

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-Data Entry Operator /Documentation Officer

SECTOR: LIFE SCIENCES

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

OCCUPATION: RESEARCH AND DEVELOPMENT

REFERENCE ID: LFS/Q0510

ALIGNED TO: NCO-2004/NIL

Data Entry Operator, also known as Documentation Officer, undertakes entry, updation and maintenance of patient, drug and test result data on computer systems and in archives.

Brief Job Description: Data Entry Operator is responsible for receiving the source document from multiple teams, entering the data into computer systems, verifying data and completing the mandated forms associated with the data processing procedure.

Personal Attributes: The individual should have good reading and writing skills and needs to be adept at working on computer applications. Attention to detail is a key requirement

Qualifications Pack Code	LFS/Q0510		
Job Role	Data Entry Operator/Documentation Officer		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	15/01/15
Sub-sector	Pharmaceutical, Bio- Pharmaceutical, Contract Research	Last reviewed on	01/08/16
Occupation	Research and Development	Next review date	01/08/19
NSQC Clearance on	20/07/2015		

Job Role	Data Entry Operator/Documentation Officer
Role Description	Responsible for entry, updation and maintenance of patient, drug and test result data on computer systems and in archives
NSQF level	4
Minimum Educational Qualifications	Diploma in Computer Science / Diploma in Computer Application/ Any Graduate/ B.Sc. (Preferred)
Maximum Educational Qualifications	B. Tech in Computer Science
Training (Suggested but not mandatory)	Typing, Computer Application, clinical trial applications, 21CFR Part 11, clinical research terminology / therapeutic subject matter, On the job training
Minimum Job Entry Age	18 Years
Experience	-
Applicable National Occupational Standards (NOS)	<p>Compulsory</p> <ol style="list-style-type: none"> LFS/N0535: Enter, update and maintain R&D data in the system LFS/N0536: Maintain associated data entry terminals LFS/N0304: Coordinate with Supervisor and colleagues within and outside the department

Job Details

	<p>Optional N.A.</p>
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Performance Criteria	As described in the relevant NOS units

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.
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

LFS/N0535 : Enter, update and maintain R&D data in the system

National Occupational Standard

Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Data Entry Operator for entering, updating and maintaining R&D-related data in the systems.

LFS/N0535 : Enter, update and maintain R&D data in the system

National Occupational Standard	Unit Code	LFS/N0535
	Unit Title (Task)	Enter, update and maintain R&D data in the system
	Description	This NOS unit is about the Data Entry Operator for entering, updating and maintaining R&D-related data in the systems
	Scope	This unit / task covers the following: <ul style="list-style-type: none"> Enter, update and maintain data
	Performance Criteria (PC) w.r.t. the Scope	
	Element	Performance Criteria
	Enter, update and maintain data	<p>To be competent, the user/individual on the job must be able to:</p> <p>PC1. prioritize service requests according to organizational guidelines</p> <p>PC2. fill and process mandated forms for receiving, processing, or tracking data</p> <p>PC3. enter data from source documents (such as patient report, test report etc.) or case report forms into computer application following standard sequence and coding protocols</p> <p>PC4. scan source documents in accordance with specific instructions</p> <p>PC5. verify data entered with source documents, checks for compliance with composition codes and style rules and corrects all typographical errors and missing or repeated data as per the source document only</p> <p>PC6. maintain files of source documents or other information related to data entered</p> <p>PC7. investigate and confirm data that is unclear before entering</p> <p>PC8. generate reports of data entry, store completed work in designated locations and perform backup operations</p> <p>PC9. update database information to reflect most current source information, such as patient profiles</p> <p>PC10. assist in the filing and storage of security and back up data files</p> <p>PC11. respond to requests for information and access relevant files</p>
	Knowledge and Understanding (K)	
	A. Organisational Context (Knowledge of the Company/ Organisation and its processes)	<p>The user/individual on the job needs to know and understand:</p> <p>KA1. the data management applications/tools used by the company</p> <p>KA2. organizational coding system</p> <p>KA3. data entry protocol</p> <p>KA4. data integrity and security policies of the company</p> <p>KA5. escalation matrix for reporting identified issues</p> <p>KA6. approved methods for carrying document control and archiving</p>
	B. Technical Knowledge	<p>The user/individual on the job needs to know and understand:</p>

