

## QUALIFICATIONS PACK - OCCUPATIONAL STANDARDS FOR LIFE SCIENCES INDUSTRY

### What are Occupational Standards (OS)?

- OS describe what individuals need to do, know and understand in order to carry out a particular job role or function
- OS are performance standards that individuals must achieve when carrying out functions in the workplace, together with specifications of the underpinning knowledge and understanding

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## Introduction

### Qualifications Pack-Scientific Medical Writer

**SECTOR:** LIFE SCIENCES

**SUB-SECTOR:** PHARMACEUTICAL, BIO PHARMACEUTICAL, CONTRACT RESEARCH

**OCCUPATION:** R&D

**JOB ROLE:** SCIENTIFIC MEDICAL WRITER

**REFERENCE ID:** LFS/Q0506

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

**Scientific Medical Writer** creates documents that effectively and clearly state all the requisite medical/scientific information and ensures that the prescribed standards of quality, compliance and regulatory requirements are fulfilled in preparation of these documents.

**Brief Job Description:** The role holder is responsible for creating documents that effectively and clearly describe scientific details, composition, use, and other medical information of the product. The medical writer also ensures that the documents comply with regulatory, scientific or other guidelines in terms of content, format, and structure.

**Personal Attributes:** The individual should have good knowledge of standard documentation procedures, rules, regulations and statutory requirements in preparation of scientific documents. The individual must demonstrate attention to detail and proactive behaviour.

Job Details

Qualifications Pack Code	LFS/Q0506		
Job Role	Scientific Medical Writer		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	15/12/14
Sub-sector	Pharmaceutical, Bio Pharmaceutical and Contract Research	Last reviewed on	01/08/16
Occupation	R&D	Next review date	01/08/19
NSQC Clearance on	20/07/2015		

Job Role	Scientific Medical Writer
Role Description	Responsible for creating documents that effectively and clearly describe scientific details, composition, use, and other medical information of the product. Also ensures that the documents comply with regulatory, scientific or other guidelines in terms of content, format, and structure.
NSQF level	5
Minimum Educational Qualifications	Master's degree in pharmaceutical, biotechnology, nursing or life sciences
Maximum Educational Qualifications	Doctorate in pharmaceutical, biotechnology, nursing or life sciences/ MBBS in allopathy or alternate medicines
Training (Suggested but not mandatory)	0-2 years, On the job training for writing research reports, GLP training
Minimum Job Entry Age	22 Years
Experience	Fresher, no prior experience required

<p><b>Applicable National Occupational Standards (NOS)</b></p>	<p><b>Compulsory:</b></p> <ol style="list-style-type: none"> <li>1 <a href="#">LFS/N0521: Carry out preparation of scientific documents.</a></li> <li>2 <a href="#">LFS/N0107: Coordinate with manager, team members and cross functional teams</a></li> <li>3 <a href="#">LFS/N0511 : Collaborate and coordinate with experts.</a></li> <li>4 <a href="#">LFS/N0102: Carry out reporting and documentation.</a></li> <li>5 <a href="#">LFS/N0101: Maintain a health, safe and secure working environment in the life sciences facility</a></li> </ol> <p><b>Optional:</b> N.A.</p>
<p><b>Performance Criteria</b></p>	<p>As described in the relevant NOS units</p>

Definitions

Keywords /Terms	Description
Core Skills/Generic Skills	Core Skills or Generic Skills are a group of skills that are key to learning and working in today's world. These skills are typically needed in any work environment. In the context of the NOS, these include communication related skills that are applicable to most job roles.
Description	Description gives a short summary of the unit content. This would be helpful to anyone searching on a database to verify that this is the appropriate NOS they are looking for.
Function	Function is an activity necessary for achieving the key purpose of the sector, occupation, or area of work, which can be carried out by a person or a group of persons. Functions are identified through functional analysis and form the basis of NOS.
Job role	Job role defines a unique set of functions that together form a unique employment opportunity in an organisation.
Knowledge and Understanding	Knowledge and Understanding are statements, which together specify the technical, generic, professional and organisational specific knowledge that an individual needs in order to perform to the required standard.
National Occupational Standards (NOS)	NOS are Occupational Standards, which apply, uniquely in the Indian context.
Occupation	Occupation is a set of job roles, which perform similar/related set of functions in an industry.
Organisational Context	Organisational Context includes the way the organisation is structured and how it operates, including the extent of operative knowledge managers have of their relevant areas of responsibility.
Performance Criteria	Performance Criteria are statements that together specify the standard of performance required when carrying out a task.
Qualifications Pack(QP)	Qualifications Pack comprises the set of NOS, together with the educational, training and other criteria required to perform a job role. A Qualifications Pack is assigned a unique qualification pack code.
Qualifications Pack Code	Qualifications Pack Code is a unique reference code that identifies a qualifications pack.
Scope	Scope is the set of statements specifying the range of variables that an individual may have to deal with in carrying out the function which have a critical impact on the quality of performance required.
Sector	Sector is a conglomeration of different business operations having similar businesses and interests. It may also be defined as a distinct subset of the economy whose components share similar characteristics and interests.

Sub-Sector	Sub-sector is derived from a further breakdown based on the characteristics and interests of its components.
Sub-functions	Sub-functions are sub-activities essential to fulfil the achieving the objectives of the function.
Technical Knowledge	Technical Knowledge is the specific knowledge needed to accomplish specific designated responsibilities.
Unit Code	Unit Code is a unique identifier for an NOS unit, which can be denoted with an 'N'.
Unit Title	Unit Title gives a clear overall statement about what the incumbent should be able to do.
Vertical	Vertical may exist within a sub-sector representing different domain areas or the client industries served by the industry.
<b>Keywords /Terms</b>	<b>Description</b>
NOS	National Occupational Standard(s)
NSQF	National Skill Qualifications Framework
NCO-2004	National Classification of Occupations-2004
OS	Occupational Standard(s)
QP	Qualifications Pack
SOP	Standard Operating Procedure
GLP	Good Laboratory Practice
ISO	International Organization for Standardization
OHSAS	Occupational Health & Safety Advisory Services

Acronyms

LFS/N0521 : Carry out preparation of scientific documents

# National Occupational Standards



## Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Scientific Medical Writer to carry out the preparation of scientific documents while ensuring they meet the standard quality, compliance and regulatory requirements.

LFS/N0521 : Carry out preparation of scientific documents

National Occupational Standard

<b>Unit Code</b>	<b>LFS/N0521</b>
<b>Unit Title (Task)</b>	<b>Carry out preparation of scientific documents</b>
<b>Description</b>	This NOS is about a Scientific Medical Writer performing the required activities to effectively carry out preparation of scientific/medical document related to the product
<b>Scope</b>	The unit/task covers the following: <ul style="list-style-type: none"> <li>• Preparing medical documents</li> <li>• Ensuring consistent, efficient and quality processes to meet deliverables</li> </ul>
<b>Performance Criteria (PC) w.r.t. the Scope</b>	
<b>Element</b>	<b>Performance Criteria</b>
<b>Preparing Medical Documents</b>	To be competent, the user/individual on the job must be able to: <ul style="list-style-type: none"> <li>PC1. author, review, and edit documents for submissions, including clinical study reports, annual reports, amendments and updates.</li> <li>PC2. help in drafting investigator’s brochure and updates once clinical strategy is finalized.</li> <li>PC3. create documentation that regulatory agencies require in the approval process for drugs, devices and biologics.</li> <li>PC4. perform medical writing activities on the assigned project in a timely and efficient manner.</li> <li>PC5. create medical journal/articles/programs as per the scientific journal standards for nurses, physicians and pharmacists for continuing medical education (CME).</li> <li>PC6. create sales literature for newly launched drugs</li> <li>PC7. author, review, and edit documents to support all phases of clinical development .</li> <li>PC8. author and edit clinical study reports for phase 1-4 trials, including full study reports and abbreviated reports .</li> <li>PC9. author and edit pre-clinical reports required for submissions.</li> </ul>
<b>Ensuring consistent, efficient and quality processes to meet deliverables</b>	<ul style="list-style-type: none"> <li>PC10. coordinate with various technical professionals to gather, organize and compile information on new products or processes.</li> <li>PC11. ensure a consistent style of presentation for documents to maintain quality.</li> <li>PC12. work effectively with other staff in clinical operations (e.g., biostatistics, data management, clinical monitoring), regulatory affairs and others in team.</li> <li>PC13. follow governmental regulations and company sops for document preparation.</li> <li>PC14. assist in developing clinical trial protocols.</li> <li>PC15. ensure marketing authorization submissions accurately and consistently present key clinical messages in accordance with program goals and regulatory requirements.</li> <li>PC16. ensure Standard Operating Procedures (SOPs) are current.</li> <li>PC17. obtain accurate information from valid sources on the processes and procedures being quality assured.</li> </ul>
<b>Knowledge and Understanding (K)</b>	
<b>A. Organisational</b>	The user/individual on the job needs to know and understand:

