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: 14 Palam Marg, 2nd rear Floor, Vasant Vihar, New Delhi-110057

E-mail: info@lsssdc.in

Introduction

Qualifications Pack-Drug Regulatory Affairs Chemist

SECTOR: LIFE SCIENCES

SUB-SECTOR: PHARMACEUTICAL AND BIOPHARMACEUTICAL

OCCUPATION: RESEARCH AND DEVELOPMENT

REFERENCE ID: LFS/Q0501

ALIGNED TO: NCO-2004/NIL

Drug Regulatory Affairs Chemist prepares dossiers to support appropriate licensing, marketing and legal compliance of products, ensure products comply with regulations and carry out proper documentation and reporting.

Brief Job Description: DRA Chemists are responsible for making dossiers submitted to the various markets and also ensue completion for forms and carry out filling of regulatory forms.

Personal Attributes: The individual should have good knowledge of the Pharmaceutical industry. He should have good documentation skills and understanding of regulatory and ethical frameworks. He should be well versed with compliance and statuary requirements for dossier preparations.

Qualifications Pack Code	**LFS/Q0501**		
Job Role	**Drug Regulatory Affairs Chemist**		
Credits(NSQF)	**TBD**	**Version number**	**1.0**
Industry	**Life Sciences**	**Drafted on**	**9/12/14**
Sub-sector	**Pharmaceutical and Biopharmaceutical**	**Last reviewed on**	**01/08/16**
Occupation	**Research and Development**	**Next review date**	**01/08/19**
NSQC Clearance on	**20/07/2015**		

Job Role	**Drug Regulatory Affairs Chemist**
Role Description	Responsible for making dossiers to be submitted to the various markets and also fill forms and take regulatory permission forms.
NSQF level	5
Minimum Educational Qualifications	Polytechnic Diploma Chemical Engineering/ Graduate in Science/ B.Pharmacy (Preferable)/ B.Tech or BE. Chemical Engineering
Maximum Educational Qualifications	Masters in science/ M. Pharmacy (Preferable)
Training (Suggested but not mandatory)	On the job training, On the job training, GLP Training
Minimum Job Entry Age	20 Years
Experience	0-2 years (if company is making only CTD), else 1-3 years experience
Applicable National Occupational Standards (NOS)	**Compulsory:** 1. LFS/N0501: Ensure appropriate licensing, marketing and legal compliance of pharmaceutical and medical products. 2. LFS/N0503: Ensure that the products comply with the regulations 3. LFS/N0502: Carryout reporting and documentation for dossier preparation 4. LFS/N0105: Coordinate with manager and team members for smooth functioning

Job Details

	Optional: N.A.
Performance Criteria	As described in the relevant NOS 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
SOP	Standard Operating Procedures
GMP	Good Manufacturing Practices
ISO	International Organization for Standardization
QC	Quality Control
OHSAS	Occupational Health and Safety Management System

National Occupational Standard

Overview

This Occupational Standard describes the knowledge, understanding and skills required for a DRA Chemist to ensure appropriate licensing, marketing and legal compliance of pharmaceutical and medical products.

LFS/N0501 : Ensure appropriate licensing, marketing and legal compliance of pharmaceutical and medical products

National Occupational Standard

Unit Code	**LFS/N0501**
Unit Title (Task)	**Ensure appropriate licensing, marketing and legal compliance of pharmaceutical and medical products.**
Description	This NOS is about a DRA chemist to ensure appropriate licensing, marketing and legal compliance of pharmaceutical and medical products
Scope	The unit/task covers the following: • Preparing protocols and reports to ensure compliance for licensing activities • Assisting scientists and manufacturers on regulatory requirements

Performance Criteria (PC) w.r.t. the Scope	
Element	**Performance Criteria**
Licensing Activities	To be competent, the user/individual on the job must be able to: PC1. prepare documents, non-conformance reports and corrective action preventative action documents for current products and procedures to ensure compliance with applicable regulation PC2. develop and write clear arguments and explanations for new product licences and licence renewals PC3. monitor and set timelines for licence variations and renewal approvals PC4. write clear, accessible product labels and patient information leaflets PC5. undertake and manage regulatory inspections PC6. prepare dossiers/ documents for IND, NDA, ANDA, CTD Submissions and also to support registrations of the new entities PC7. liaison with, and make presentations to, regulatory authorities PC8. develop and register new medicines, vaccines, diagnostic tests and pharmaceutical products with regulatory authorities like MHRA, MCC, USFDA, TGA, Malaysia, European Union etc in concurrence with the regulations promulgated by a whole range of agencies like the Environmental Protection Agency, Federal Trade Commission, Occupational Safety & Health Administration and Drug Enforcement Administration PC9. manage and oversee the laboratory work PC10. review company practices and providing advice on changes to systems PC11. identify and assess regulatory risks and project issues and make recommendations to regulatory management PC12. associating with the marketing personnel to ensure applicability of regulatory framework PC13. keep abreast of international legislation, guidelines and customer practices in all countries where the Company sells its products
Assistance to other team	PC14. assist scientists, medical writers and manufacturers on regulatory requirements PC15. provide regulatory related advice to senior management throughout the development of a new product PC16. assist project managing teams of colleagues involved with the development of new products

