QUALIFICATIONS PACK - OCCUPATIONAL STANDARDS FOR LIFE SCIENCES INDUSTRY

Contents

What are Occupational Standards (OS)?

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

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Introduction

Qualifications Pack-Clinical Research Associate

SECTOR: LIFE SCIENCES

SUB-SECTOR: PHARMACEUTICAL, BIO PHARMACEUTICAL, CONTRACT RESEARCH

OCCUPATION: RESEARCH AND DEVELOPMENT

REFERENCE ID: LFS/Q0503

ALIGNED TO: NCO-2004/NIL

Clinical Research Associate is involved in all stages of the clinical trial, including supporting the identification of an investigational site and setting up, initiating, monitoring and closing down the trial.

Brief Job Description: Clinical Research Associate supports clinical trial activities, carries out reporting and documentation for monitoring of research activities so as to ensure regulatory compliance and good clinical practices as per ICH and coordinates with site staff members, investigators, SMO and Sponsor/CRO.

Personal Attributes: The individual should have in depth knowledge of pharmaceutical drug development process, clinical trial related process regulatory requirement and scientific aspect of study. Individual must demonstrate, excellent communication skills, analytical and critical thinking, attention to detail, decision making and proactive planning and organizing skills.

Qualifications Pack Code	**LFS/Q0503**		
Job Role	**Clinical Research Associate**		
Credits(NSQF)	**TBD**	**Version number**	**1.0**
Industry	**Life Sciences**	**Drafted on**	**11/12/14**
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	**Clinical Research Associate**
Role Description	Responsible for supporting clinical trial activities, carrying out reporting and documentation of research activities and coordinating with site staff, investigators and SMO
NSQF level	5
Minimum Educational Qualifications	B. Pharma preferable/ B. Sc. / Clinical Research certification/ B. Tech. (Biotechnology)
Maximum Educational Qualifications	M. Pharma / M. Sc. / Ph.D. in Pharmacology/ BDS/ MBBS/ BHMS/ BAMS/ BUMS/ MD/DM/MDS
Training (Suggested but not mandatory)	On the job training
Minimum Job Entry Age	20 Years
Experience	Fresher, 1-2 years clinical research experience preferred
Applicable National Occupational Standards (NOS)	**Compulsory:** 1. LFS/N0508: Support clinical trial activities 2. LFS/N0509: Carry out reporting and documentation for clinical trials 3. LFS/N0101: Maintain a healthy, safe and secure working environment in the life sciences facility 4. LFS/N0510: Coordinate with team members and site **Optional:**

Job Details

	N.A.

Performance Criteria	As described in the relevant NOS units

Definitions

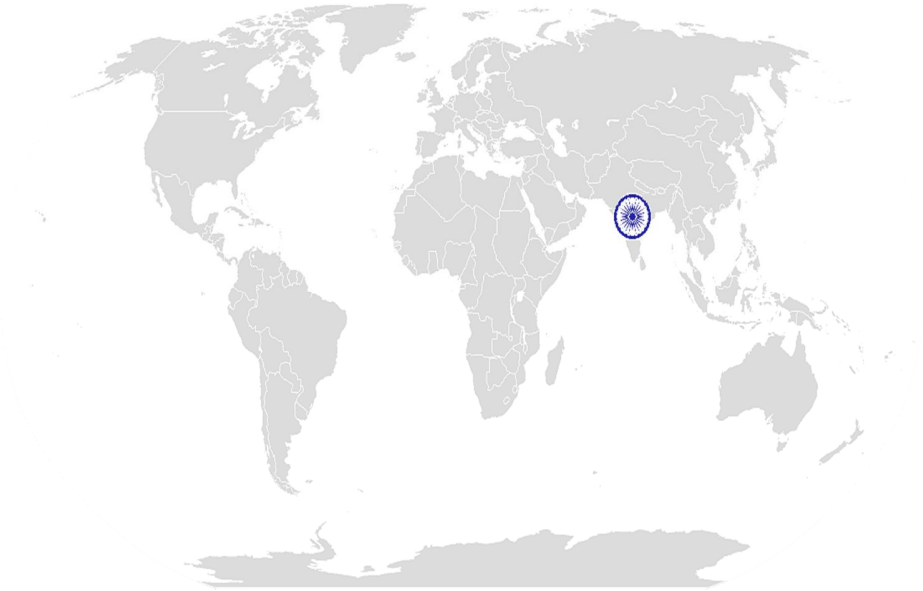
Keywords /Terms	Description
Core Skills/Generic Skills	Core Skills or Generic Skills are a group of skills that are key to learning and working in today's world. These skills are typically needed in any work environment. In the context of the NOS, these include communication related skills that are applicable 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.
Vertical	Vertical may exist within a sub-sector representing different domain areas or the client industries served by the industry.

