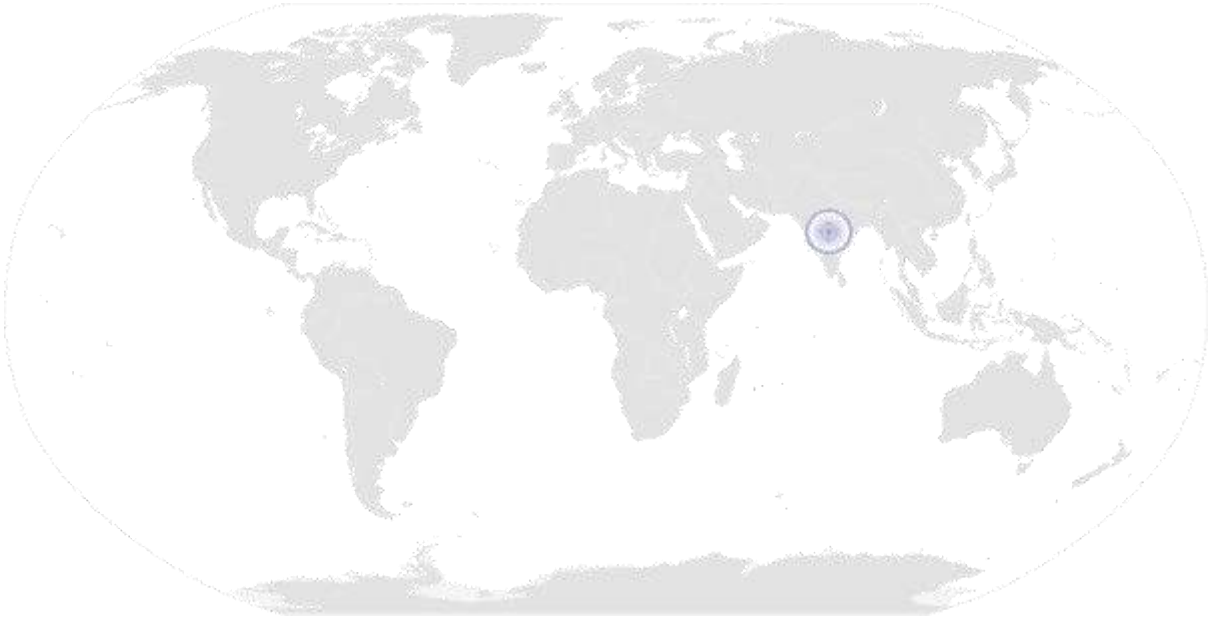
LFS/N0312 : **Monitor and conduct cleaning, process and equipment validation activities during the manufacturing process**

NOS Version Control

NOS Code	LFS/N0312		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	15/12/14
Industry Sub-sector	Pharmaceutical and Biopharmaceutical	Last reviewed on	25/02/15
Occupation	Quality	Next review date	01/06/17

LFS/N0313 : Provide guidance to workmen on validation issues and documentation

National Occupational Standard



Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Validation Supervisor to provide guidance to workmen on validation issues and documentation.

LFS/N0313 : Provide guidance to workmen on validation issues and documentation

National Occupational Standard

Unit Code	**LFS/N0313**
Unit Title (Task)	**Provide guidance to workmen on validation issues and documentation**
Description	This NOS unit is about a Validation Supervisor to provide guidance to workmen on validation issues and documentation
Scope	The unit/ task covers the following: 1. guiding the work men on validation issues and documentation. 2. ensuring that the workmen comply with the validation procedures.
Performance Criteria (PC) w.r.t. the Scope	
Element	**Performance Criteria**
Guiding the workmen	To be competent, the user/individual on the job must be able to: PC1. identify the existing level of knowledge among the work men regarding validation issues PC2. identify the requirements of the workmen regarding validation issues PC3. provide guidance on validation issues and documentation regarding quality checks PC4. communicate validation issues and requirements to plant personnel on a frequent basis PC5. Communicate any potential hazards or expected process disruptions
Ensuring compliance to validation procedures	PC6. ensure that there is adequate usage of safety measures for the work being carried out PC7. ensure that GMP are being followed PC8. ensure that the quality of the products, process and equipment is as per standards PC9. report to the appropriate person any disturbances in material flow or equipment PC10. ensure that there is no oily substance on the floor to avoids slippage PC11. ensure that no scrap material is lying around PC12. follow work place procedures to deal with any accidental damage caused during the production process PC13. ensure that the work place is left clean and dry and meets requirements on completion of the work PC14. ensure that the equipment, materials and personal protective equipment that were used are returned to the right places making sure they are clean, safe and securely stored PC15. ensure that the waste garnered from the activity is disposed in an appropriate manner
Knowledge and Understanding (K)	
A. Organisational Context (Knowledge of the Company/	The user/individual on the job needs to know and understand: KA1. material disposal procedure, importance of appropriate disposal of material and implications of not following the material disposal