**LFS/N0521 : Carry out preparation of scientific documents**

<p><b>Context</b> (Knowledge of the Company/ Organisation and its processes)</p>	<p>KA1. the principles and processes to provide patient care, including patient need assessment, meeting quality standards for services and evaluation of customer standards.</p> <p>KA2. organizational coding system of finished products</p> <p>KA3. different quality management systems (ISO-9000, ISO-14001, OHSAS-18000)</p> <p>KA4. types of documentation in the organization, importance of maintaining the same and different methods of recording information.</p> <p>KA5. the importance of complete and accurate documentation.</p> <p>KA6. characteristics of the product/material.</p> <p>KA7. protocol writing guidelines and documentation procedures</p> <p>KA8. organizational coding system and company manual</p> <p>KA9. types of documentation in organization, importance of maintaining the same and different methods of recording information.</p>
<p><b>B. Technical Knowledge</b></p>	<p>The user/individual on the job needs to know and understand:</p> <p>KA10. clinical trial process and good clinical practices</p> <p>KA11. use of computer/application software.</p> <p>KA12. processing of information by compiling, coding, categorizing, calculating, tabulating, auditing or verifying data.</p> <p>KA13. ability to relate individual elements of clinical development programs to specific needs for document preparation and production.</p> <p>KA14. different scientific/medical documents – reports, forms, plans – associated with product quality and compliance as required by different regulatory agencies</p> <p>KA15. good documentation practices</p> <p>KA16. different quality management systems, good laboratory and manufacturing practices.</p>
<p><b>Skills (S)</b></p>	
<p><b>A. Core Skills/ Generic Skills</b></p>	<p><b>Writing skills</b></p> <p>The user/ individual on the job needs to know and understand how to:</p> <p>SA1. record and communicate details of work using written/typed report or computer based record/electronic mail</p> <p>SA2. maintain proper and concise records as per given format.</p> <p>SA3. capture data and information accurately</p> <p>SA4. maintain confidentiality of information and data</p> <p>SA5. ensure the appropriate amount of detail and preciseness when writing medical/clinical investigation reports</p> <p><b>Reading skills</b></p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SA6. read and understand manuals, SOPs, health and safety instructions, memos, reports, job cards etc.</p>

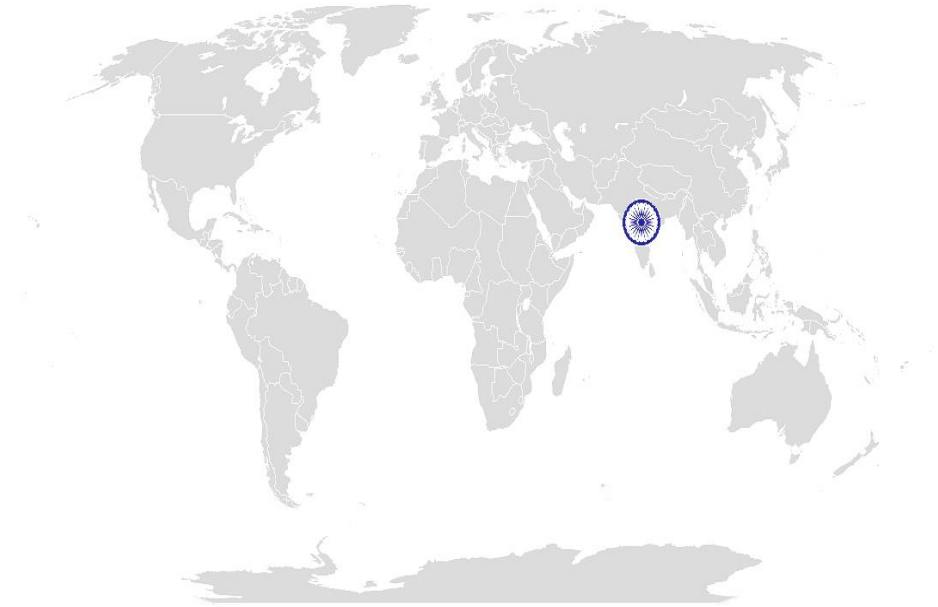


**LFS/N0521 : Carry out preparation of scientific documents**

	SA7. read images, graphs, diagrams. SA8. understand the various coding systems as per company norms.
	<b>Oral Communication (Listening and Speaking skills)</b>
	The user/individual on the job needs to know and understand how to:  SA9. communicate with multiple internal and external stakeholders SA10. communicate effectively within the team SA11. communicate confidential and sensitive information discretely to authorized person as per SOP
<b>B. Professional Skills</b>	<b>Analytical Thinking</b>
	The user/individual on the job needs to know and understand how to:  SB1. capture and analyse data and information to create medical/clinical documents and reports SB2. suggest improvements(if any) in process/formats for medical/clinical reports/documentation based on experience and observation SB3. use available data and computer software medical/clinical reports and documentation SB4. improve processes by interacting with others and adopting best practices
	<b>Critical Thinking</b>
	The user/individual on the job needs to know and understand how to:  SB5. apply balanced judgement to different situations at work SB6. apply, analyse and evaluation information to define action steps for reporting/document preparation
	<b>Problem Solving</b>
	The user/individual on the job needs to know and understand how to:  SB7. identify, define and resolve problems using a structured methodology SB8. resolve conflicts, negotiate on behalf of the team and company SB9. identify immediate or temporary solutions to resolve reporting/process/communication delays
	<b>Decision Making</b>
	The user/individual on the job needs to know and understand how to:  SB10. evaluate multiple options on defined, objective parameters when taking decisions SB11. appropriately use the escalation matrix for complex or high-risk decisions
	<b>Plan and Organize</b>
	The user/individual on the job needs to know and understand how to:  SB12. plan and organize assigned work in order to achieve specified report/document submission deadlines, both internal and external SB13. effectively interact with the various internal and external stakeholders to complete assigned tasks