Acronyms

Keywords /Terms	Description
NOS	National Occupational Standard(s)
NSQF	National Skill Qualifications Framework
NCO-2004	National Classification of Occupations-2004
OS	Occupational Standard(s)
QP	Qualifications Pack
CRF	Case Report Form
SoP	Standard Operating Procedures
CRO	Clinical Research Organization

National Occupational Standards



Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Clinical Research Associate to support the clinical trial activities.

LFS/N0508 : Support clinical trial activities

National Occupational Standard

Unit Code	LFS/N0508
Unit Title (Task)	**Support clinical trial activities**
Description	This NOS is about a clinical research associate performing the required activities to effectively support the clinical trial activities
Scope	The unit/task covers the following: • Monitor clinical trials for effectiveness, ethical practices and safety • Monitor participants during a clinical trial for safety and rights of participants
Performance Criteria (PC) w.r.t. the Scope	
Element	**Performance Criteria**
Monitor clinical trials for effectiveness, ethical practices and Safety	To be competent, the user/individual on the job must be able to: PC1. organise investigator's start-up meeting and study site initiation meetings PC2. monitor that the clinical trial protocol should be complied with during all the research activities and effectively communicate with principal Investigator, co-investigator and clinical research coordinators - to gather information for reviewing and assessing the clinical trial process followed by study team; to ascertain if study procedures are being consistently carried out by the study team across all participants; to ensure that principal investigator is submitting documents to ethics committee in a timely manner PC3. perform source data verification, review source documents, informed consent procedures and forms for evaluating the participant's eligibility and assessing protection of participant's rights PC4. review efficacy related aspects of the participants, investigational product compliance by participants and review case report forms (CRFs) PC5. carry out on site visits and support in conduction audit for the sites to ensure that all investigational products are stored and drug accountability is maintained as per SOP PC6. ensure optimal usage of resources by effective deployment of the same
Monitor participant's during a clinical trial for safety and rights of participants	PC7. ensure safety and rights of participants, review safety events and ensure that drug related Adverse Events (AE) are identified and promptly reported to all concerned stakeholders and ethics committee within prescribed timelines and as per SOPs PC8. record and review the rate of subject recruitment, visits that subjects fail to make and tests that are not conducted and ensure documentation exists at site to follow up with patient for any missing test/ procedure and recommend participant enrolment and retention plan with principal investigator and co-investigator PC9. ensure the documentation of the withdrawals of enrolled subjects with reasons on the CRFs by the site coordinators and principal investigators PC10. Identify anomalies in study conduct from a misconduct or fraud perspective
Knowledge and Understanding (K)	
A. Organisational Context	The user/individual on the job needs to know and understand:

LFS/N0508 : Support clinical trial activities

(Knowledge of the Company/ Organisation and its processes)	KA1. organization's SoPs KA2. impact of various practices on cost, quality, productivity, delivery and safety KA3. availability of trial material on trial sites KA4. country regulations and compliances relevant to clinical trial process
B. Technical Knowledge	The user/individual on the job needs to know and understand: KB1. physiology and reason of disease condition KB2. standard of care, treatment options and dose of medication KB3. clinical trial protocol KB4. investigator brochure and knowledge of the characteristics of the investigational drug in the study KB5. Required regulatory clearance – "No Objection Certificate" as well as relevant licenses for study drug import and biological sample exports KB6. procedures and responsibility for reporting research and performance information KB7. availability and use of monitoring and measuring devices and regulations KB8. basics of finance and accounts to keep a track of site payments and patient compensation KB9. principles of ICH-GCP, Indian GCP and ICMR guidelines, Good Documentation Practices and Good Laboratory Practices
Skills (S)	
A. Core Skills/ Generic Skills	**Writing skills**
	The user/ individual on the job needs to know and understand how to: SA1. make legible entries with the permanent ink in monitoring documents as well as entry the monitoring data in the defines formats in online systems in English language SA2. write detailed reports for monitoring SA3. pay attention to detail while recording research parameters and monitoring reports
	Reading skills
	The user/individual on the job needs to know and understand how to: SA4. read important documents, reports and procedures accurately SA5. read the guidelines and interpret them correctly
	Oral Communication (Listening and Speaking skills)
	The user/individual on the job needs to know and understand how to: SA6. interact with people to effectively gather information SA7. listen effectively and orally communicate information accurately SA8. ask for clarification and advice from others SA9. maintain confidentiality of sensitive information
	Decision making