LFS/N0313 : Provide guidance to workmen on validation issues and documentation

Organisation and its processes)	procedure KA2. importance of identifying non-conforming products and storage of the same KA3. risk and impact of not following defined procedures/work instructions KA4. escalation matrix for reporting identified issues, hazards and breakage KA5. health, safety and environment guidelines, legislation and regulations as applicable and impact of non-conformance/poor practices KA6. which personal protective equipment to be used and how KA7. procedures for reporting any unresolved issues and hazards KA8. the importance of complete and accurate documentation KA9. proper procedure for selecting the material/product and performing quality checks without affecting the material KA10. the reason and impact of the occurrence of problems KA11. measures, steps and possible solutions that have been taken/identified to address the previous problems KA12. the correct method for carrying out corrective actions outlined for each problem KA13. The knowledge about the appropriate authority for reporting any imbalances
B Technical Knowledge	The user/individual on the job needs to know and understand: KB1. method of implementing validation protocols KB2. pharmaceutical GMPs and regulatory requirements KB3. basics of tactical decision making on safety, process, scheduling and personnel-related issues KB4. method of using testing equipment, related test methods and purpose of tests KB5. typical equipment fault sand related causes, including recognition of signs and symptoms of faulty equipment and early warning signs of potential problems KB6. Procedure sand 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 write detailed reports for investigation. SA2. maintain proper and concise records as per the given format
	Reading Skills
	The user/individual on the job needs to know and understand how to:

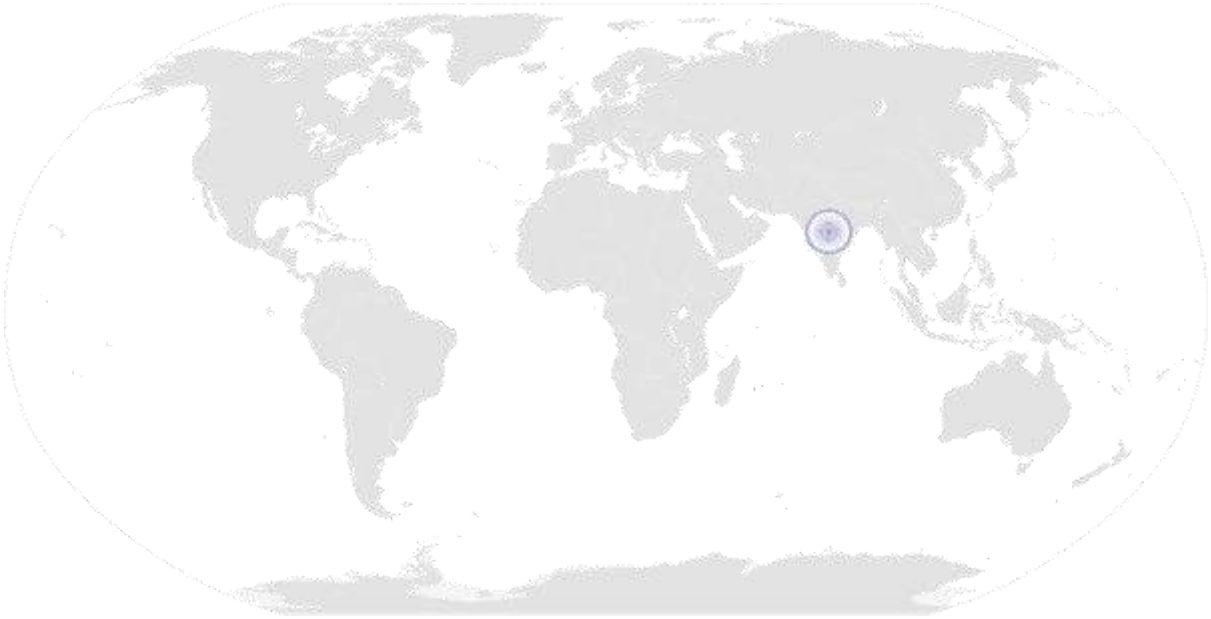
LFS/N0313 : Provide guidance to workmen on validation issues and documentation

	SA3. read and understand manuals, SOPs, health and safety instructions, memos, reports, job cards etc. SA4. read images, graphs, diagrams SA5. use and interpret 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: SA6. communicate confidential and sensitive information discretely to authorized person as per the SOP SA7. maintain confidentiality of information and data.
B. Professional Skills	**Analytical Thinking**
	The user/individual on the job needs to know and understand how to: SB1. pay attention to detail SB2. use basic computer applications/software. SB3. apply statistics to data SB4. use logic and reasoning to identify the strengths and weaknesses of each of the members in the team SB5. combine pieces of information to form general rules or conclusions
	Problem Solving
	The user/individual on the job needs to know and understand how to: SB6. identify, define and resolve problems using a structured methodology SB7. use the right mathematical methods or formulas to solve a problem SB8. apply general rules to specific problems to produce answers that make sense
	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
	Plan and Organise
	The user/individual on the job needs to know and understand how to: SB10. take responsibility for completing one's own work assignment. SB11. take initiative to enhance/learn skills in one's area of work.
	Decision Making
	Not Applicable
	Customer Centricity
	Not Applicable