LFS/N0501 : Ensure appropriate licensing, marketing and legal compliance of pharmaceutical and medical products

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, ISO-14001, OHSAS-18000), good laboratory and manufacturing practices KA2. organizational Coding system of finished material, compounds and company manual KA3. escalation matrix for reporting identified issues KA4. records to be maintained and implications of non-maintenance of the same KA5. health, Safety and Environment guidelines, legislation and regulations as applicable KA6. the reason and impact of the occurrence of problems KA7. measures, steps and possible solutions that have been taken/identified to address the previous problems KA8. the correct method for carrying out corrective actions outlined for each problem
B. Technical Knowledge	The user/individual on the job needs to know and understand: KB1. broad knowledge of Regulatory Affairs and specific working knowledge of current regulations and guidance KB2. excellent knowledge of IND, NDA, ANDA, CTD Submissions KB3. knowledge of regulatory authorities like MHRA, MCC, USFDA, TGA, Malaysia, European Union etc in concurrence with the regulations promulgated by a whole range of agencies like the Environmental Protection Agency, Federal Trade Commission, Occupational Safety & Health Administration and Drug Enforcement Administration KB4. associated experience in Quality Assurance and Document Control is required in certain cases KB5. knowledge of pharmaceutical dossiers like the master formula of the product, manufacturing procedure and the equipments list used in the production, the Stability data, preclinical and clinical data, specifications used in testing the final product and other regulatory documents KB6. adequate training for the competent performance of tests, operation of equipment and basic techniques, e.g. counting of colonies, plate pouring, serial dilutions, etc. KB7. training in necessary procedures for filing licenses and liaising with regulatory authorities of different countries KB8. good knowledge of GMP, GLP and Safety requirements KB9. use of sophisticated scientific/laboratory instruments KB10. testing equipment and related test method and purpose of tests KB11. national/international standard test methods for different compounds KB12. factors that adversely affect integrity of the sample

LFS/N0501 : Ensure appropriate licensing, marketing and legal compliance of pharmaceutical and medical products

Skills (S)	
A. Core Skills/Generic Skills	**Writing Skills**
	SA1. excellent report writing skills SA2. record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail SA3. maintain proper records as per given format
	Reading & Understanding Skills
	SA4. read and understand manuals, SOPs, health and safety instructions, memos, reports, job cards etc SA5. read images, graphs, diagrams SA6. understand the various coding systems as per company norms
	Oral Communication (Listening and Speaking skills)
	SA7. communication with upstream and downstream teams SA8. communicate with job owners like sample originating section, supplier etc. SA9. work in a team and other behavioral skills required to support the small group activities (eg. quality circle, cross functional team, suggestion scheme) SA10. disclose information only to those who have the right and need to know it SA11. maintain confidentiality of information
B. Professional Skills	**Decision Making**
	The user/individual on the job needs to know and understand how to: SB1. act objectively , rather than impulsively or emotionally when faced with difficult/stressful or emotional situations
	Analytical Thinking
	SB2. arithmetic aptitude SB3. application of statistics to analyse trends and data SB4. use of computer/ application software SB5. attention to detail SB6. use the existing data to arrive at specific point
	Plan and Organise
	SB7. planning skills with the ability to multi-task and adapt SB8. ability to prioritize needs and effectively schedule work to effectively support multiple projects at one time SB9. take responsibility for completing one's own work assignment SB10. take initiative to enhance/learn skills in ones's area of work SB11. the capacity to learn from experience in a range of settings and scenarios and the capacity to reflect on and analyse one's learning SB12. is open to new ways of doing things SB13. the capacity to envisage and articulate personal goals; to develop strategies and take action to achieve them
	Problem Solving
	SB14. ability to identify, define and resolve problems using a structured methodology

LFS/N0501 : Ensure appropriate licensing, marketing and legal compliance of pharmaceutical and medical products

	SB15. resolve any difficulties in relationships with colleagues , or get help from an appropriate person, in a way that preserves goodwill and trust
	Critical Thinking
	SB16. suggest improvements(if any) in process based on experience
	Customer Centricity
	NA

LFS/N0501 : Ensure appropriate licensing, marketing and legal compliance of pharmaceutical and medical products

NOS Version Control

NOS Code	LFS/N0501		
Credits(NSQF)	TBD	Version number	
Industry	Life Sciences	Drafted on	09/12/14
Industry Sub-sector	Pharmaceutical and Bio Pharmaceuticals	Last reviewed on	01/08/16
Occupation	R&D	Next review date	01/08/19

National Occupational Standard

Overview

This Occupational Standard describes the knowledge, understanding and skills required of a DRA Chemist to ensure that the products comply with the regulations.