LFS/N0535 : Enter, update and maintain R&D data in the system

	<p>KB1. basic understanding of life sciences terminology KB2. importance of compliance with company protocols while carrying out research KB3. understand computer and its terminology KB4. work on different software needed for report writing including MS office suit or open source office KB5. undertake basic and advance workstation configuration, maintenance, networking as well as trouble shooting KB6. guidelines as per 21 CFR Part 11 KB7. basic therapeutic subject matter; and clinical research and medical terminology</p>
Skills (S)	
A. Core Skills/ Generic Skills	<p>Writing skills</p> <p>The user/ individual on the job needs to know and understand how to:</p> <p>SA1. efficiently enter data into computer applications SA2. prepare legible reports / fill mandates data processing forms</p> <p>Reading skills</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SA3. read and understand manuals, SOPs, instructions, memos, reports, job cards etc. SA4. read the data captured in source documents SA5. Read and interpret patient information and records</p> <p>Oral Communication (Listening and Speaking skills)</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SA6. communicate effectively with the team members and supervisors SA7. maintain confidentiality of information</p>
B. Professional Skills	<p>Analytical Skills</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SB1. use computer applications SB2. apply basic logic to identify data errors SB3. pay attention to details</p> <p>Plan and Organise</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SB4. plan assigned tasks within timeline and as per priority order specified</p> <p>Critical Thinking</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SB5. identify process improvements</p> <p>Problem solving</p>

LFS/N0535 : Enter, update and maintain R&D data in the system

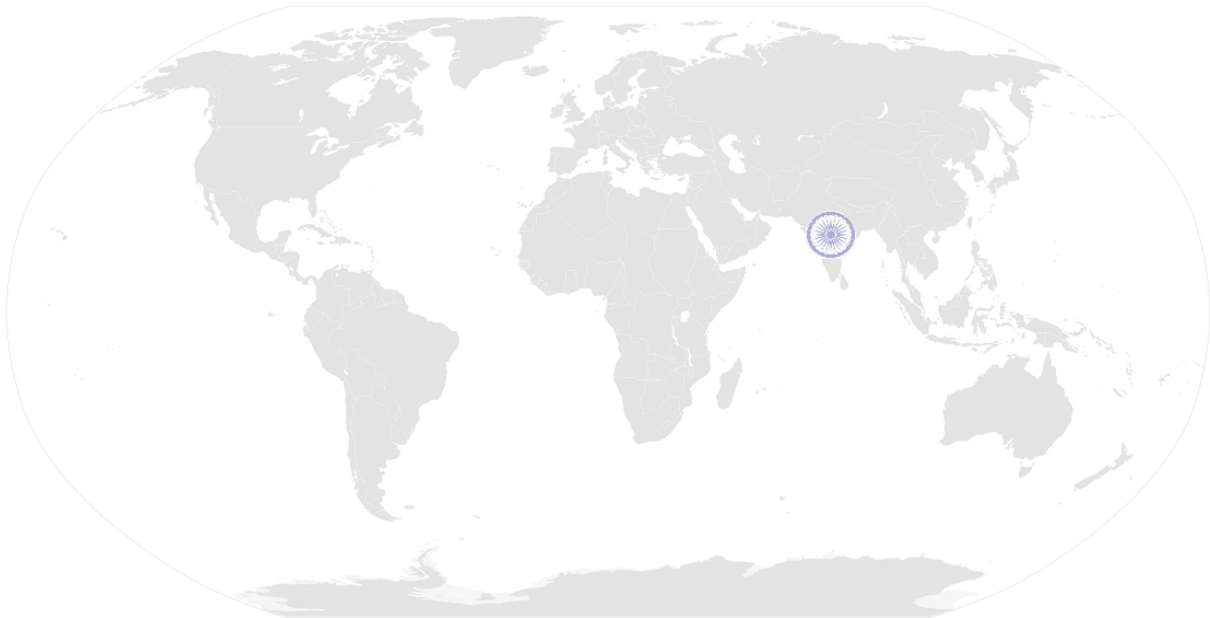
	The user/individual on the job needs to know and understand how to: SB6. reach out to supervisor for problems faced in assigned tasks
	Analytical Thinking
	NA
	Customer Centricity
	NA

NOS Version Control

NOS Code	LFS/N0535		
Credits(NSQF)	TBD	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/N0536 : Maintain associated data entry terminals

National Occupational Standard



Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Data Entry Operator to maintain and manage the data entry systems being worked on.