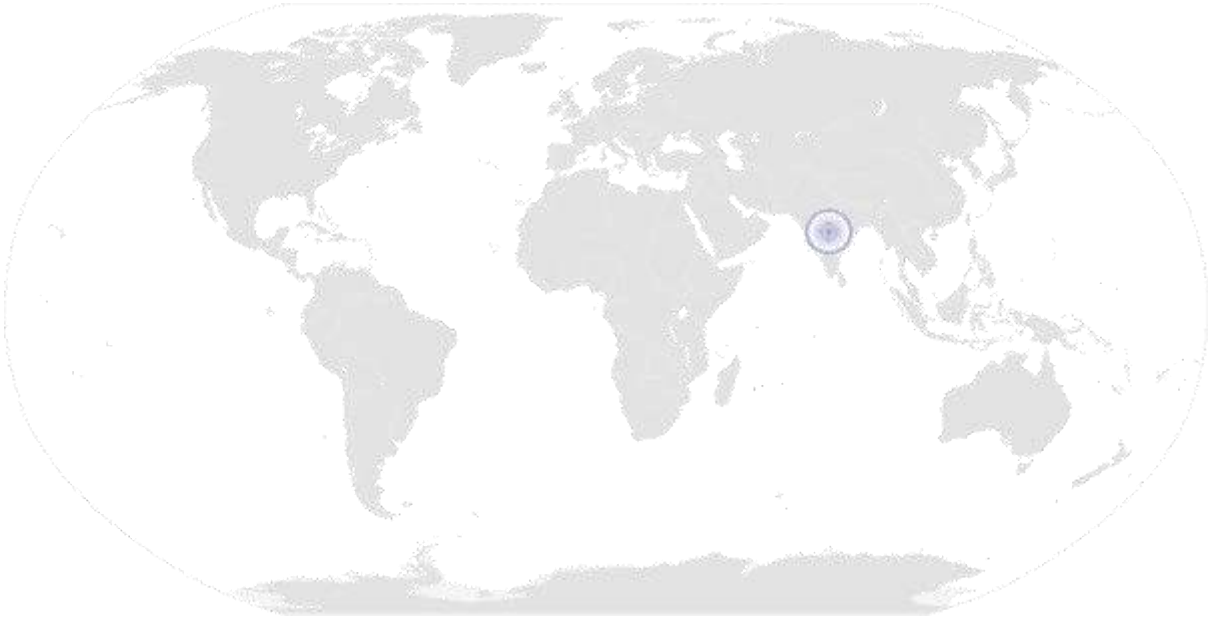
LFS/N0313 : Provide guidance to workmen on validation issues and documentation

NOS Version Control

NOS Code	LFS/N0313		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	15/12/14
Industry Sub-sector	Pharmaceutical and Biopharmaceutical	Last reviewed on	25/02/15
Occupation	Quality	Next review date	01/06/17



National Occupational Standard



Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Validation Supervisor to 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 NOS unit is about the Validation Supervisor 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

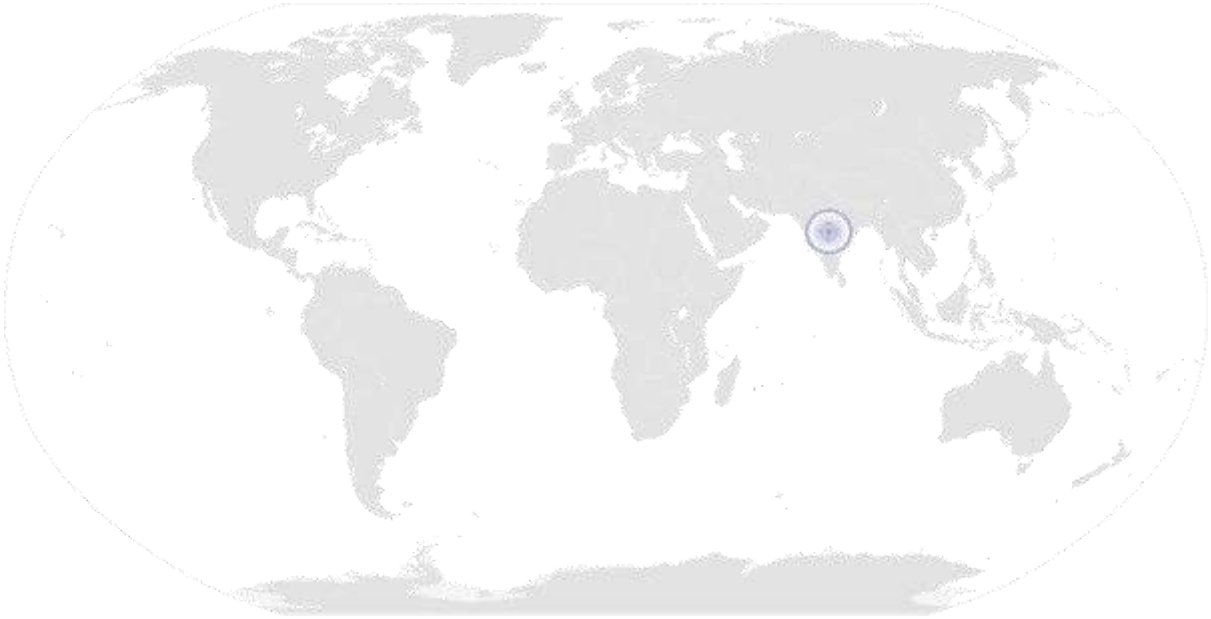
Performance Criteria (PC) w.r.t. the Scope	
Element	**Performance Criteria**
Coordinate with supervisor	To be competent, the user/individual on the job must be able to: PC1. understand the work output requirements PC2. comply with company policy and rule PC3. proactively inform supervisor on issues requiring 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 jobsheet
	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