LFS/N0503 : Ensure that the products comply with the regulations

National Occupational Standard

Unit Code	**LFS/N0503**
Unit Title (Task)	**Ensure that the products comply with the regulations**
Description	This NOS is about a DRA chemist to ensure that the products comply with regulations
Scope	The unit/task covers the following: • Ensure that quality is maintained • Support research • Validate test methods

Performance Criteria (PC) w.r.t. the Scope	
Element	**Performance Criteria**
Quality Checks	To be competent, the user/individual on the job must be able to: PC1. ensure that the product is according to standards and regulations PC2. ensure that GMP and GLP are followed PC3. evaluate compliance procedures for new products
Research	PC4. supervise the work of biological technicians and other workers to evaluate accuracy of their results PC5. work with technicians, chemists and scientists of other fields as many scientific research projects involve multiple disciplines PC6. present research findings to scientists, non-scientist executives, engineers ,other colleagues, and the public PC7. work with specialist computer software to undertake studies and research
Validate test methods	PC8. support continuous process performance evaluation and continuous process improvement for highest efficiency PC9. keep up with new research PC10. minimize the risks of cross-contamination, false-positive results and false-negative PC11. define alert and action limits

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, ISO-14001, OHSAS-18000), good laboratory and manufacturing practices KA2. organizational coding system of finished material, compounds and company manual KA3. implications of not adhering to quality control procedures KA4. quality requirements and products and processes KA5. quality and damage checks to be done and importance of the same KA6. quality control procedures followed by the company and importance of the same

LFS/N0503 : Ensure that the products comply with the regulations

	KA7. escalation matrix for reporting identified issues KA8. records to be maintained and implications of non-maintenance of the same KA9. impact of poor practices on health, safety and environment KA10. impact of various practices on cost, quality, productivity, delivery and safety KA11. handover/ takeover the equipment/ work area as per company's SOP KA12. the levels of hygiene required by workplace and importance of maintaining the same KA13. reporting incidents where standard operating procedures are not followed KA14. the importance of complete and accurate documentation KA15. the importance of quality control procedures KA16. the reason and impact of the occurrence of problems KA17. measures, steps and possible solutions that have been taken/identified to address the previous problems KA18. the correct method for carrying out corrective actions outlined for each problem
B. Technical Knowledge	The user/individual on the job needs to know and understand: KB1. broad knowledge of regulatory affairs and specific working knowledge of current regulations and guidance KB2. characteristics and composition of products KB3. health, safety and environment guidelines, legislation and regulations as applicable KB4. associated experience in quality assurance and document control is required in certain cases KB5. knowledge of pharmaceutical dossiers like the master formula of the product, manufacturing procedure and the equipments list used in the production, the stability data, preclinical and clinical data, specifications used in testing the final product and other regulatory documents KB6. training in necessary procedures for filing licenses and liaising with regulatory authorities KB7. broad knowledge of GMP, GLP and Safety requirements KB8. importance of quality checks along with quality and production targets KB9. standard method of drawing samples and preparing them for testing KB10. methods and techniques involved in evaluating information KB11. current knowledge of starting-up and qualifying new facilities, tech transfers and manufacturing operations
Skills (S)	
A. Core Skills / Generic Skills	**Writing Skills** SA1. excellent report writing skills SA2. record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail SA3. maintain proper records as per given format

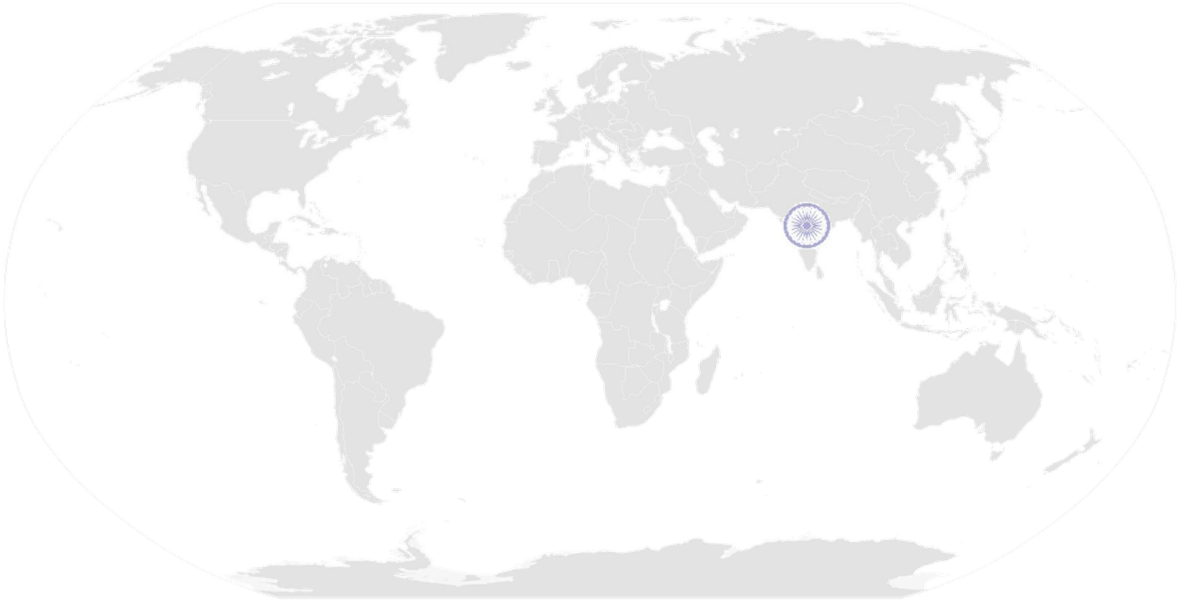
LFS/N0503 : Ensure that the products comply with the regulations