## LFS/N0521 : Carry out preparation of scientific documents

	<b>Customer Centricity</b>
	NA



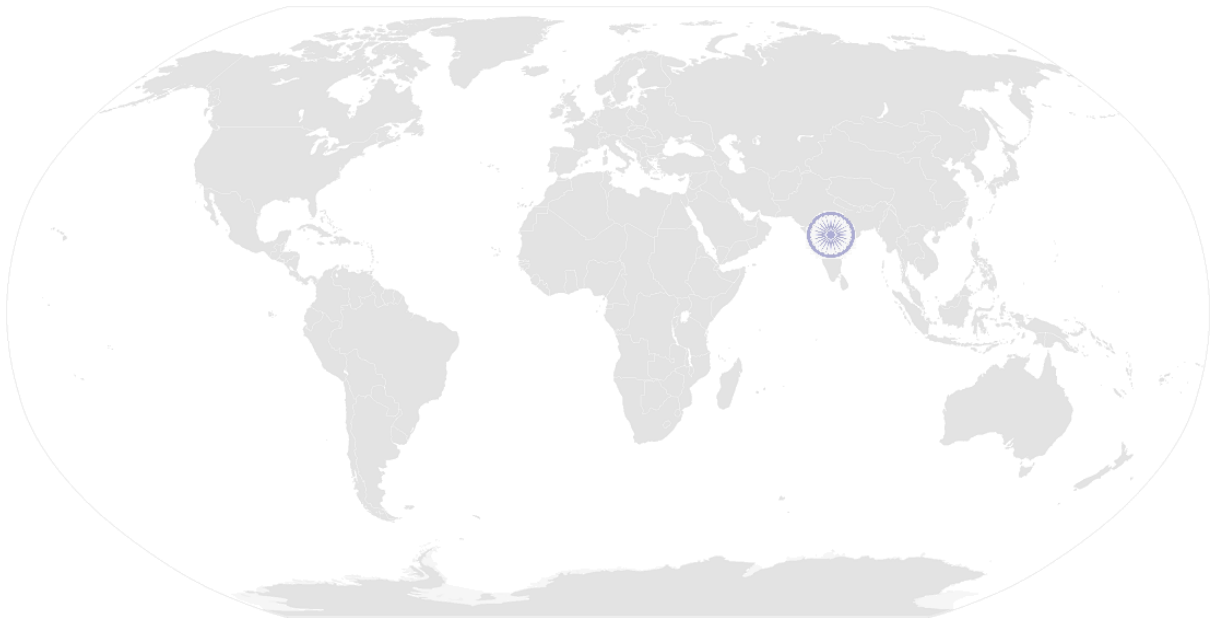
LFS/N0521 : Carry out preparation of scientific documents

## NOS Version Control

NOS Code	LFS/N0521		
Credits(NSQF)		Version number	1.0
Industry	Life Sciences	Drafted on	15/12/14
Industry Sub-sector	Pharmaceutical, Bio Pharmaceutical and Contract Research	Last reviewed on	01/08/16
Occupation	R&D	Next review date	01/08/16

LFS/N0107 : Coordinate with manager, team members and cross functional teams

# National Occupational Standards



## Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Scientific Medical Writer to effectively coordinate with manager and team members.

**LFS/N0107 : Coordinate with manager, team members and cross functional teams**

National Occupational Standard

<b>Unit Code</b>	<b>LFS/N0107</b>
<b>Unit Title (Task)</b>	<b>Coordinate with manager, team members and cross functional teams</b>
<b>Description</b>	This NOS unit is about the Scientific Medical Writer coordinating with manager, within team members and other teams in order to undertake assigned activities
<b>Scope</b>	The unit/ task covers the following: <ul style="list-style-type: none"> <li>• Coordinating with manager</li> <li>• Coordinating with team members</li> <li>• Coordinating with</li> </ul>
<b>Performance Criteria (PC) w.r.t. the Scope</b>	
<b>Element</b>	<b>Performance Criteria</b>
Coordination with manager	To be competent, the user/individual on the job must be able to: <ul style="list-style-type: none"> <li>PC1. receive work instructions from reporting manager and understand work output requirements</li> <li>PC2. seek advice and opinion from manager on approach taken for carrying out work as well as output</li> <li>PC3. report any challenges, obstacles to completing the work as per specifications and timelines</li> <li>PC4. assist the manager with his/her responsibilities</li> </ul>
Coordination with team members	<ul style="list-style-type: none"> <li>PC5. work as a team with colleagues and share work as per their or own work load and skills</li> <li>PC6. put team over individual goals</li> <li>PC7. work to resolve conflicts within the team</li> </ul>
Coordination with cross functional teams	<ul style="list-style-type: none"> <li>PC8. articulate support/ inputs/data needed from cross-functional teams</li> <li>PC9. interact with the necessary cross functional teams to gather the required data</li> <li>PC10. pro-actively provide support/ inputs/data requested by other teams</li> <li>PC11. participate in cross-functional team meetings and contribute relevant information</li> </ul>
<b>Knowledge and Understanding (K)</b>	
<b>A. Organisational Context</b> (Knowledge of the Company/ Organisation and its processes)	The user/individual on the job needs to know and understand: <ul style="list-style-type: none"> <li>KA1. reporting structure in the company</li> <li>KA2. company's policies on: preferred communication medium, reporting and escalation policy, quality delivery standards, and personnel management</li> <li>KA3. company's SOPs to understand interface with other functions</li> </ul>
<b>B. Technical Knowledge</b>	The user/individual on the job needs to know and understand: <ul style="list-style-type: none"> <li>KB1. importance of effective interpersonal communication</li> <li>KB2. conflict-resolution techniques</li> </ul>

**LFS/N0107 : Coordinate with manager, team members and cross functional teams**

	KB3. importance of collaborative working
<b>Skills (S)</b>	
<b>A. Core Skills/ Generic Skills</b>	<b>Writing skills</b>
	The user/ individual on the job needs to know and understand how to:
	SA1. record and communicate details of work done to appropriate people using written/typed report
	SA2. communicate with supervisor and team members data/ information/ support/ advice needed
	<b>Reading skills</b>
	The user/individual on the job needs to know and understand how to:
SA3. read and interpret written data/information/ communication carefully	
<b>B. Professional Skills</b>	<b>Oral Communication (Listening and Speaking skills)</b>
	The user/individual on the job needs to know and understand how to:
	SA4. be clear and precise in communication
	SA5. listen effectively
	<b>Critical Thinking</b>
	The user/individual on the job needs to know and understand how to:
SB1. apply balanced judgement to different situations	
SB2. provide sound, constructive, objective opinion	
<b>B. Professional Skills</b>	<b>Plan and Organize</b>
	The user/individual on the job needs to know and understand how to:
	SB3. work effectively with cross-functional team members across multiple functions, locations and hierarchy level
	<b>Decision Making</b>
	The user/individual on the job needs to know and understand how to:
	SB4. act objectively when faced with difficult/stressful or emotional situations
SB5. appropriately use the escalation matrix for complex team decisions	
SB6. collaborate with the team for taking decisions	
<b>B. Professional Skills</b>	<b>Problem Solving</b>
	The user/individual on the job needs to know and understand how to:
	SB7. apply problem solving approaches to different situations
SB8. solve conflicts within the team	

**LFS/N0107 : Coordinate with manager, team members and cross functional teams**

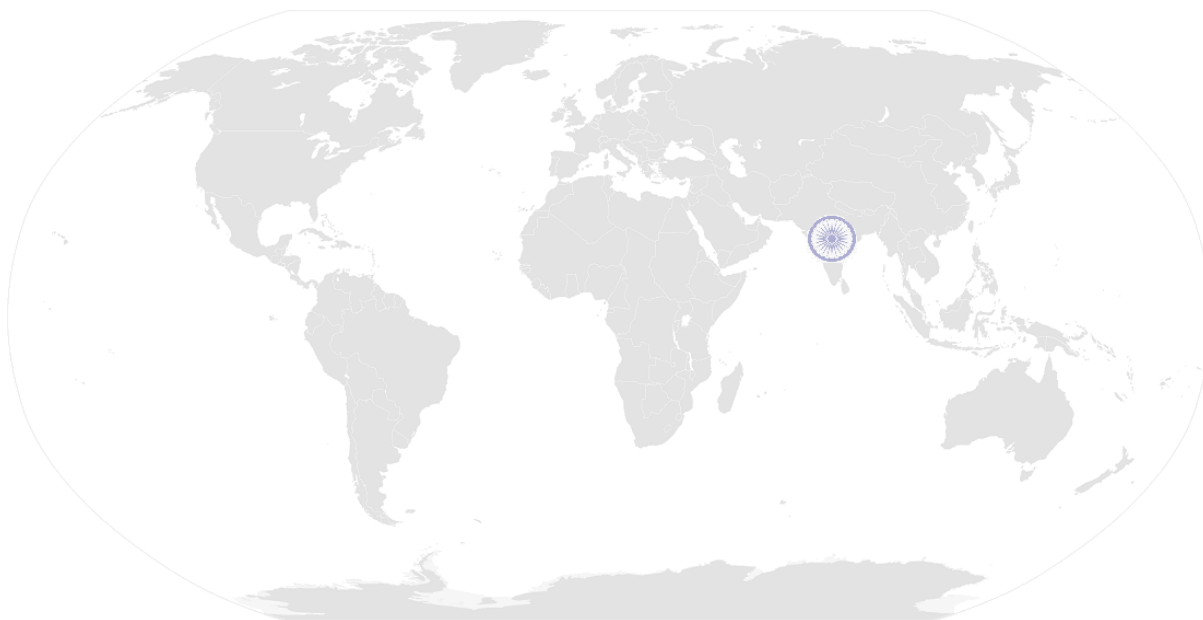
	<b>Analytical Thinking</b>
	NA
	<b>Customer Centricity</b>
	NA

**NOS Version Control**

NOS Code	LFS/N0107		
Credits(NSQF)		Version number	1.0
Industry	Life Sciences	Drafted on	15/12/14
Industry Sub-sector	Pharmaceutical, Bio Pharmaceutical and Contract Research	Last reviewed on	01/08/16
Occupation	R&D	Next review date	01/08/19

LFS/N0511 : Collaborate and coordinate with experts.