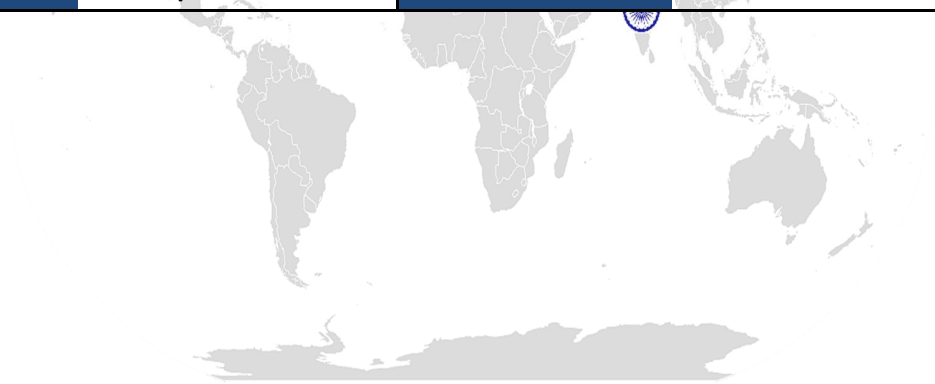
LFS/N0508 : Support clinical trial activities

B. Professional Skills	The user/individual on the job needs to know and understand how to: SB1. make decisions on a suitable course of action or response SB2. make decisions in a team considering the ideas of the team
	Plan and Organise
	The user/individual on the job needs to know and understand how to: SB3. plan work assigned on a daily basis and provide estimates of time required for each piece of work SB4. multi-task and adapt to meet work timelines
	Problem solving
	The user/individual on the job needs to know and understand how to: SB5. seek clarification on problems from others SB6. use effective problem solving techniques
	Critical thinking
	The user/individual on the job needs to know and understand how to: SB7. apply, analyse and evaluate information to define action steps SB8. apply balanced judgments to different approaches SB9. understand the depth of the issue and apply a proactive approach
	Analytical Thinking
	NA
	Customer Centricity
	NA

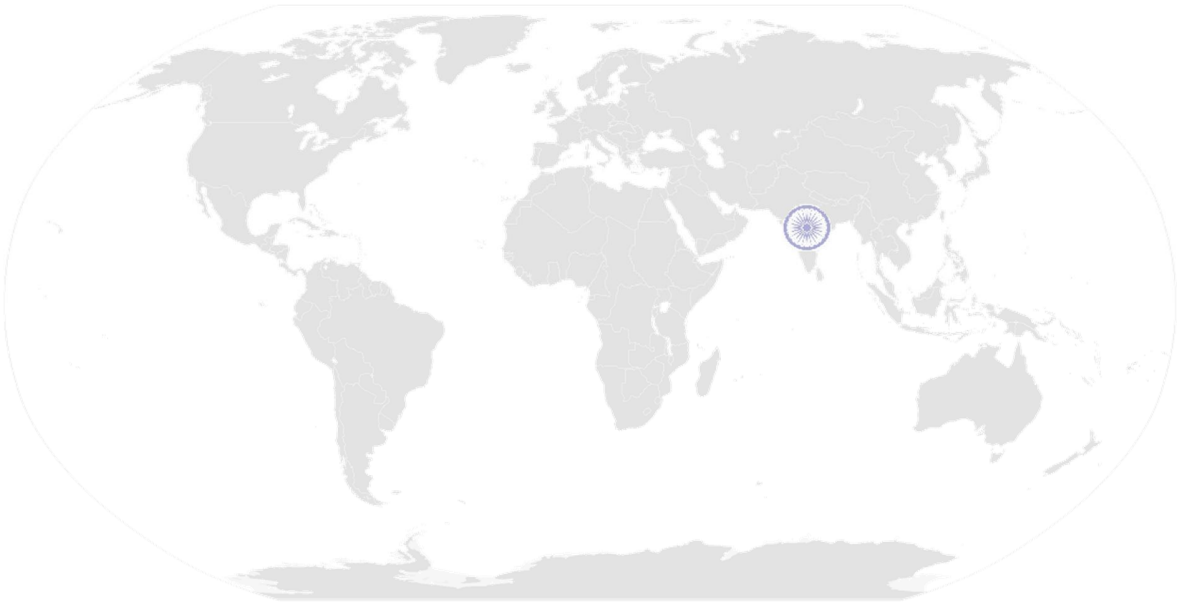
LFS/N0508 : Support clinical trial activities

NOS Version Control

NOS Code	LFS/N0508		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	11/12/14
Industry Sub-sector	Pharmaceutical and Biopharmaceutical	Last reviewed on	01/08/16
Occupation	Research and Development	Next review date	01/08/19



National Occupational Standards



Overview

This Occupational Standard describes the knowledge, understanding and skills required of a Clinical Research Associate to carry out reporting and documentation for clinical trials.