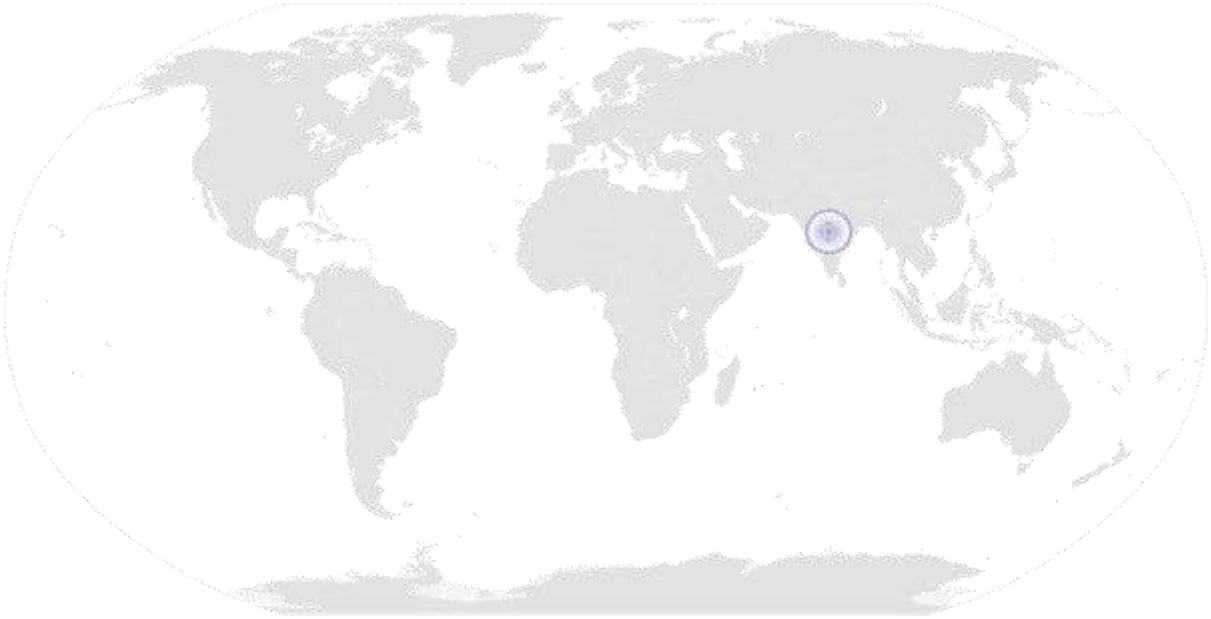
	The user/individual on the job needs to know and understand how to: SB3. improve work processes by interacting with others and adopting best practices
	Critical Thinking
	The user/individual on the job needs to know and understand how to: SB4. spot process disruptions and delays and report and communicate with solutions
	Analytical Thinking
	Not Applicable
	Plan and Organise
	Not Applicable
	Customer Centricity
	Not Applicable



LFS/N0104 : Coordinate with Supervisor and team members

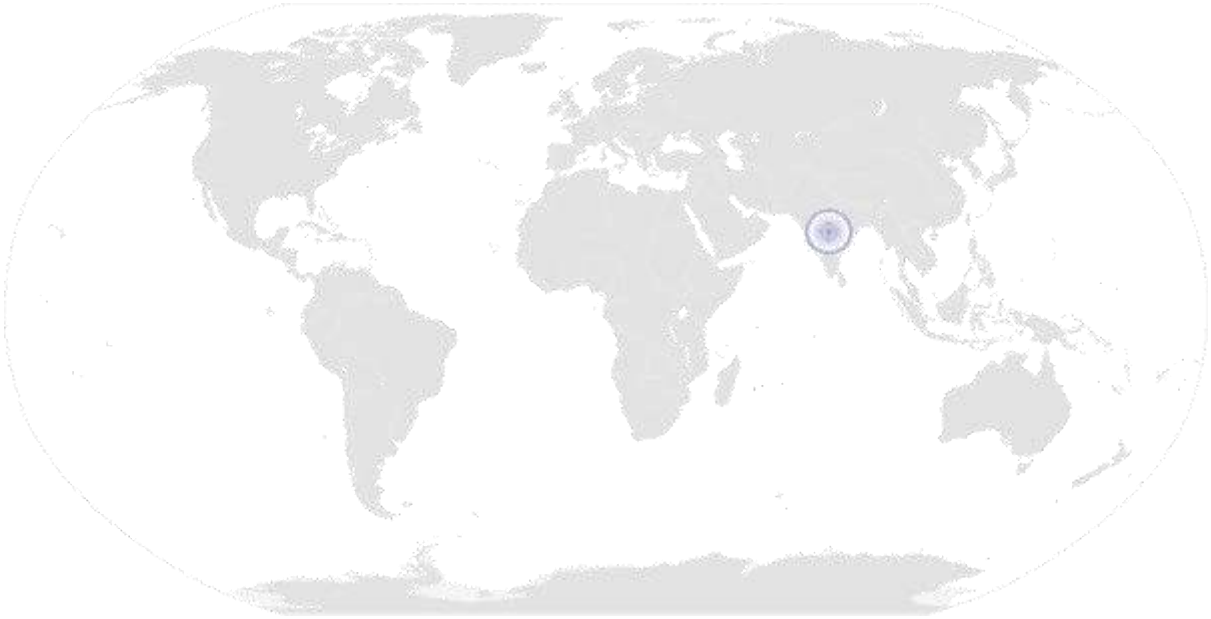
NOS Version Control

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



LFS/N0308: **Work with cross functional teams to carry out validation activities**

National Occupational Standards



Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Validation Supervisor to effectively work with cross functional teams to perform validation activities