	Reading & Understanding Skills
	SA4. read and understand manuals, SOPs, health and safety instructions, memos, reports, job cards etc SA5. read images, graphs, diagrams SA6. understand the various coding systems as per company norms
	Oral Communication (Listening and Speaking skills)
	SA7. communication with upstream and downstream teams SA8. communicate with job owners like sample originating section, supplier etc. SA9. work in a team and other behavioral skills required to support the small group activities (eg. quality circle, cross functional team, suggestion scheme) SA10. disclose information only to those who have the right and need to know it SA11. maintain confidentiality of information
B. Professional Skills	**Decision Making**
	The user/individual on the job needs to know and understand how to: SB1. act objectively , rather than impulsively or emotionally when faced with difficult/stressful or emotional situations
	Analytical Thinking
	SB2. arithmetic aptitude SB3. application of statistics to analyse trends and data SB4. use of computer/ application software SB5. attention to detail SB6. use the existing data to arrive at specific point
	Plan and Organise
	SB7. planning skills with the ability to multi-task and adapt SB8. ability to prioritize needs and effectively schedule work to effectively support multiple projects at one time SB9. take responsibility for completing one's own work assignment SB10. take initiative to enhance/learn skills in ones's area of work SB11. the capacity to learn from experience in a range of settings and scenarios and the capacity to reflect on and analyse one's learning SB12. is open to new ways of doing things SB13. the capacity to envisage and articulate personal goals; to develop strategies and take action to achieve them
	Problem Solving
	SB14. ability to identify, define and resolve problems using a structured methodology SB15. resolve any difficulties in relationships with colleagues , or get help from an appropriate person, in a way that preserves goodwill and trust
	Critical Thinking
	SB16. suggest improvements(if any) in process based on experience
	Customer Centricity
	NA

NOS Version Control

NOS Code	LFS/N0503		
Credits(NSQF)	TBD	Version number	
Industry	Life Sciences	Drafted on	09/12/14
Industry Sub-sector	Pharmaceuticals and Bio Pharmaceuticals	Last reviewed on	25/02/15
Occupation	R&D	Next review date	25/02/16

National Occupational Standard



Overview

This Occupational Standard describes the knowledge, understanding and skills required of a DRA Chemist to carry out reporting and documentation for dossier preparation.

LFS/N0502 : Carry out reporting and documentation for dossier preparation

National Occupational Standard

Unit Code	**LFS/N0502**
Unit Title (Task)	**Carry out reporting and documentation for dossier preparation**
Description	This NOS explains the reporting and documentation performed by a DRA Chemist to meet quality standards and ensure that the final documents meet regulatory and compliance requirements for dossier preparation.
Scope	The unit/task covers the following: 1. Reporting of defects/problem/incidents/quality issues/test results 2. Recording and Documentation 3. 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 ina 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 & Documentation	PC6. identify documentation to be completed relating to one's role for dossier preparation PC7. record details accurately in appropriate format prescribed by regulatory authorities 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
Information Security	PC11. respond to requests for information in an appropriate manner whilst following organizational procedures PC12. 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. different quality management systems (ISO-9000, ISO-14001, OHSAS-18000), good laboratory and manufacturing practices KA2. quality requirements and products and processes KA3. quality and damage checks to be done and importance of the same KA4. impact of various practices on cost, quality, productivity, delivery and safety KA5. handover/ Takeover the equipment/ work area as per company's SOP

LFS/N0502 : Carry out reporting and documentation for dossier preparation

	KA6. the levels of hygiene required by workplace and importance of maintaining the same KA7. reporting incidents where standard operating procedures are not followed KA8. the importance of complete and accurate documentation KA9. the importance of quality control procedures
B Technical Knowledge	The user/individual on the job needs to know and understand: KB1. knowledge of pharmaceutical dossiers like the master formula of the product, manufacturing procedure and the equipments list used in the production, the Stability data, preclinical and clinical data, specifications used in testing the final product and other regulatory documents KB2. training in necessary procedures for filing licenses and liaising with regulatory authorities KB3. good Knowledge of GMP, GLP and Safety requirements KB4. use of computer/application software KB5. importance of quality checks along with quality and production targets KB6. standard method of drawing samples and preparing them for testing KB7. methods and techniques involved in evaluating information KB8. units of measurement KB9. current knowledge or proven interest in starting-up and qualifying new facilities, tech transfers and manufacturing operations KB10. statistical analysis of test data
Skills (S)	
A . Core / 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 SA2. maintain proper records as per 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. ability to read and interpret images, graphs, diagrams for typical product specifications, job sheets, procedures, basic machine control panels, material labels and safety information as provided SA5. 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: SA6. disclose information only to those who have the right and need to know it.