LFS/N0509 : Carry out Reporting and Documentation for Clinical Trials

National Occupational Standard

Unit Code	**LFS/N0509**
Unit Title (Task)	**Carry out reporting and documentation for clinical trials**
Description	This NOS is about a clinical research associate performing the required activities to effectively report and document the clinical trials monitoring process
Scope	• Pre research activities • Activities to be carried out during research process • Post research activities
Performance Criteria (PC) w.r.t. the Scope	
Element	**Performance Criteria**
Pre research activities	To be competent, the user/individual on the job must be able to: PC1. assist in outlining the purpose and methodology of a trial PC2. assist in developing, drafting and writing the Trial Protocols, Patient Information Sheet, Informed Consent Form, Patient Diaries, CRFs, development of regulatory dossier for regulatory and ethics committee submissions PC3. assist in presenting trial protocols to a steering committee PC4. assist in generating regulatory authority applications and approvals PC5. assist in identification, selection and evaluation of trial sites and investigators and provide inputs in investigator grants and agreements
Research process activities	PC6. develop training materials for site for site initiations PC7. prepare follow up letters to principal investigator, complete site monitoring documentation and prepare site monitoring visit reports, maintain records of communication with site staff and investigator, letters of agreement, lab reference ranges and schedule of payment PC8. maintain project files including: ethics committee approvals; curriculum vitae of investigators and study personnel; Investigator's Undertaking etc. PC9. maintain documentation on clinical trial material shipping orders and prepare relevant monitoring reports PC10. ensure that adverse events are correctly documented and reported PC11. coordinate with the site for obtaining filled documents/CRFs
Post research activities	PC12. provide inputs to medical/ scientific teams as well as bio-statistician, who analyses technical trial data and writes technical trial reports PC13. ensure the scientific integrity of the data collected and ensure it is protected and verified PC14. provide support in preparing final reports, occasionally manuscripts for publication PC15. ensure that unfavourable occurrences (e.g. protocol deviations) are clearly reported and documented PC16. archive study documentation, and trial related correspondence PC17. coordinate with the pharmaco-vigilance teams for documenting post-marketing adverse drug reactions
Knowledge and Understanding (K)	

LFS/N0509 : Carry out Reporting and Documentation for Clinical Trials

A. Organisational Context (Knowledge of the Company/ Organisation and its processes)	The user/individual on the job needs to know and understand: KA1. ICH-GCP guidelines, legislation and regulations as applicable and impact of non-conformance/poor practices KA2. how to implement the relevant company SOPs for the fulfilment of each clinical trial
B. Technical Knowledge	The user/individual on the job needs to know and understand: KB1. use of computer/application software KB2. procedures and responsibility for reporting research and performance information KB3. the reason and impact of the occurrence of problems KB4. basics of finance and accounts to keep a track of site payments and patient compensation
Skills (S)	
A. Core Skills/ Generic Skills	**Writing skills**
	The user/ individual on the job needs to know and understand how to: SA1. draft letters pertaining to site and write detailed reports for monitoring with sensitivity, ensuring confidentiality of data SA2. complete document accurately as per ICH GCP and GDP
	Reading skills
	The user/individual on the job needs to know and understand how to: SA3. read the clinical trial documents, protocols and SOPs/ guidelines and interpret them correctly SA4. read notes/comments from supervisors
	Oral Communication (Listening and Speaking skills)
	The user/individual on the job needs to know and understand how to: SA5. listen effectively and verbally communicate information accurately SA6. ask for clarification and advice from supervisors when needed SA7. maintain confidentiality of sensitive information
B. Professional Skills	**Analytical Thinking**
	The user/individual on the job needs to know and understand how to: SB1. analyse data and information for preparing reports SB2. pay attention to detail SB3. identify anomalies in data SB4. suggest improvements(if any) in process/formats for reports/documentation based on experience and observation SB5. use available data and computer software to create required documentation

LFS/N0509 : Carry out Reporting and Documentation for Clinical Trials

	Decision making
	The user/individual on the job needs to know and understand how to: SB6. make decisions on a suitable course of action or response
	Plan and Organize
	The user/individual on the job needs to know and understand how to: SB7. plan and organize assigned work in order to achieve specified deadlines SB8. multi-task and adapt to meet work timelines SB9. effectively interact with the various stakeholders to complete assigned tasks
	Critical Thinking
	NA
	Problem Solving
	NA
	Customer Centricity
	NA