# National Occupational Standards



## Overview

This Occupational Standard describes the knowledge, understanding and skills required of a Scientific Medical Writer to collaborate and coordinate with experts.



**LFS/N0511 : Collaborate and coordinate with experts.**

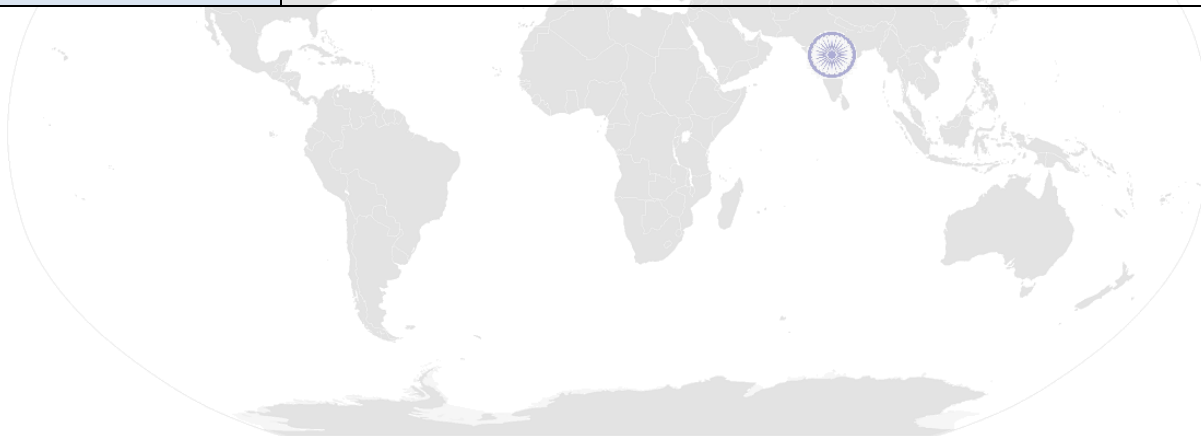
National Occupational Standard	<b>Unit Code</b>	<b>LFS/N0511</b>
	<b>Unit Title (Task)</b>	<b>Collaborate and Coordinate with experts</b>
	<b>Description</b>	This NOS unit is about the importance of collaborating and coordinating with experts by the Scientific Medical Writer.
	<b>Scope</b>	The unit/task covers the following: <ul style="list-style-type: none"> <li>Connecting with scientists, doctors for collecting information on document writing</li> <li>Establishing a network of industry experts</li> </ul>
	<b>Performance Criteria (PC) w.r.t. the Scope</b>	
	<b>Element</b>	<b>Performance Criteria</b>
	Connecting with scientists, doctors for collecting information on document writing	To be competent, the user/individual on the job must be able to: <ul style="list-style-type: none"> <li>PC1. conduct interviews with scientists, doctors and academics .</li> <li>PC2. visit research establishments.</li> <li>PC3. read and research specialist media and literature, e.g. scientific papers, company reports, newspapers, magazines and journals, press releases and internet resources including social media .</li> <li>PC4. meeting with colleagues to plan the content of a document or publication.</li> <li>PC5. conduct reference searches.</li> </ul>
	Establishing a network of industry experts	<ul style="list-style-type: none"> <li>PC6. establish a network of industry experts .</li> <li>PC7. attend academic and press conferences</li> <li>PC8. attend meetings or taking part in conference calls with clients, scientists or writing professionals.</li> <li>PC9. meeting with customer under appropriate departmental supervision as primary technical contact.</li> </ul>
	<b>Knowledge and Understanding (K)</b>	
	<b>A. Organisational Context</b> (Knowledge of the Company/ Organisation and its processes)	The user/individual on the job needs to know and understand: <ul style="list-style-type: none"> <li>KA1. the compositions of the life sciences fraternity – awareness of the renewed and relevant scientists, doctors and academics to the organizations area of focus</li> <li>KA2. relevance of various research establishments (in India and globally) to the organizations area of focus</li> <li>KA3. procedure for accessing company reports</li> <li>KA4. importance and interest of clients, scientists or writing professionals to collaborate with for meetings and conference</li> <li>KA5. SOP as primary technical contact of the firm</li> </ul>

**LFS/N0511 : Collaborate and coordinate with experts.**

<p><b>B. Technical Knowledge</b></p>	<p>The user/individual on the job needs to know and understand:</p> <p>KB1. the life sciences fraternity – awareness of the renewed and relevant scientists, doctors and academics in the sector</p> <p>KB2. relevance of various research establishments ((in India and globally) and their areas of specialization</p> <p>KB3. source of relevant scientific papers, newspapers, magazines and journals that need be accessed regularly</p> <p>KB4. source for relevant press releases and internet resources including social media</p> <p>KB5. source for identifying upcoming academic and press conferences</p> <p>KB6. relevant industry groups and forums for participation</p>
<p><b>Skills (S)</b></p>	
<p><b>A. Core Skills/ Generic Skills</b></p>	<p><b>Writing skills</b></p> <p>The user/ individual on the job needs to know and understand how to:</p> <p>SA1. record and communicate details of work to appropriate people using written/typed report or computer based record/electronic mail</p> <p>SA2. write reports</p> <p>SA3. prepare presentations</p> <p><b>Reading skills</b></p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SA4. read and understand guidelines, reports, databases, research papers etc. – both internal and external</p> <p><b>Oral Communication (Listening and Speaking skills)</b></p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SA5. communicate in a precise and persuasive manner, with internal and external stakeholders</p> <p>SA6. communicate with people in a form and manner and using language that is open and respectful</p> <p>SA7. present/speak at public forms</p>
<p><b>B. Professional Skills</b></p>	<p><b>Decision Making</b></p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SB1. evaluate multiple options on defined, objective parameters for identifying research areas, appropriate experts, relevant conferences etc.</p> <p>SB2. collaborate with the trusted internal and external advisors for taking decisions</p> <p><b>Plan and Organize</b></p>