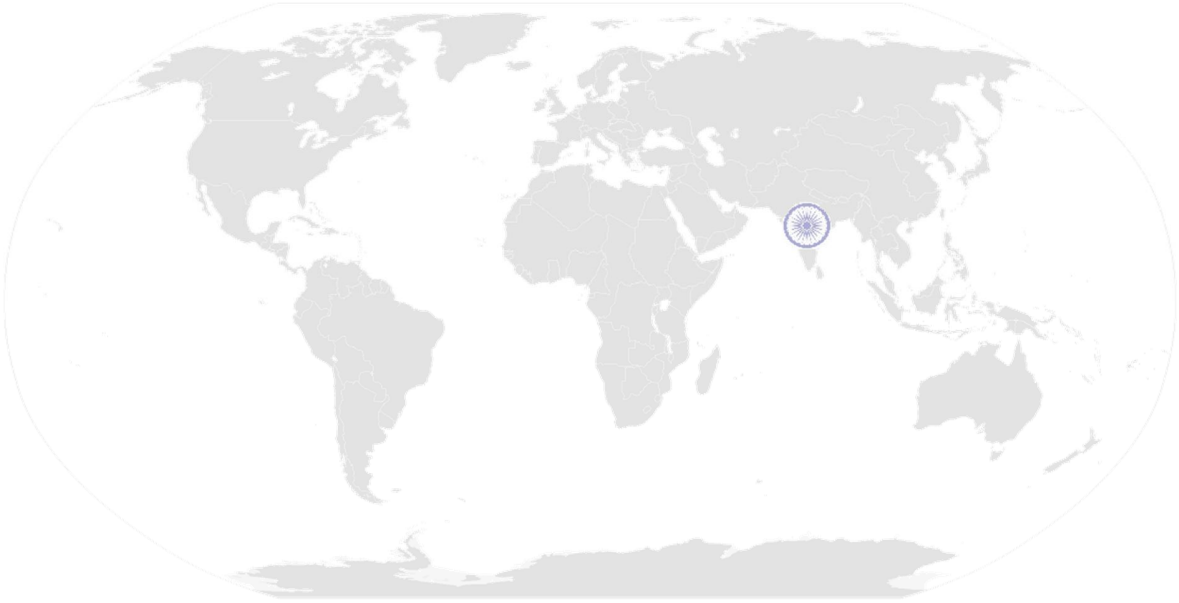
LFS/N0502 : Carry out reporting and documentation for dossier preparation

	SA7. communicate confidential and sensitive information discretely to authorized person as per SOP SA8. communicate with people in a form and manner and using language that is open and respectful
B. Professional Skills	**Analytical Thinking**
	The user/individual on the job needs to know and understand how to: SB1. attention to detail SB2. use of automated report writing and documentation technologies
	Critical Thinking
	The user/individual on the job needs to know and understand how to: SB3. 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: SB4. capacity and skill to learn from experience in a range of settings and scenarios and the capacity to reflect on and analyze one's learning.
	Problem Solving
	The user/individual on the job needs to know and understand how to: SB5. act objectively , rather than impulsively or emotionally when faced with difficult/stressful or emotional situations
	Decision Making
	NA
	Customer Centricity
	NA