NOS Version Control

NOS Code	**LFS/N0509**		
Credits(NSQF)	**TBD**	**Version number**	**1.0**
Industry	**Life Sciences**	**Drafted on**	**11/12/14**
Industry Sub-sector	**Pharmaceutical and Biopharmaceutical**	**Last reviewed on**	**01/08/16**
Occupation	**Research and Development**	**Next review date**	**01/08/19**

National Occupational Standards

Overview

This Occupational Standard is about the knowledge, understanding and skills required by a Clinical Research Associate to ensure healthy, safe and secure working environment in the life sciences facility

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

National Occupational Standard

Unit Code	**LFS /N0101**
Unit Title (Task)	**Maintain a healthy, safe and secure working environment in the life sciences facility**
Description	This NOS unit is about a Clinical Research Associate monitoring the working environment and making sure that it meets the requirements for health, safety and security in the pharmaceutical/contract research/biopharmaceutical facility/ manufacturing/ testing/ analysis/ research laboratory.
Scope	This unit / task covers the following: **Ensuring healthy, safe and secure working environment:** • self monitor and adhere to safety principles and standards • ensure behavioural safety by workmen to cGMP and applicable safety standards on the shop floor/ laboratory • report any identified breaches in health, safety, and security policies and procedures to the designated person **Managing emergency procedures**: • illness • accidents • fires • other reasons to evacuate the premises • breaches of security

Performance Criteria (PC) wrt the Scope	
Element	**Performance Criteria**
Ensuring healthy, safe and secure working environment	To be competent, you must be able to: PC1. observe and comply with your company's current health, safety and security policies and procedures PC2. while carrying out work, use appropriate safety gears like head gear, masks, gloves and other accessories as mentioned in the guidelines PC3. report any identified breaches in health, safety, and security policies and procedures to the designated person PC4. responsible for maintaining discipline at the shop-floor/ production area PC5. identify and correct any hazards that you can deal with safely, competently and within the limits of your authority PC6. adhere and comply to storage and handling guidelines for hazardous material PC7. identify and recommend opportunities for improving health, safety, and security to the designated person PC8. complete any health, safety and security activities like safety drills and prepare records legibly and accurately
Managing emergency procedures	PC9. report any hazards that you are not competent to deal with to the relevant person in line with organizational procedures and warn other people who may be affected

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

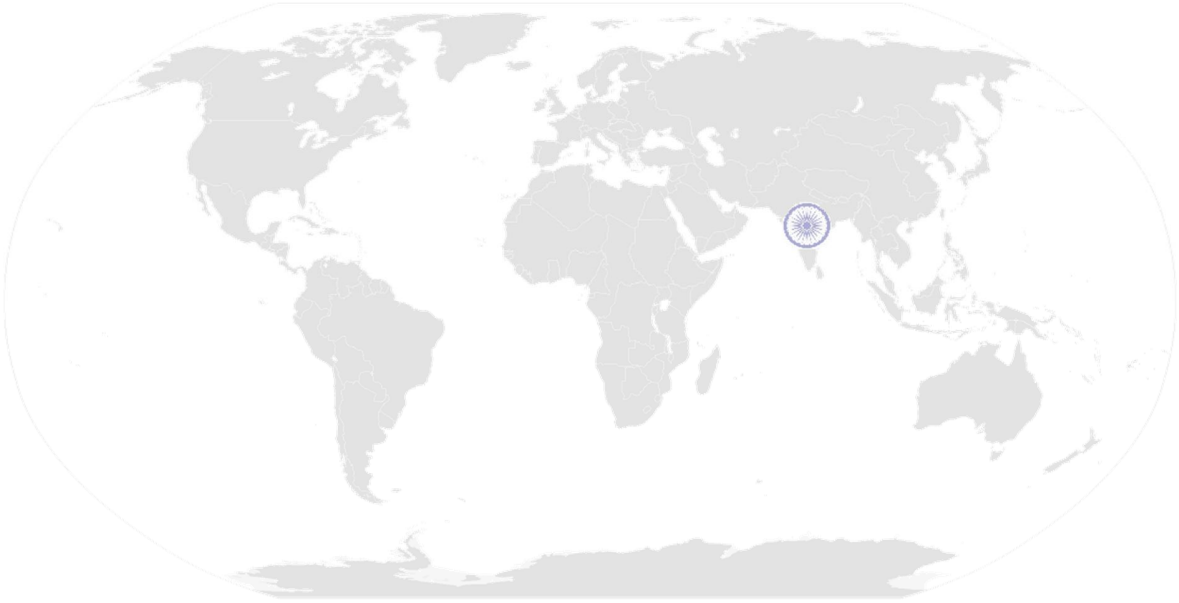
	PC10. follow your company's emergency procedures promptly, calmly, and efficiently
Knowledge and Understanding (K)	
A. Organisational Context (Knowledge of the Company/ Organisation and its processes)	You need to know and understand: KA1. legislative requirements and company's procedures for health, safety and security and your role and responsibilities in relation to this KA2. what is meant by a hazard, including the different types of health and safety hazards that can be found in the workplace KA3. how and when to report hazards KA4. limits of your responsibility for dealing with hazards KA5. your organization's emergency procedures for different emergency situations and the importance of following these KA6. the importance of maintaining high standards of health, safety and security KA7. implications that any non-compliance with health, safety and security may have on individuals and the organization KA8. health hazards and its implications if any in the production process
B Technical Knowledge	You need to know and understand: KB1. different types of breaches in health, safety and security and how and when to report these KB2. evacuation procedures for workers and visitors KB3. how to summon medical assistance and the emergency services, where necessary KB4. how to use the health, safety and accident reporting procedures and the importance of these KB5. different types of occupational health hazards KB6. knowledge of chemical substances, their characteristics and required precaution and safety measures
Skills (S)	
A. Core Skills/ Generic Skills	**Writing skills** You need to know and understand: SA1. complete accurate, well written work with attention to detail
	Reading skills You need to know and understand: SA2. read instructions, guidelines, procedures, rules and service level agreements