**LFS/N0511 : Collaborate and coordinate with experts.**

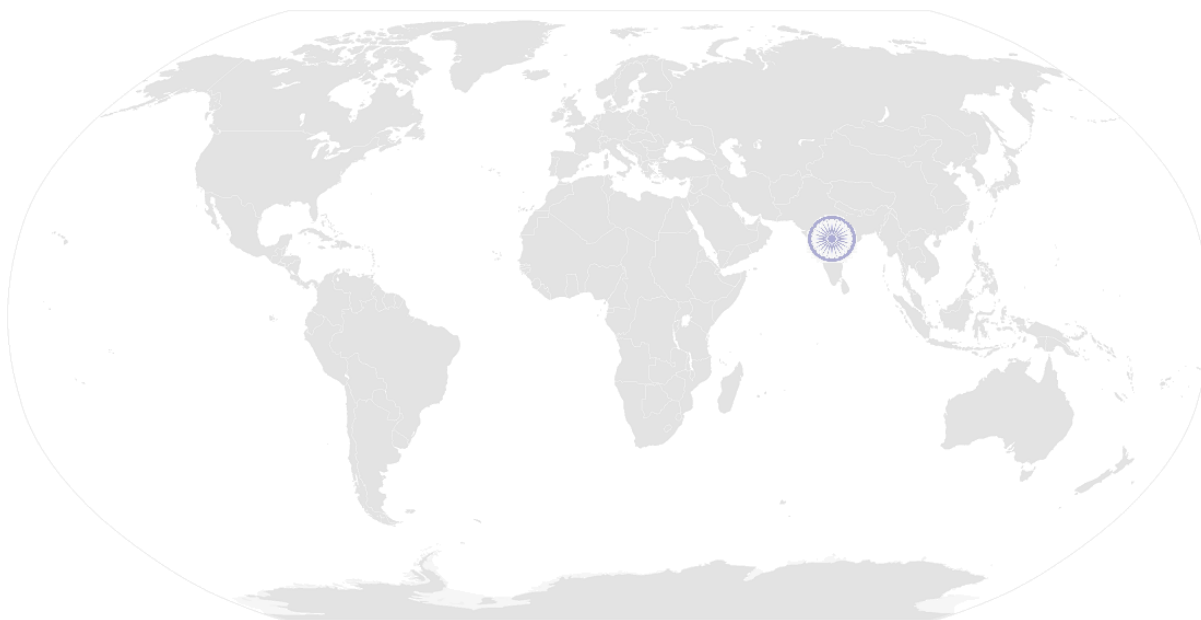
	The user/individual on the job needs to know and understand how to:
	SB3. plan and organize meetings, research etc. in order to achieve specified targets and deadlines
	SB4. multi-task and adapt to meet work timelines
	SB5. effectively interact with the various internal and external stakeholders to complete planned activities
	SB6. establish rapport and effective working relationships with business partners, department leadership and peers within and outside the organization
	<b>Critical Thinking</b>
	The user/individual on the job needs to know and understand how to:
	SB7. apply balanced judgement to different internal and external situations
SB8. obtain and provide sound, constructive, objective opinion	
<b>Analytical Thinking</b>	
NA	
<b>Problem Solving</b>	
NA	
<b>Customer Centricity</b>	
NA	



LFS/N0511 : Collaborate and coordinate with experts.

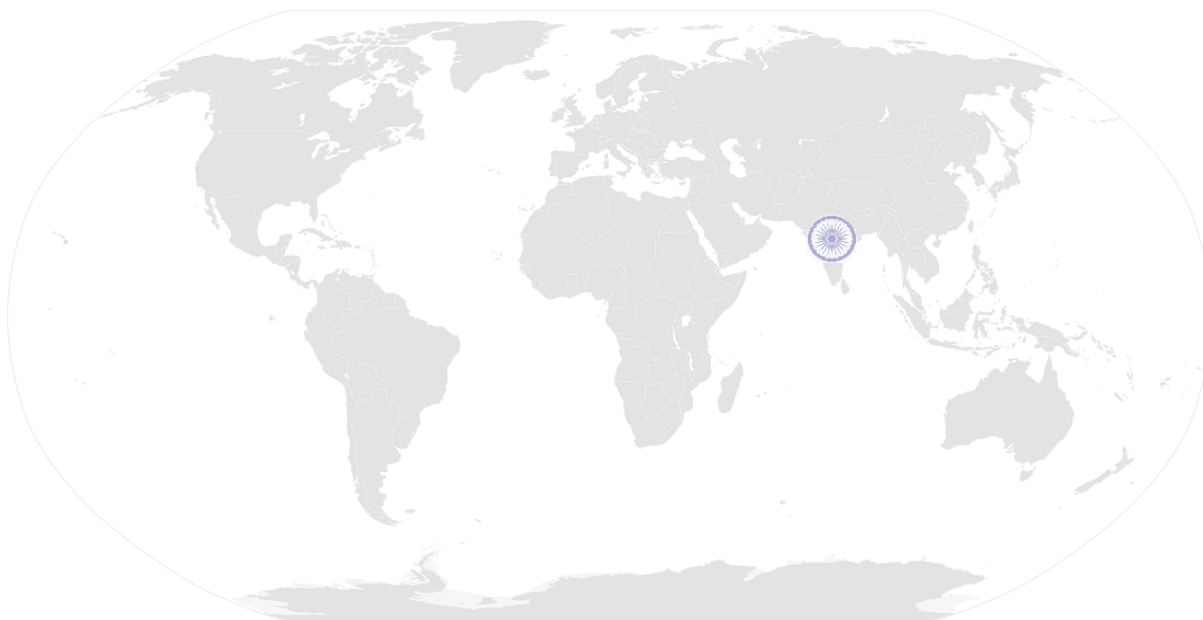
## NOS Version Control

NOS Code	LFS/N0511		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	15/12/14
Industry Sub-sector	Pharmaceuticals, Biopharmaceuticals	Last reviewed on	01/08/16
Occupation	Manufacturing, Quality, Supply Chain, R&D	Next review date	01/08/19



LFS/N0102 : Carry out reporting and documentation.

# National Occupational Standards



## Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Scientific Medical writer to carry out reporting and documentation

**LFS/N0102 : Carry out reporting and documentation.**

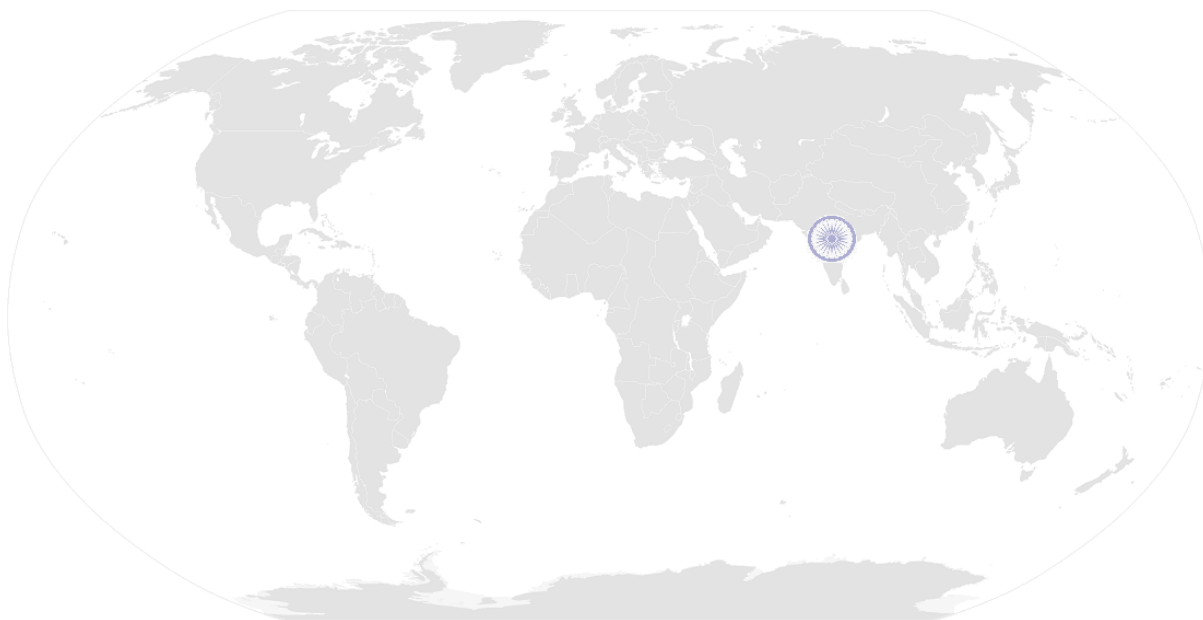
National Occupational Standard	<b>Unit Code</b>	<b>LFS/N0102</b>
	<b>Unit Title (Task)</b>	<b>Carry out reporting and documentation.</b>
	<b>Description</b>	This OS is about a Scientific Medical Writer for reporting ,recording and documentation of data/problem/incidents etc. and to maintain information security
	<b>Scope</b>	The unit/task covers the following: <ul style="list-style-type: none"> <li>• Reporting.</li> <li>• Recording and documentation</li> <li>• Information security</li> </ul>
	<b>Performance Criteria (PC) w.r.t. the Scope</b>	
	<b>Element</b>	<b>Performance Criteria</b>
	<b>Reporting</b>	To be competent, the user/individual on the job must be able to: PC1. report data/problems/incidents 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
	<b>Recording and documentation</b>	PC4. identify documentation to be completed relating to one’s role PC5. record details accurately in an appropriate format PC6. complete all documentation within stipulated time according to company procedure PC7. ensure that the final document meets regulatory and compliance requirements PC8. make sure documents are available to all appropriate authorities to inspect
	<b>Information Security</b>	PC9. respond to requests for information in an appropriate manner whilst following organizational procedures PC10. inform the appropriate authority of requests for information received
	<b>Knowledge and Understanding (K)</b>	
<b>B. Organisational Context</b> (Knowledge of the Company/ Organisation and its processes)	The user/individual on the job needs to know and understand: <ul style="list-style-type: none"> <li>KA1. types of documentation in organization, importance of maintaining the same and different methods of recording information</li> <li>KA2. reporting incidents where standard operating procedures are not followed</li> <li>KA3. the importance of complete and accurate documentation</li> <li>KA4. knowledge of production workflow sequences and materials demand</li> <li>KA5. escalation matrix for reporting identified issues, hazards and breakage</li> </ul>	
<b>B. Technical Knowledge</b>	The user/individual on the job needs to know and understand: <ul style="list-style-type: none"> <li>KB1. obtain and interpret records, charts, specifications, equipment manuals, history/technical support reports and other documents</li> </ul>	
<b>Skills (S)</b>		