National Occupational Standard

LFS/N0308: Work with cross functional teams to carry out validation activities

Unit Code	**LFS/N0308**
Unit Title (Task)	**Work with cross functional teams to carry out validation activities**
Description	This NOS unit is about a Validation Supervisor working with cross functional teams for undertaking validation activities
Scope	The unit/ task covers the following: 1. working with quality assurance teams 2. working with the manufacturing department to solve issues on validation 3. participating in meetings with engineering, R&D and management
Performance Criteria (PC) w.r.t. the Scope	
Element	**Performance Criteria**
Working with quality assurance teams	To be competent, the user/individual on the job must be able to: PC1. Work closely with QA site support team and QA validation team to ensure alignment between quality systems PC2. Identify the existing level of knowledge among the employees / workers regarding validation issues PC3. Identify the training requirements for the employees / workmen regarding validation issues
Working with the manufacturing department	PC4. Work closely with manufacturing groups to ensure effective communication on issues related to validation PC5. Communicate validation issues and requirements to plant personnel on frequent basis through participation in engineering, R&D and management staff meetings, as well as applicable project teams
Participating in meetings	PC6. Maintain close communication with stakeholders and team members to keep them apprised of computerized system needs, impacts on computer validation, project validation status, and other relevant issues
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 systems and procedures KA2. risk and impact of not following defined procedures/work instructions KA3. types of documentation used in the organization, importance of maintaining the same and different methods of recording information KA4. impact of various practices on cost, quality, productivity, delivery and safety KA5. procedures for reporting any unresolved issues and hazards KA6. reporting incidents where standard operating procedures are not followed KA7. method of reporting any imbalances to the appropriate authority

LFS/N0308: Work with cross functional teams to carry out validation activities

B Technical Knowledge	The user/individual on the job needs to know and understand: KB1. different standard reference materials KB2. basics of tactical decision making on safety, process, scheduling and personnel-related issues KB3. use of basic computer applications/software KB4. validation activities to include protocol generation, execution and deviation resolution
Skills (S)	
A. Core Skills/ Generic Skills	**Writing Skills**
	The user/ individual on the job needs to know and understand how to: SA1. write reports
	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 jobsheet
	Oral Communication (Listening and Speaking skills)
	The user/individual on the job needs to know and understand how to: SA4. 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
	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

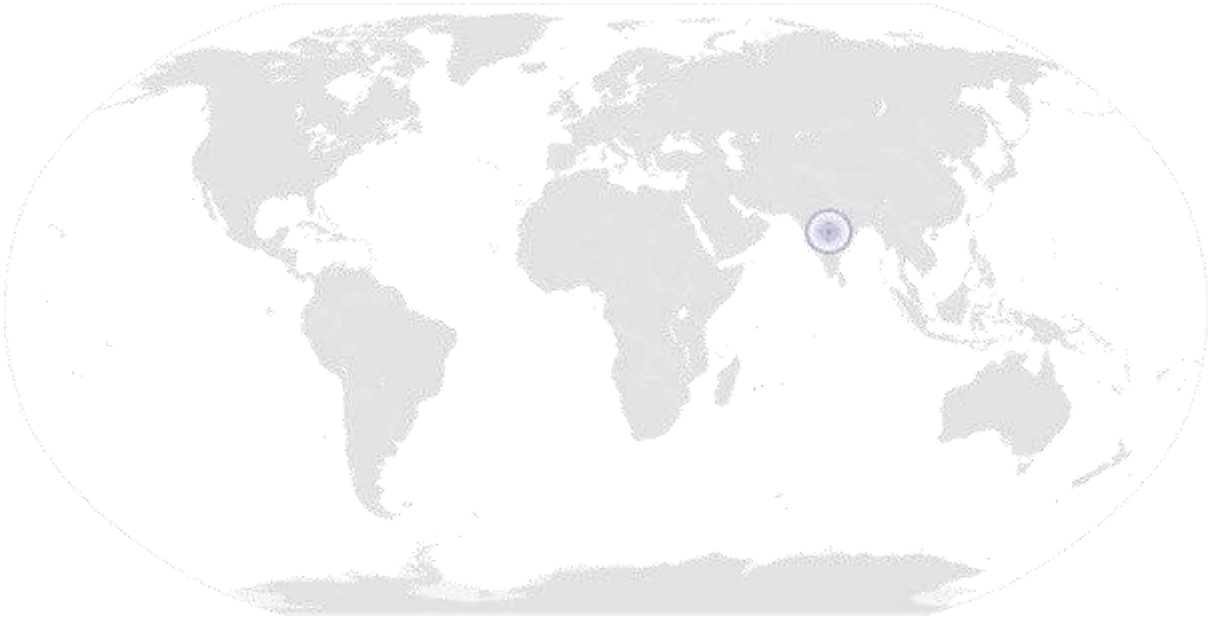
LFS/N0308: Work with cross functional teams to carry out validation activities

	Analytical Thinking
	Not Applicable
	Plan and Organise
	Not Applicable
	Customer Centricity
	Not Applicable

NOS Version Control

NOS Code	**LFS/N0308**		
Credits(NSQF)	**TBD**	**Version number**	**1.0**
Industry	**Life Sciences**	**Drafted on**	**15/12/14**
Industry Sub-sector	**Pharmaceutical and Biopharmaceutical**	**Last reviewed on**	**25/02/15**
Occupation	**Quality**	**Next review date**	**01/06/17**

National Occupational Standard



Overview

This Occupational Standard describes the knowledge, understanding and skills required of a Validation Supervisorto 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 NOS unit is about the Validation Supervisor 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)