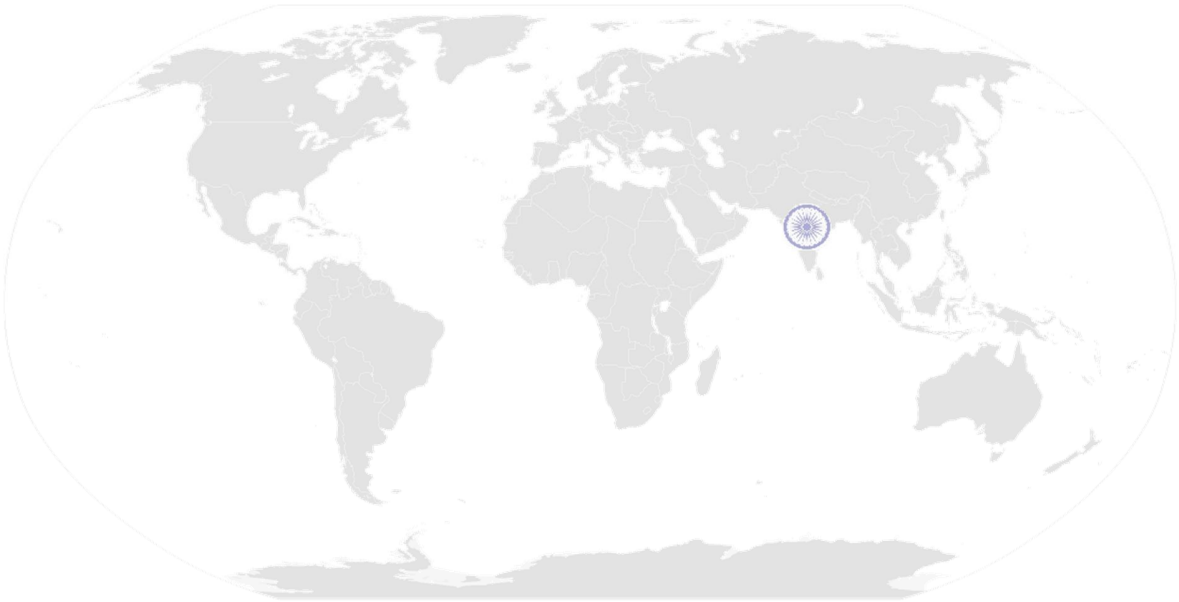
LFS/N0502 : Carry out reporting and documentation for dossier preparation

NOS Version Control

NOS Code	LFS/N0502		
Credits(NSQF)	TBD	Version number	
Industry	Life Sciences	Drafted on	09/12/14
Industry Sub-sector	Pharmaceutical and Bio Pharmaceuticals	Last reviewed on	01/08/16
Occupation	Quality, R&D	Next review date	01/08/19



National Occupational Standard



Overview

This Occupational Standard describes the knowledge, understanding and skills required of a DRA Chemist to effectively coordinate with manager and team members for smooth functioning.

LFS/N0105 : Coordinate with manager and team members for smooth functioning

National Occupational Standard

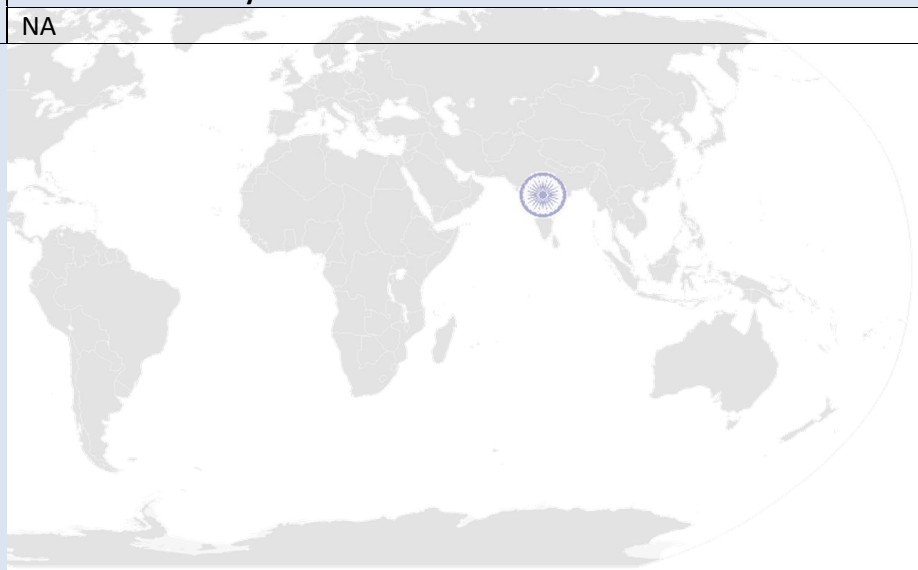
Unit Code	**LFS/N0105**
Unit Title (Task)	**Coordinate with managers and team members for smooth functioning.**
Description	This NOS unit is about the DRA Chemist's carrying out effective coordinate with managers and team members.
Scope	The unit/task covers the following: • Coordinating with manager • Coordinating with team members
Performance Criteria (PC) w.r.t. the Scope	
Element	**Performance Criteria**
Coordination with Manager	PC1. receive work instructions from reporting manager PC2. communicate to reporting supervisor about process-flow improvements, quality defects received from previous process PC3. communicate any potential hazards or expected process disruptions PC4. provide requisite information, documents, clarifications to manager during actual audits
Coordination with team members	PC1. work as a team with colleagues and share work as per their or own workload and skills. PC2. support/assign personnel/team members to support internal and external audit activities as per instructions of superiors/supervisor. PC3. provide documented shift handovers to the next person in the shift. PC4. communicate and discuss work flow related difficulties in order to find solutions with mutual agreement. PC5. provide support in training initiatives
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 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. commercial awareness of pharmaceutical products and overall healthcare sector
Skills (S)	