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

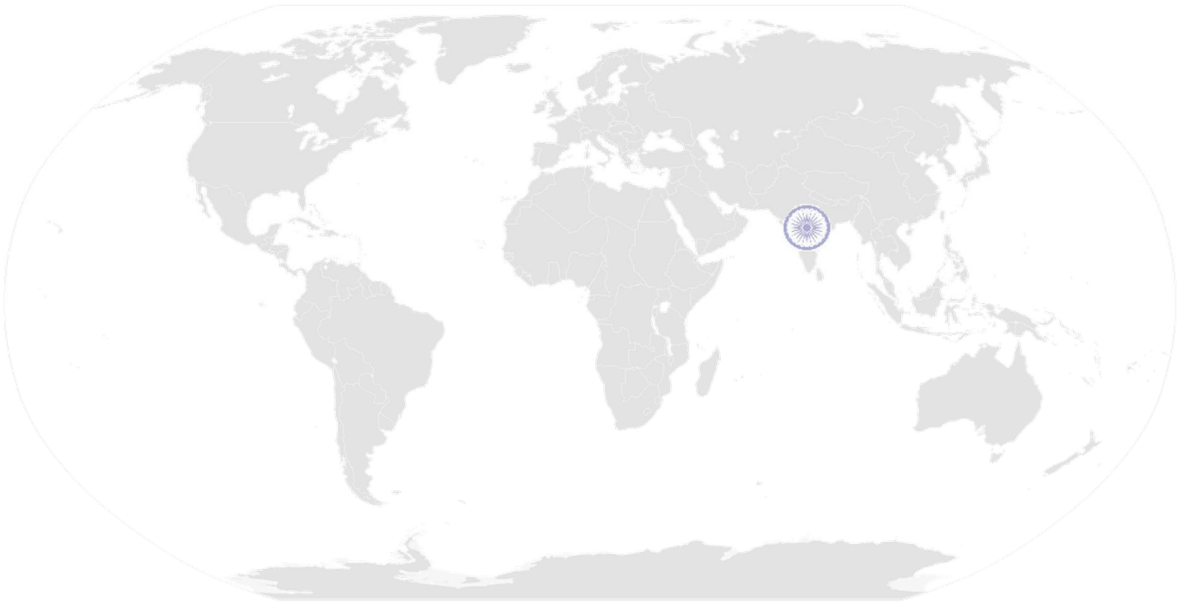
	Oral Communication (Listening and Speaking skills)
	You need to know and understand: SA3. listen effectively and orally communicate information accurately
B. Professional Skills	**Decision making**
	You need to know and understand: SB1. make decisions on suitable courses of action
	Plan and Organise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

NOS Version Control

NOS Code	LFS/N0101		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	11/12/14
Industry Sub-sector	Pharmaceutical and Biopharmaceutical	Last reviewed on	01/08/16
Occupation	Research and Development	Next review date	01/08/19



National Occupational Standards



Overview

This Occupational Standard describes the knowledge, understanding and skills required of a Clinical Research Associate to work as a team member and coordinate with the site.