**LFS/N0102 : Carry out reporting and documentation.**

<b>A. Core Skills/ Generic Skills</b>	<b>Writing skills</b>
	The user/ individual on the job needs to know and understand how to:  SA1. record and communicate details of work done to appropriate people using written/typed report SA2. maintain proper records as per given format
	<b>Reading skills</b>
	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
	<b>Oral Communication (Listening and Speaking skills)</b>
<b>B. Professional Skills</b>	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. 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>Analytical Thinking</b>
	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
	<b>Critical Thinking</b>
	The user/individual on the job needs to know and understand how to:  SB3. suggest improvements(if any) in process based on experience
	<b>Plan and Organise</b>
	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.
	<b>Problem Solving</b>

**LFS/N0102 : Carry out reporting and documentation.**

	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
	<b>Decision Making</b>
	NA
	<b>Customer Centricity</b>
	NA

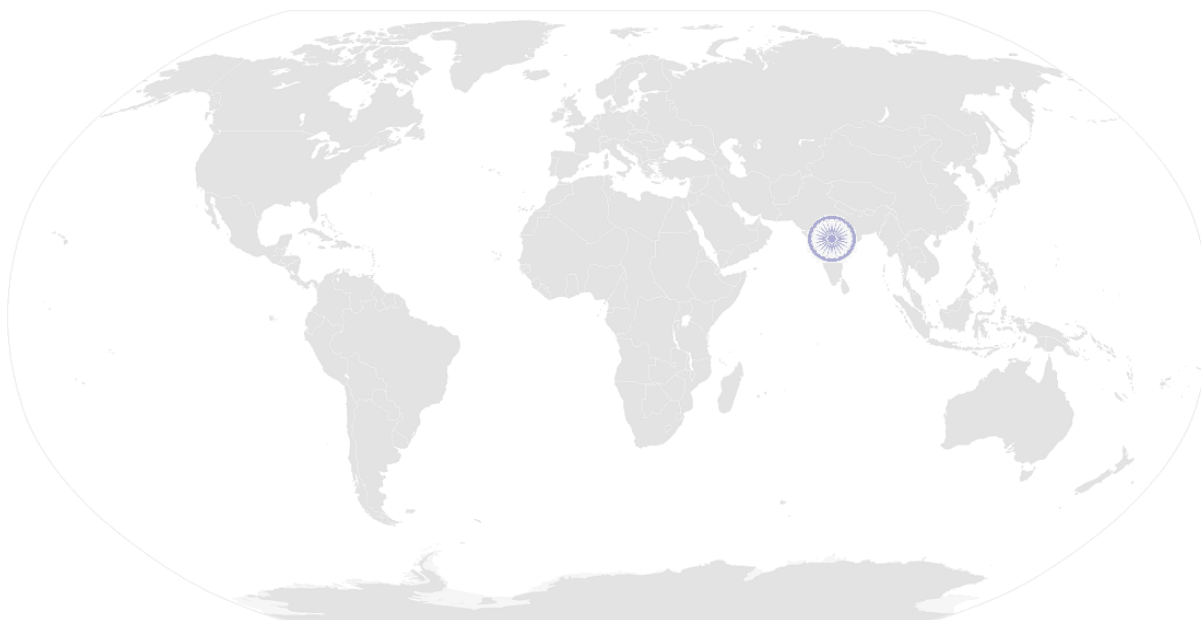




LFS/N0102 : Carry out reporting and documentation.

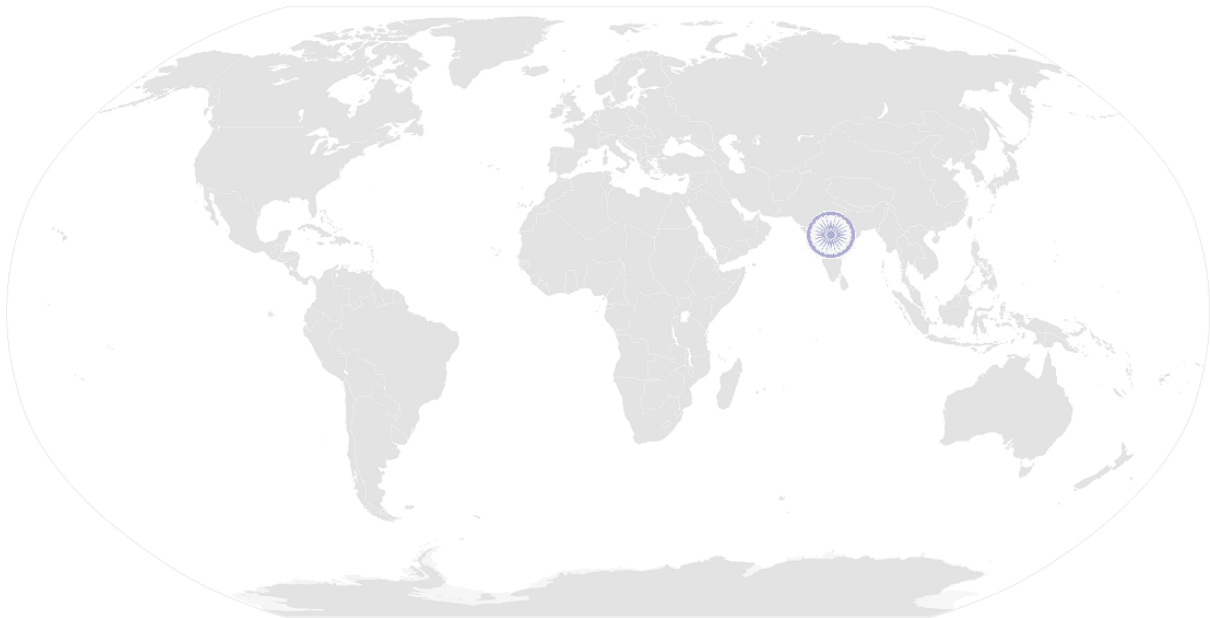
## NOS Version Control

NOS Code	LFS/N0102		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	15/12/14
Industry Sub-sector	Pharmaceuticals, Biopharmaceuticals	Last reviewed on	01/08/16
Occupation	Manufacturing, Quality, Supply Chain, R&D	Next review date	01/08/19



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

# National Occupational Standards



## Overview

**This Occupational Standard describes the knowledge, understanding and skills required by a Scientific Medical Writer to ensure healthy, safe and secure working environment in the life sciences facility.**