LFS/N0105 : Coordinate with manager and team members for smooth functioning

A. Core / 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 formal
	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, memo SA4. read images, graphs, diagrams SA5. 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: SA6. communication with upstream and downstream teams SA7. communicate with job owners like sample originating section, supplier etc. SA8. maintain confidentiality of information and data SA9. communicate with people in a form and manner and using language that is open and respectful SA10. clear and timely communication for trust building
B. Professional Skills	**Decision Making**
	The user/individual on the job needs to know and understand how to: SB1. strong emotional intelligence and communication skills that facilitate decision making and execution SB2. appropriate skill to analyse the available information and take timely decisions to improve coordination and increase business
	Plan and Organise
	The user/individual on the job needs to know and understand how to: SB3. develop specific goals and plans to priorities SB4. organize and accomplish work SB5. follow up with other members to evaluate progress, give constructive feedback and praise to other for work well done SB6. take responsibility for completing one's own work assignment SB7. take initiative to enhance/learn skills in one's area of work SB8. capacity to learn from experience in a range of settings and scenarios and the capacity to reflect on and analyze one's learning SB9. open to new ways of doing things SB10. effective delegation and leading without authority
	Problem Solving

LFS/N0105 : Coordinate with manager and team members for smooth functioning

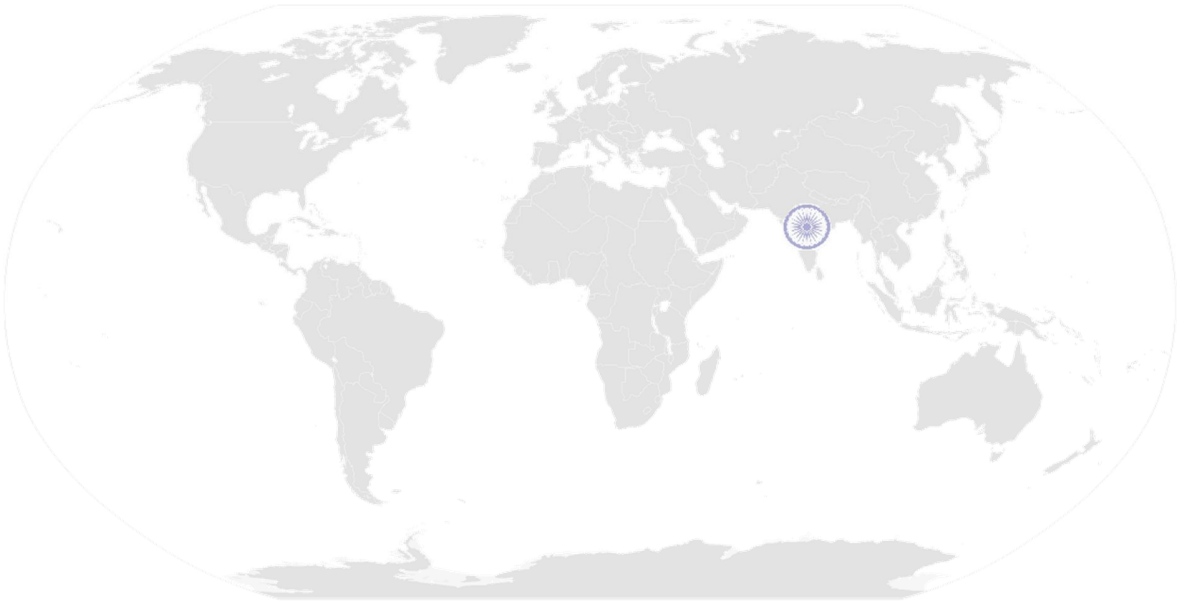
	The user/individual on the job needs to know and understand how to: SB11. act objectively , rather than impulsively or emotionally when faced with difficult/stressful or emotional situations SB12. resolve any difficulties in relationships with colleagues , in a way that preserves goodwill and trust SB13. ability to communicate, solve conflicts, negotiate on behalf of the team and company
	Critical Thinking
	SB14. spot and communicate potential areas of disruptions to work process and report the same
	Analytical Thinking
	NA
	Customer Centricity
	NA



LFS/N0105 : Coordinate with manager and team members for smooth functioning

NOS Version Control

NOS Code	LFS/N0105		
Credits(NSQF)	TBD	Version number	
Industry	Life Sciences	Drafted on	09/12/14
Industry Sub-sector	Pharmaceutical and Bio Pharmaceuticals	Last reviewed on	01/08/16
Occupation	Quality, R&D	Next review date	01/08/19



Annexure

Nomenclature for QP and NOS

Qualification Pack

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 for Drug Regulatory Affairs Chemist

CRITERIA FOR ASSESSMENT OF TRAINEES

Job Role Drug Regulatory Affairs Chemist
Qualification Pack LFS/Q0501
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 Outcomes**	**Total Marks**	**Out of**	**Theory**	**Practical**
LFS/N0501 (Ensure appropriate licensing, marketing and legal compliance of pharmaceutical and medical products)	PC1. prepare documents, non-conformance reports and corrective action, Preventative action documents for current products and procedures to ensure compliance with applicable regulation	100	7	3	4
	PC2. develop and write clear arguments and explanations for new product licences and licence renewals		7	3	4
	PC3. monitor and set timelines for licence variations and renewal approvals		5	3	2
	PC4. write clear, accessible product labels and patient information leaflets		5	2	3