LFS/N0510 : Coordinate with team members and site

National Occupational Standard

Unit Code	LFS/N0510
Unit Title (Task)	**Coordinate with team members and site**
Description	This NOS unit is about communicating with colleagues and working in coordination with site
Scope	This unit/task covers the following: • Coordination and communication with team members • Coordinating with vendors and site staff
Performance Criteria (PC) w.r.t. the Scope	
Element	**Performance Criteria**
Coordination with team members	To be competent, the user/individual on the job must be able to: PC1. work as a team with colleagues and share work as per their or own work load and skills PC2. provide documented shift handovers to the next person in the shift or during transition from one project to other project PC3. effectively communicate with team members in case of research related difficulties and escalate issues to manager or designated personnel in cases where support is required
Coordinating with site	PC4. coordinate with the site/ CRO team for clinical research (in phase 1 or BA/ BE studies)– this may include volunteer management; protocol deployment; sample handling; data management and training and expectation setting of site staff PC5. coordinate with principal investigator, site manager, vendor, clinical research coordinator for clinical trial (in phase 2- phase 4 trial)- this may include logistics coordination related to drug supplies, lab kits; coordination and follow up with site for investigator meeting, subject enrolment, trial performance, quality of study conduct, feedback during site monitoring, technical discussions about compliance to protocol, collecting essential documents as per GCP/ regulatory requirements, coordinating for internal or external quality audits, coordinating responses from the Principal Investigator; imparting training to site staff
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. SOPs and organizational policies about communication, code of conduct KA2. clinical research team reporting structure KA3. correct method for carrying out corrective actions outlined for trial-related problems KA4. sponsors and CRO roles and responsibilities KA5. site roles and responsibilities KA6. working in cross functional, cross geographical and cross cultural teams KA7. information security and confidentiality policy

LFS/N0510 : Coordinate with team members and site

B. Technical Knowledge	The user/individual on the job needs to know and understand: KB1. clinical trial-related regulations and compliances KB2. sample handling procedures KB3. knowledge of trial protocol
Skills (S)	
A. Core Skills/ Generic Skills	**Writing skills**
	The user/ individual on the job needs to know and understand how to: SA1. write mails, monitoring reports and documents, letters in English language with sensitivity towards cross cultural differences SA2. complete documentation accurately and as per GDP
	Reading skills
	The user/individual on the job needs to know and understand how to: SA3. read notes/comments from the supervisor SA4. read trial related documents (written in english) and interpret technical details mentioned in the trial related documents
	Oral Communication (Listening and Speaking skills)
	The user/individual on the job needs to know and understand how to: SA5. interact with team members, sponsors and site staff efficiently in English with sensitivity towards cross cultural differences SA6. listen effectively and be sensitive for cross cultural differences
B. Professional Skills	**Decision making**
	The user/individual on the job needs to know and understand how to: SB1. make decisions on a suitable course of action or response SB2. appropriately use the escalation matrix for complex decisions
	Plan and Organize
	The user/individual on the job needs to know and understand how to: SB10. plan and organize assigned work in order to effectively interact with the various stakeholders SB11. multi-task and adapt to meet timelines
	Analytical thinking
	The user/individual on the job needs to know and understand how to: SB3. spot process disruptions and delays and report and communicate with solutions SB4. improve processes by interacting with others and adopting best practices SB5. identify communication delays and address them with appropriate solutions
	Critical Thinking

LFS/N0510 : Coordinate with team members and site

	NA
	Problem Solving
	NA
	Customer Centricity
	NA

NOS Version Control

NOS Code	LFS/N0510		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	11/12/14
Industry Sub-sector	Pharmaceutical and Biopharmaceutical	Last reviewed on	01/08/16
Occupation	Research and Development	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

CRITERIA FOR ASSESSMENT OF TRAINEES

Job Role Clinical Research Associate
Qualification Pack LFS/Q0503
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 (400)**	**Out of**	**Theory**	**Skills Practical**
LFS/N0508 (Support Clinical Research Activities)	PC1. organise investigator's start-up meeting and study site initiation meetings	100	10	4	6
	PC2. monitor that the clinical trial protocol should be complied with during all the research activities and effectively communicate with principal Investigator, co-investigator and clinical research coordinators - to gather information for reviewing and assessing the clinical trial process followed by study team; to ascertain if study procedures are being consistently carried out by the study team across all participants; to ensure that principal investigator is submitting documents to ethics committee in a timely manner		16	6	10
	PC3. perform source data verification, review source		16	6	10