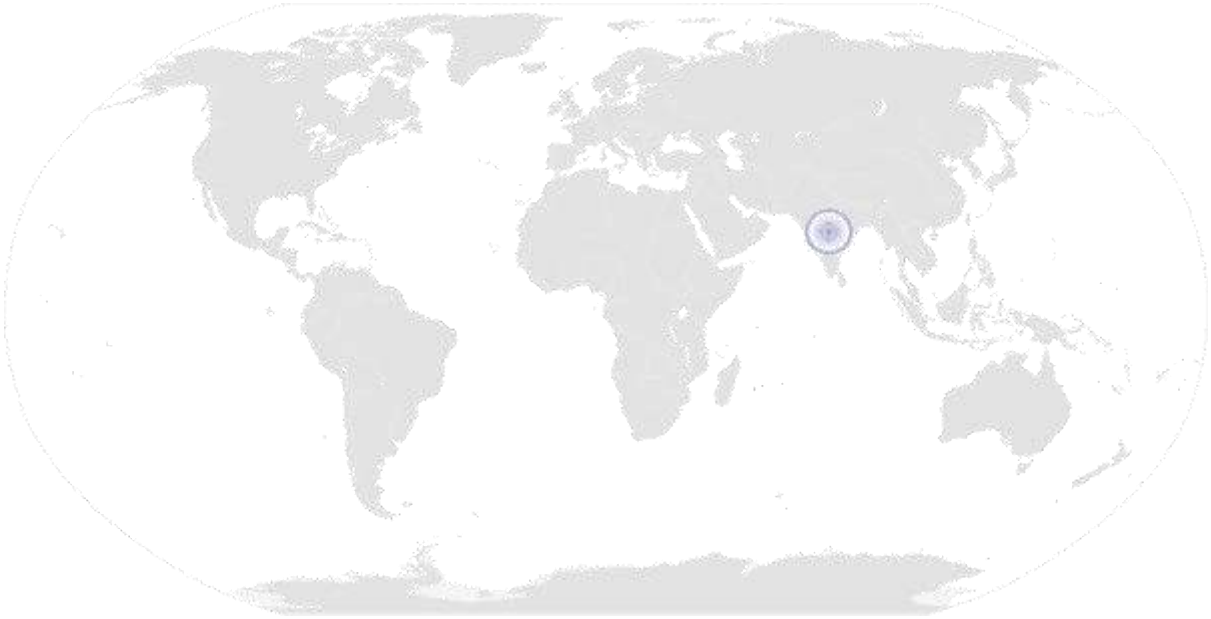
LFS/N0314 : Carry out reporting and documentation to meet quality standards

	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
	Customer Centricity
	Not Applicable

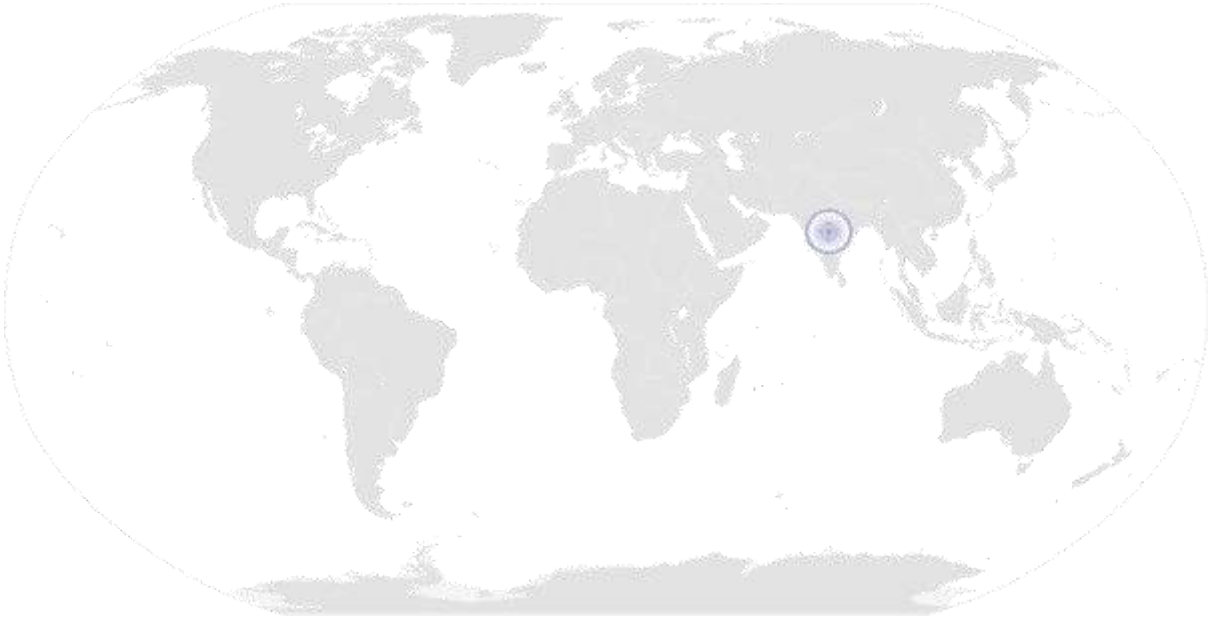
LFS/N0314 : Carry out reporting and documentation to meet quality standards

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 for a Validation Supervisor to assist in maintaining a healthy, safe and secure working environment in the life sciences facility.