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

National Occupational Standard	<b>Unit Code</b>	<b>LFS /N0101</b>
	<b>Unit Title (Task)</b>	<b>Maintain a healthy, safe and secure working environment in the life sciences facility</b>
	<b>Description</b>	This NOS unit is about a Scientific Medical Writer monitoring the working environment and making sure that it meets the requirements for health, safety and security in the pharmaceutical/contract research/biopharmaceutical facility/ manufacturing/ testing/ analysis/ research laboratory.
	<b>Scope</b>	<p>This unit / task covers the following:</p> <p><b>Ensuring healthy, safe and secure working environment:</b></p> <ul style="list-style-type: none"> <li>• self monitor and adhere to safety principles and standards</li> <li>• ensure behavioural safety by workmen to cGMP and applicable safety standards on the shop floor/ laboratory</li> <li>• report any identified breaches in health, safety, and security policies and procedures to the designated person</li> </ul> <p><b>Managing emergency procedures:</b></p> <ul style="list-style-type: none"> <li>• illness</li> <li>• accidents</li> <li>• fires</li> <li>• other reasons to evacuate the premises</li> <li>• breaches of security</li> </ul>
<b>Performance Criteria (PC) wrt the Scope</b>		
<b>Element</b>	<b>Performance Criteria</b>	
<b>Ensuring healthy, safe and secure working environment</b>	<p>To be competent, you must be able to:</p> <p>PC1. observe and comply with your company's current health, safety and security policies and procedures</p> <p>PC2. while carrying out work, use appropriate safety gears like head gear, masks, gloves and other accessories as mentioned in the guidelines</p> <p>PC3. report any identified breaches in health, safety, and security policies and procedures to the designated person</p> <p>PC4. responsible for maintaining discipline at the shop-floor/ production area</p> <p>PC5. identify and correct any hazards that you can deal with safely, competently and within the limits of your authority</p> <p>PC6. adhere and comply to storage and handling guidelines for hazardous material</p> <p>PC7. identify and recommend opportunities for improving health, safety, and security to the designated person</p> <p>PC8. complete any health, safety and security activities like safety drills and prepare records legibly and accurately</p>	
<b>Managing emergency procedures</b>	<p>PC9. report any hazards that you are not competent to deal with to the relevant person in line with organizational procedures and warn other people who may be affected</p> <p>PC10. follow your company's emergency procedures promptly, calmly, and efficiently</p>	

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

Knowledge and Understanding (K)	
<p><b>A. Organisational Context</b> (Knowledge of the Company/ Organisation and its processes)</p>	<p>You need to know and understand:</p> <p>KA1. legislative requirements and company’s procedures for health, safety and security and your role and responsibilities in relation to this</p> <p>KA2. what is meant by a hazard, including the different types of health and safety hazards that can be found in the workplace</p> <p>KA3. how and when to report hazards</p> <p>KA4. limits of your responsibility for dealing with hazards</p> <p>KA5. your organization’s emergency procedures for different emergency situations and the importance of following these</p> <p>KA6. the importance of maintaining high standards of health, safety and security</p> <p>KA7. implications that any non-compliance with health, safety and security may have on individuals and the organization</p> <p>KA8. health hazards and its implications if any in the production process</p>
<p><b>B Technical Knowledge</b></p>	<p>You need to know and understand:</p> <p>KB1. different types of breaches in health, safety and security and how and when to report these</p> <p>KB2. evacuation procedures for workers and visitors</p> <p>KB3. how to summon medical assistance and the emergency services, where necessary</p> <p>KB4. how to use the health, safety and accident reporting procedures and the importance of these</p> <p>KB5. different types of occupational health hazards</p> <p>KB6. knowledge of chemical substances, their characteristics and required precaution and safety measures</p>
Skills (S)	
<p><b>A. Core Skills/ Generic Skills</b></p>	<p><b>Writing skills</b></p>
	<p>You need to know and understand:</p> <p>SA1. complete accurate, well written work with attention to detail</p>
	<p><b>Reading skills</b></p>
	<p>You need to know and understand:</p> <p>SA2. read instructions, guidelines, procedures, rules and service level agreements</p>
	<p><b>Oral Communication (Listening and Speaking skills)</b></p>
	<p>You need to know and understand:</p>

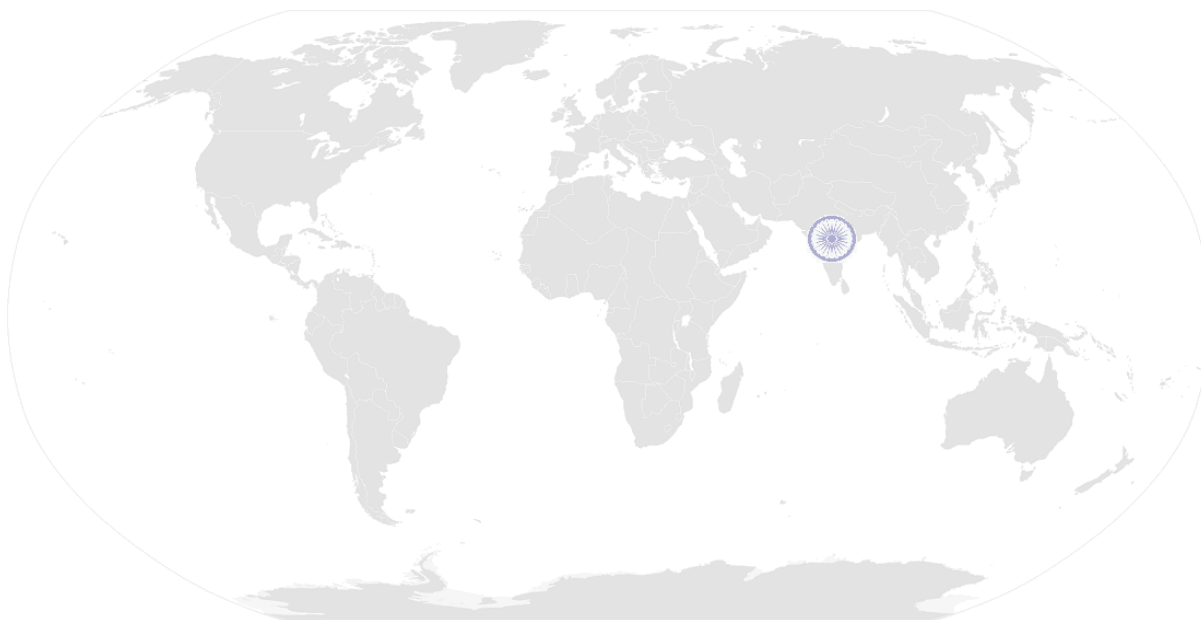
**LFS/N0101 : Maintain a healthy, safe and secure working environment in the life sciences facility**

	SA3. listen effectively and orally communicate information accurately
<b>B. Professional Skills</b>	<b>Decision making</b>
	You need to know and understand:
	SB1. make decisions on suitable courses of action
	<b>Plan and Organise</b>
	The user/individual on the job needs to know and understand how to:
	SB2. plan and organize your work to meet health, safety and security requirements
	<b>Problem solving</b>
	You need to know and understand:
	SB3. apply problem solving approaches in different situations
	<b>Analytical thinking</b>
	You need to know and understand:
	SB4. analyse data and activities
<b>Critical thinking</b>	
You need to know and understand:	
SB5. apply balanced judgments to different situations	
<b>Customer Centricity</b>	
NA	

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

**NOS Version Control**

NOS Code	LFS /N0101		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	26/06/14
Industry Sub-sector	Pharmaceuticals, Bio Pharmaceuticals	Last reviewed on	01/08/16
Occupation	Manufacturing, Quality, Supply Chain, R&D	Next review date	01/08/19