	PC5. undertake and manage regulatory inspections		7	3	4
	PC6. prepare dossiers/ documents for IND, NDA, ANDA, CTD Submissions and also to support registrations of the new entitie		10	5	5
	PC7. liaison with, and make presentations to, regulatory authorities		8	4	4
	PC8. develop and register new medicines, vaccines, diagnostic tests and pharmaceutical products with regulatory authorities like MHRA, MCC, USFDA, TGA, Malaysia, European Union etc in concurrence with the regulations promulgated by a whole range of agencies like the Environmental Protection Agency, Federal Trade Commission, Occupational Safety & Health Administration and Drug Enforcement Administration		7	3	4
	PC9. manage and oversee the laboratory work		5	2	3
	PC10. review company practices and providing advice on changes to systems		5	2	3
	PC11. identify and assess regulatory risks and project issues and make recommendations to regulatory management		7	3	4
	PC12. associating with the marketing personnel to ensure applicability of Regulatory framework		7	3	4
	PC13. keep abreast of international legislation, guidelines and customer practices in all countries		5	3	2

	where the Company sells its products				
	PC14. assist scientists and manufacturers on regulatory requirements		5	2	3
	PC 15. provide regulatory related advice to senior management throughout the Development of a new product		5	2	3
	PC 16. assist project managing teams of colleagues involved with the development of new products		5	2	3
		Total	100	45	55
LFS/N0503 (Ensure that the products comply with the regulations)	PC1. ensure that the product is according to standards and regulations	100	10	5	5
	PC2. ensure that GMP and GLP are followed		10	5	5
	PC3. evaluate compliance procedures for new products		10	5	5
	PC4. supervise the work of technicians and other workers to evaluate Accuracy of their results		5	2	3
	PC5. work with technicians, chemists and scientists of other fields as many Scientific research projects involve multiple disciplines		10	5	5
	PC6. present research findings to scientists, non-scientist executives, engineers, Other colleagues, and the public		10	5	5
	PC7. work with specialist computer software to undertake studies and research		10	5	5
	PC8. support continuous process performance evaluation and continuous Process improvement for highest efficiency		5	2	3

	PC9. keep up with new research		5	2	3
	PC10.minimize the risks of cross-contamination, false-positive results and false-negative		10	5	5
	PC11. define alert and action limits		5	2	3
	PC12. support continuous process performance evaluation and continuous Process improvement for highest efficiency		10	5	5
		Total	100	48	52
LFS/N0509 (Carry out reporting and documentation to prepare dossiers)	PC1. report defects/ problem/ incidents/quality issues/test results as applicable in a timely manner	100	6	3	3
	PC2. report to the appropriate authority as laid down by the company		6	3	3
	PC3. follow reporting procedures as prescribed by the company		6	3	3
	PC4. work with production management and Quality Assurance to provide Feedback regarding quality standards and issues		5	2	3
	PC5. help other R&D lab staff with any other testing required during the developmental work		6	3	3
	PC6.identify documentation to be completed relating to one's role		6	3	3
	PC7.record details accurately inappropriate format		7	3	4
	PC8.accurately document the results of the inspections and testing		6	3	3
	PC9.maintain all controlled document files and test records in a timely and Accurate manner		6	3	3

	PC10.ensure that the final document meets regulatory and compliance requirements		6	3	3
	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		7	3	4
	PC13.perform review of records and other documentation for compliance to Established procedures and Good Documentation Practices		6	3	3
	PC14.write and update the inspection procedures, protocols and checklists		6	3	3
	PC15.prepare inspection reports as per the inspection activity performed		7	3	4
	PC16.respond to requests for information in an appropriate manner whilst Following organizational procedures		5	2	3
	PC17. inform the appropriate authority of requests for information received		4	2	2
		Total	100	47	53
LFS/N0105 (Coordinate with manager and team members)	PC1. receive work instructions from reporting manager	**100**	20	10	10
	PC2. communicate to reporting supervisor about process-flow improvements, quality defects received from previous process		18	8	10
	PC3. communicate any potential hazards or expected process disruptions		13	5	8
	PC4. provide requisite information, documents,		11	5	6

	clarifications to manager during actual audits				
	PC5. work as a team with colleagues and share work as per their or own work load and skills		8	4	4
	PC6. support/assign personnel/team members to support internal and external audit activities as per instructions of superiors/supervisor		8	4	4
	PC7. provide documented shift handovers to the next person in the shift		8	4	4
	PC8. communicate and discuss workflow related difficulties in order to find solutions with mutual agreement		7	3	4
	PC9. provide support in training initiatives		7	3	4
	Total		100	46	54