LFS/N0101 : Maintain 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 Validation Supervisor 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: PC1. observe and comply with the company's current health, safety and security policies and procedures PC2. while carrying out work, use appropriate safety gears like head gear, masks, gloves and other accessories as mentioned in the guidelines PC3. report any identified breaches in health, safety, and security policies and procedures to the designated person PC4. responsible for maintaining discipline at the shop-floor/ production area PC5. identify and correct any hazards that the individual can deal with safely, competently and within the limits of their authority PC6. adhere and comply to storage and handling guidelines for hazardous material PC7. identify and recommend opportunities for improving health, safety, and security to the designated person PC8. 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 individualis 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

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

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

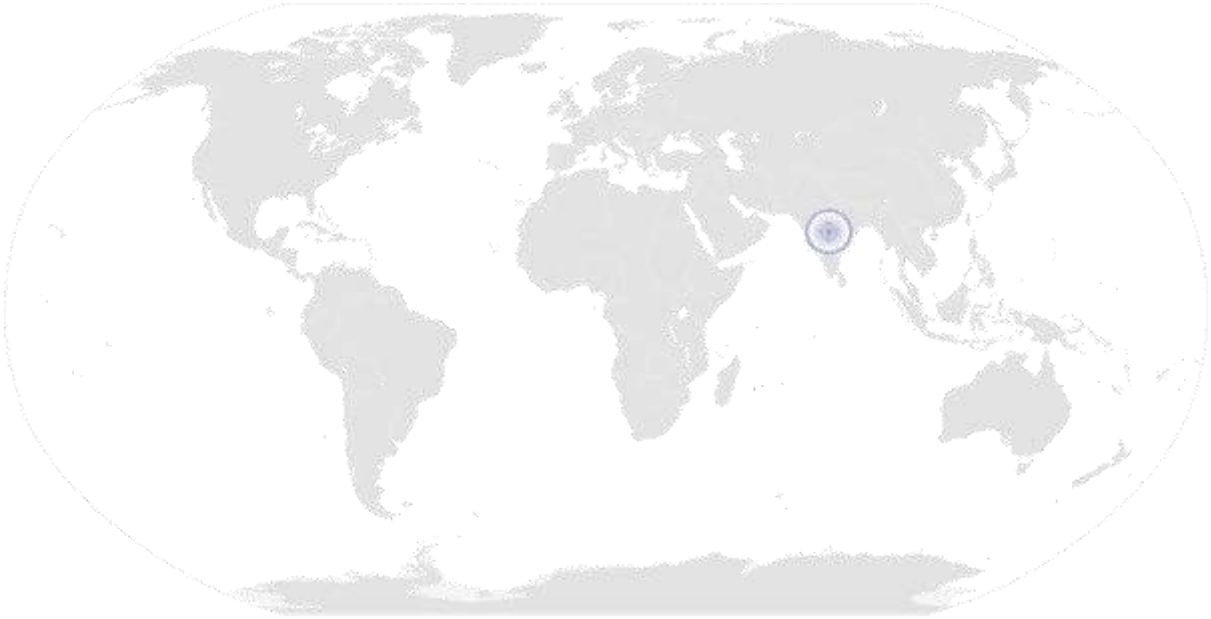
LFS/N0101 : Maintain healthy, safe and secure working environment in the life sciences facility

	SA3. listen effectively and orally communicate information accurately
B. Professional Skills	**Decision making**
	The user/ individual on the job needs to know and understand how to: SB1. make decisions on suitable courses of action
	Plan and Organise
	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
	Problem solving
	The user/ individual on the job needs to know and understand how to: SB3. apply problem solving approaches in different situations
	Analytical thinking
	The user/ individual on the job needs to know and understand how to: SB4. analyse data and activities
	Critical thinking
	The user/ individual on the job needs to know and understand how to: SB5. apply balanced judgments to different situations
	Customer centricity
	Not Applicable

LFS/N0101 : **Maintain 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



Annexure

Nomenclature for QP and NOS

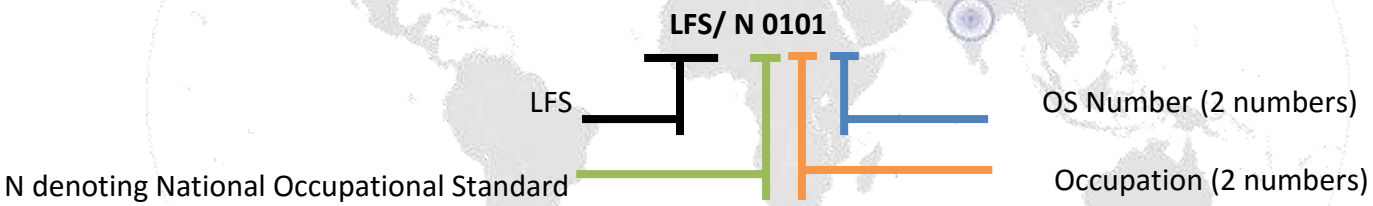
Qualifications Pack

9 characters

Occupational Standard

An example of NOS with 'N'

9 characters



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	N
Next two numbers	Occupation code	01
Next two numbers	OS number	01