	documents, informed consent procedures and forms for evaluating the participant's eligibility and assessing protection of participant's rights				
	PC4. review efficacy related aspects of the participants, investigational product compliance by participants and review case report forms (CRFs)		10	4	6
	PC5. carry out on site visits and support in conduction audit for the sites to ensure that all investigational products are stored and drug accountability is maintained as per SOP		10	4	6
	PC6. ensure optimal usage of resources by effective deployment of the same		10	4	6
	PC7. ensure safety and rights of participants, review safety events and ensure that drug related Adverse Events (AE) are identified and promptly reported to all concerned stakeholders and ethics committee within prescribed timelines and as per SOPs		6	3	3
	PC8. record and review the rate of subject recruitment, visits that subjects fail to make and tests that are not conducted and ensure documentation exists at site to follow up with patient for any missing test/ procedure and recommend participant enrolment and retention plan with principal investigator and co- investigator		10	5	5
	PC9. ensure the documentation of the withdrawals of enrolled subjects is being done by site staff with reasons on the CRFs by the site coordinators and principal investigators		6	2	4
	PC10. Identify anomalies in study conduct from a misconduct or fraud perspective		6	2	4
	Total		100	40	60

LFS/N0509 (Carry out Reporting and Documentation)	PC1. assist in outlining the purpose and methodology of a trial	100	10	4	6
	PC2. assist in developing, drafting and writing the Trial Protocols, Patient Information Sheet, Informed Consent Form, Patient Diaries, CRFs, development of regulatory dossier for regulatory and ethics committee submissions		10	4	6
	PC3. assist in presenting trial protocols to a steering committee		6	2	4
	PC4. assist in generating regulatory authority applications and approvals		10	4	6
	PC5. assist in identification, selection and evaluation of trial sites and investigators and provide inputs in investigator grants and agreements		6	2	4
	PC6. develop training materials for site for site initiations		4	2	2
	PC7. prepare follow up letters to principal investigator, complete site monitoring documentation and prepare site monitoring visit reports, maintain records of communication with site staff and investigator, letters of agreement, lab reference ranges and schedule of payment		10	4	6
	PC8. maintain project files including: ethics committee approvals; curriculum vitae of investigators and study personnel; Investigator's Undertaking etc.		4	2	2
	PC9. maintain documentation on clinical trial material shipping orders and prepare relevant monitoring reports		4	2	2
	PC10. ensure that adverse events are correctly documented and reported		8	4	4
	PC11. coordinate with the site for obtaining filled documents/CRFs		6	4	2
	PC12. provide inputs to medical/ scientific teams as well as bio-statistician, who analyses		4	2	2

Qualifications Pack For Clinical Research Associate

	technical trial data and writes technical trial reports				
	PC13. ensure the scientific integrity of the data collected and ensure it is protected and verified		3	2	1
	PC14. provide support in preparing final reports, occasionally manuscripts for publication		6	2	4
	PC15. ensure that unfavourable occurrences (e.g. protocol deviations) are clearly reported and documented		4	2	2
	PC16. archive study documentation, and trial related correspondence		2	1	1
	PC17. coordinate with the pharma co-vigilance teams for documenting post-marketing adverse drug reactions		3	2	1
	Total		100	45	55
LFS/N0101 (Maintain a healthy, safe and secure working environment at 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 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 incompetent to deal with to relevant person in line with organizational procedures and warn other people affected		10	4	6
	PC10. follow your company's emergency procedures promptly, calmly, and efficiently		10	5	5
	Total		100	48	52
LFS/N0510 (Coordinate with team members and site)	PC1. work as a team with colleagues and share work as per their or own work load and skills	100	10	4	6
	PC2. provide documented shift handovers to the next person in the shift or during transition from one project to other project		20	10	10
	PC3. effectively communicate with team members in case of research related difficulties and escalate issues to manager or designated personnel in cases where support is required		10	4	6
	PC4. coordinate with the site/ CRO team for clinical research (in phase 1 or BA/ BE studies)– this may include volunteer management; protocol deployment; sample handling; data management and training and expectation setting of site staff		30	10	20
	PC5. Coordinate with principal investigator, site manager, vendor, clinical research coordinator for clinical trial (in phase 2- phase 4 trial)- this may include logistics coordination related to drug supplies, lab kits; coordination and follow up with site for investigator meeting, subject enrolment, trial performance, quality of study conduct, feedback during site monitoring, technical discussions about compliance to protocol, collecting essential documents as per GCP/ regulatory requirements,		30	10	20

	coordinating for internal or external quality audits, coordinating responses from the Principal Investigator; imparting training to site staff				
	Total		100	38	62