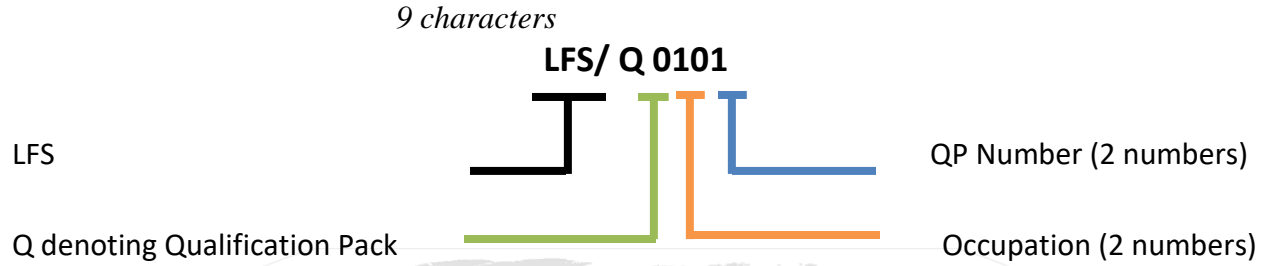


Qualification pack for Scientific Medical Writer

## Annexure

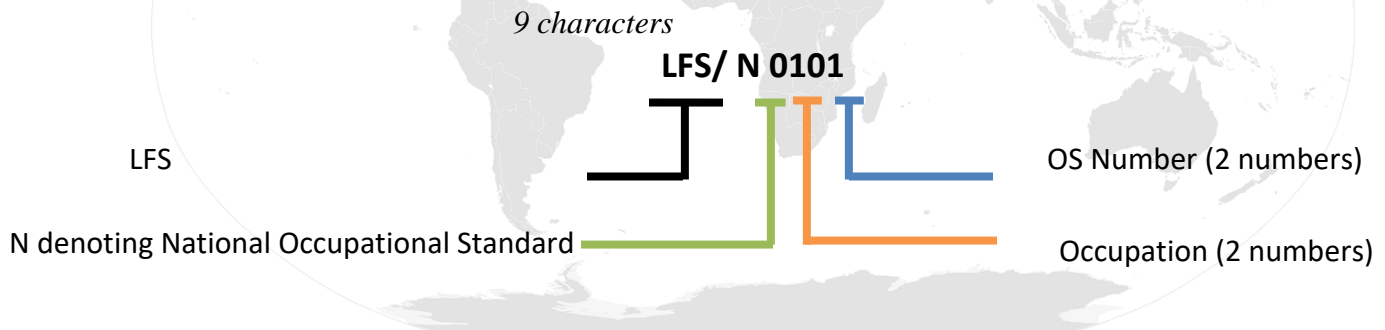
### Nomenclature for QP and NOS

#### Qualifications Pack



#### Occupational Standard

An example of NOS with 'N'



*Qualification pack for Scientific Medical Writer*

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

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

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



Qualification pack for Scientific Medical Writer

**CRITERIA FOR ASSESSMENT OF TRAINEES**

**Job Role** Scientific Medical Writer

**Qualification Pack** LFS/Q0506

**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.

Assessment Outcome	Assessment Criteria of Outcome	Total Marks (500)	Out of	Marks Allocation	
				Theory	Skills Practical
LFS/N0521 (Carry out the preparation of scientific documents)	PC1. author, review, and edit documents for submissions, including clinical study reports, annual reports, amendments and updates	100	10	4	6
	PC2. help in drafting Investigator's Brochure and IB updates once clinical strategy is finalized		10	4	6
	PC3. create documentation that regulatory agencies require in the approval process for drugs, devices and biologics		10	4	6
	PC4. perform Medical Writing activities on the assigned project in a timely and efficient manner		8	3	5
	PC5. create medical journal/articles/programs as per the scientific journal standards for nurses, physicians and pharmacists for continuing medical education (CME).		8	3	5

*Qualification pack for Scientific Medical Writer*

PC6. create sales literature for newly launched drugs		8	3	5
PC7. author, review, and edit documents to support all phases of clinical development		8	3	5
PC8. author and edit clinical study reports for Phase 1-4 trials, including full study reports and abbreviated reports		6	2	4
PC9. author and Edit pre-clinical reports required for submissions		6	2	4
PC10. coordinate with various technical professionals to gather, organize and compile information on new products or processes.		4	2	2
PC11. ensure a consistent style of presentation for documents to maintain quality		2	1	1
PC12. work effectively with other staff in clinical operations (e.g., biostatistics, data management, clinical monitoring), regulatory affairs and others in team		3	2	1
PC13. follow governmental regulations and company SOPs for document preparation.		4	2	2
PC14. assist in developing Clinical Trial protocols		3	2	1
PC15. ensure marketing authorization submissions accurately and consistently present key clinical messages in accordance with program goals and regulatory requirements		4	2	2
PC16. ensure Standard Operating Procedures (SOPs) are current		3	2	1
PC17. obtain accurate information from valid sources on the processes and procedures being quality assured		3	2	1

*Qualification pack for Scientific Medical Writer*

	<b>Total</b>		100	43	57
LFS/N0107 (Coordinate with manager, team members and cross functional teams)	PC1. receive work instructions from reporting manager and understand work output requirements	100	12	6	6
	PC2. seek advice and opinion from manager on approach taken for carrying out work as well as output		12	4	8
	PC3. report any challenges, obstacles to completing the work as per specifications and timelines		12	4	8
	PC4. assist the manager with his/her responsibilities		8	4	4
	PC5. work as a team with colleagues and share work as per their or own work load and skills		12	6	6
	PC6. put team over individual goals		12	6	6
	PC7. work to resolve conflicts within the team		8	3	5
	PC8. articulate support/ inputs/data needed from cross-functional teams		6	4	2
	PC9. interact with the necessary cross functional teams to gather the required data		6	4	2
	PC10. pro-actively provide support/ inputs/data requested by other teams		6	4	2
	PC11. participate in cross-functional team meetings and contribute relevant information		6	4	2
	<b>Total</b>		100	49	51
LFS/N0511 (Collaborate and coordinate with experts)	PC1. conduct interviews with scientists, doctors and academics .	100	18	8	10
	PC2. visit research establishments.		16	6	10
	PC3. read and research specialist media and literature, e.g. scientific papers, company reports,		20	8	12

*Qualification pack for Scientific Medical Writer*

	newspapers, magazines and journals, press releases and internet resources including social media .				
	PC4. meeting with colleagues to plan the content of a document or publication.		16	6	10
	PC5. conduct reference searches.		10	4	6
	PC6. establish a network of industry experts .		3	2	1
	PC7. attend academic and press conferences		3	2	1
	PC8. attend meetings or taking part in conference calls with clients, scientists or writing professionals.		4	2	2
	PC9. meeting with customer under appropriate departmental supervision as primary technical contact.		10	4	6
	<b>Total</b>		<b>100</b>	<b>42</b>	<b>58</b>
LFS/N0102 (Carry out reporting and documentation)	PC1. report data/problems/incidents as applicable in a timely manner	100	10	5	5
	PC2. report to the appropriate authority as laid down by the company		10	5	5
	PC3. follow reporting procedures as prescribed by the company		10	5	5
	PC4. identify documentation to be completed relating to one's role		10	5	5
	PC5. record details accurately in an appropriate format		10	5	5
	PC6. complete all documentation within stipulated time according to company procedure		10	5	5
	PC7. ensure that the final document meets regulatory and compliance requirements		10	5	5
	PC8. make sure documents are available to all appropriate authorities to inspect		10	5	5

*Qualification pack for Scientific Medical Writer*

	PC9. respond to requests for information in an appropriate manner whilst following organizational procedures		10	5	5
	PC10. inform the appropriate authority of requests for information received		10	4	6
	<b>Total</b>		100	49	51
LFS/N0101 (Maintain a healthy, safe and secure working environment in the life sciences facility)	PC1. observe and comply with your company's current health, safety and security policies and procedures	100	10	5	5
	PC2. while carrying out work, use appropriate safety gears like head gear, masks, gloves and other accessories as mentioned in the guidelines		10	5	5
	PC3. report any identified breaches in health, safety, and security policies and procedures to the designated person		10	5	5
	PC4. responsible for maintaining discipline at the shop-floor/ production area		10	5	5
	PC5. identify and correct any hazards that you can deal with safely, competently and within the limits of your authority		10	5	5
	PC6. adhere and comply to storage and handling guidelines for hazardous material		10	5	5
	PC7. identify and recommend opportunities for improving health, safety, and security to the designated person		10	5	5
	PC8. complete any health, safety and security records legibly and accurately		10	4	6
	PC9. report any hazards that you are 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

*Qualification pack for Scientific Medical Writer*

	PC10. follow your company's emergency procedures promptly, calmly, and efficiently.		10	5	5
	<b>Total</b>		100	48	52