CRITERIA FOR ASSESSMENT OF TRAINEES

Job Role Validation Supervisor
Qualification Pack LFS/Q0305
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 (600)**	**Out Of**	**Theory**	**Practical**
LFS/N0312 (Monitor and conduct cleaning, process and equipment validation activities during the manufacturing process)	PC1. ensure and assist in the implementation of the overall validation program for systems, facilities, equipment, manufacturing processes and cleaning activities	100	5	2	3
	PC2. ensure support in preparation of validation protocols, , inspection maps and timely review and approval of validation protocols/summary reports, master plans and SOPs		5	3	2
	PC3. support in compilation of deviations, change controls and report the defect trends		5	3	2
	PC4. setup appropriate equipment or apparatus for		5	2	3

	testing				
	PC5. calibrate the testing equipment periodically as per the SOP		5	2	3
	PC6. identify defective equipment/apparat us, materials and processes and corrective steps to be taken		5	2	3
	PC7. release or hold the production for further inspection as per findings		5	2	3
	PC8. ensure that disposal of waste and leftover tested material is carried on safely as per the SOP		4	2	2
	PC9. ensure the disposal of all materials used in the experiment safely as per health and safety management system of the company		4	2	2
	PC10. monitor and adjust the processes to achieve required quality outcomes and support teams during tech transfers		5	3	2
	PC11. take corrective action in response to typical faults and inconsistencies		5	3	3
	PC12. troubleshoot/investigate validationrelated deviations		5	2	3
	PC13. ensure that all safety measures are in place		5	2	3
	PC14. review and approve facility equipment and software changes		5	2	3
	PC15. take up the results of the findings with the appropriate authority		5	2	3
	PC16. conduct sampling tests to ensure the use of quality procedures as per		6	2	3

	approved/standard protocols				
	PC17. ensure that sampling is done as per the process flow sheet with control points mentioned in protocols		5	2	3
	PC18. identify the sample by labeling/numbering as per the SOP		5	2	3
	PC19. ensure that sample quality is same as mentioned in protocol for test/analysis		5	2	3
	PC20. identify defect/problem		6	3	3
	Total		100	45	55
LFS/N0313 (Provide guidance to workmen on validation issues and documentation)	PC1 identify the existing level knowledge among the work r regarding validation issues	100	5	2	3
	PC2. identify the requirements of the workmen regarding validation issues		10	5	5
	PC3. provide guidance on validation issues and documentation regarding quality checks		10	5	5
	PC4. communicate validation issues and requirements to plant personnel on a frequent basis		10	5	5
	PC5. communicate any potential hazards or expected process disruptions		5	2	3
	PC6. ensure that there is adequate usage of safety measures for the work being carried out		10	5	5
	PC7. ensure that GMP are being followed		10	5	5
	PC8. ensure that the quality of the products, process and equipment is as per standards		5	2	3
	PC9. report to the appropriate person any		5	2	3

	disturbances in material flow or equipment				
	PC10. ensure that there is no oily substance on the floor to avoid slippage		5	2	3
	PC11. ensure that no scrap material is lying around		5	2	3
	PC12. follow work place procedures to deal with any accidental damage caused during the production process		5	2	3
	PC13. ensure that the work place is left clean and dry and meets requirements on completion of the work		5	2	3
	PC14. ensure that the equipment, materials and personal protective equipment that were used are returned to the right places making sure they are clean, safe and securely stored		5	2	3
	PC15. ensure that the waste garnered from the activity is disposed in an appropriate manner		5	2	3
	Total		100	40	60
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-		8	4	4

	task relevant activities				
	PC8 impart training to team members/cross-function team members		14	6	8
	Total		100	46	54
LFS/N0308 (Work with cross functional teams)	PC1. work closely with QA site support team and QA validation team to ensure alignment between quality systems	100	20	10	10
	PC2. identify the existing level of knowledge among the employees/workers regarding validation issues		20	10	10
	PC3. identify the training requirements for the employees/workmen regarding validation issues		10	5	5
	PC4. work closely with manufacturing groups to ensure effective communication on issues related to validation		20	10	10
	PC5. communicate validation issues and requirements to plant personnel on frequent basis through participation in engineering, R&D and management staff meetings, as well as applicable project teams		20	10	10
	PC6. maintain close communication with stakeholders and team members to keepthem apprised of computerized system needs, impacts on computer		10	5	5

	validation,project validation status,and other relevant issues				
	Total		100	50	50
LFS/N0314 (Carry out reporting and documentation to meet quality standards)	PC1. report defects/problem/incidents/ quality issues/test results as applicable in a timely manner	100	10	5	5
	PC2. report to the appropriate authority as laid down by the company		3	1	2
	PC3. follow reporting procedures as prescribed by the company		4	2	2
	PC4. work with production management and quality assurance to provide feedback regarding quality standards and issues		4	2	2
	PC5. help other R&D lab staff with any other testing required during the developmental work		4	2	2
	PC6. identify documentation to be completed relating to one's role		7	3	4
	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/N0101 (Maintain a safe, healthy and secure working environment)	PC1. observe and comply with the company's current health, safety and security policies and procedures	100	10	5	5
	PC2. whilecarrying 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,		10	5	5

	competently and within the limits of their authority				
	PC6. adhere and comply to storage and handling guidelines for hazardous material		10	5	5
	PC7. identify and recommend opportunities for improving health, safety, and security to the designated person		10	5	5
	PC8. Complete any health, safety and security records legibly and accurately		10	4	6
	PC9. report any hazards that the individual is not competent to deal with to the relevant person in line with organizational procedures and warn other people who may be affected		10	4	6
	PC10. follow the company's procedures promptly, calmly and efficiently		10	5	5
	Total		100	48	52