LFS/N0536 : Maintain associated data entry terminals

National Occupational Standard	Unit Code	LFS/N0536
	Unit Title (Task)	Maintain associated data entry terminals
	Description	This NOS unit is about the Data Entry Operator to maintaining and managing the data entry systems he/she is working on.
	Scope	This unit / task covers the following: <ul style="list-style-type: none"> Basic data entry terminal/system maintenance
	Performance Criteria (PC) w.r.t. the Scope	
	Element	Performance Criteria
	Basic data entry terminal/system maintenance	To be competent, the user/individual on the job must be able to: <ul style="list-style-type: none"> PC1. maintain logbooks or records for data entry job runs on the terminal PC2. operate the terminal as per the defined organization procedures PC3. be attentive for error lights and indicators and highlight the same to the concerned authority PC4. correctly load files onto storage media of the system PC5. check for network and servers functioning prior to job commencement PC6. clear the terminal surrounding at the end of the jobs PC7. notify the appropriate authority of malfunctions
	Knowledge and Understanding (K)	
	B. Organisational Context (Knowledge of the Company/ Organisation and its processes)	The user/individual on the job needs to know and understand: <ul style="list-style-type: none"> KA1. the data management applications/tools used by the company KA2. data entry protocol KA3. data integrity and security policies of the company KA4. escalation matrix for reporting identified issues
	B. Technical Knowledge	The user/individual on the job needs to know and understand: <ul style="list-style-type: none"> KB1. importance of compliance with company protocols KB2. computer terminals and its terminology KB3. undertake basic and advance workstation configuration, maintenance, networking as well as trouble shooting
Skills (S)		
A. Core Skills/ Generic Skills	Writing Skills	
	The user/ individual on the job needs to know and understand how to: <ul style="list-style-type: none"> SA1. efficiently enter data into computer applications SA2. prepare legible reports / fill mandates data processing forms 	

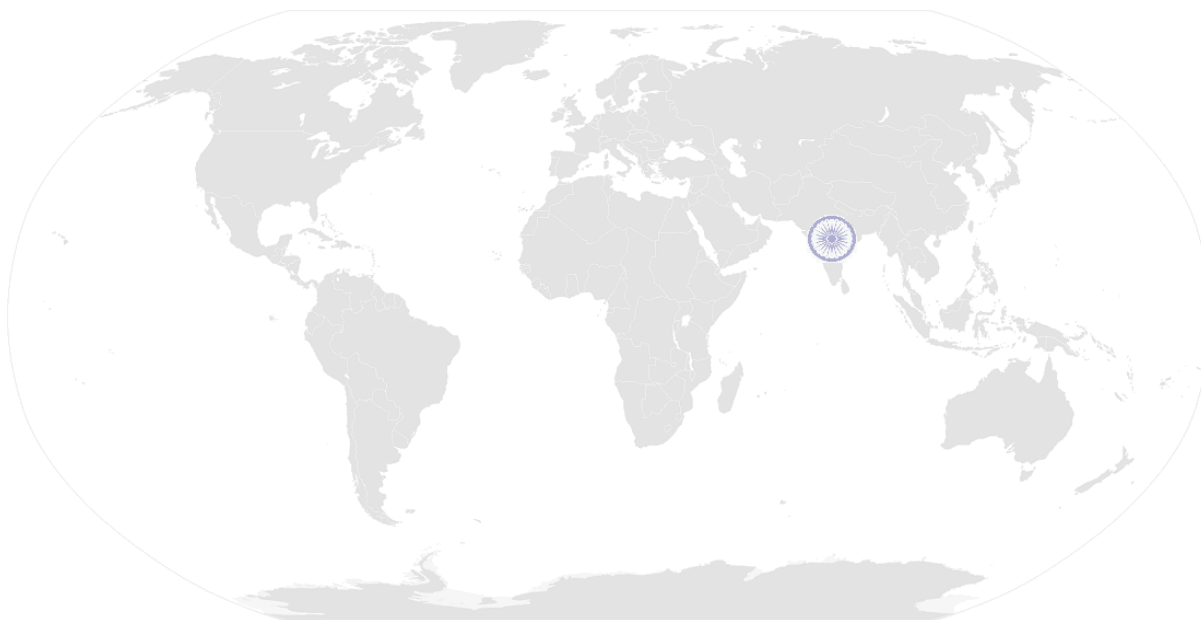
LFS/N0536 : Maintain associated data entry terminals

	Reading Skills
	The user/individual on the job needs to know and understand how to:
	SA3. read and understand manuals, SOPs, health and safety instructions, memos, reports, job cards etc.
	SA4. read the data captured in source documents
	SA5. Read and interpret patient records
	Oral Communication (Listening and Speaking skills)
The user/individual on the job needs to know and understand how to:	
SA6. communicate effectively to share information	
SA7. listen attentively to gather information	
B. Professional Skills	Analytical Thinking
	The user/individual on the job needs to know and understand how to:
	SB1. use computer terminals
	SB2. use computer applications
	SB3. apply basic logic to identify data errors
	SB4. pay attention to details
	Critical Thinking
	The user/individual on the job needs to know and understand how to:
	SB5. Identify and resolve process improvements
	Problem Solving
	The user/individual on the job needs to know and understand how to:
SB6. reach out to supervisor for problems faced in assigned tasks	
Decision Making	
NA	
Plan and Organize	
NA	
Customer Centricity	
NA	

LFS/N0536 : Maintain associated data entry terminals

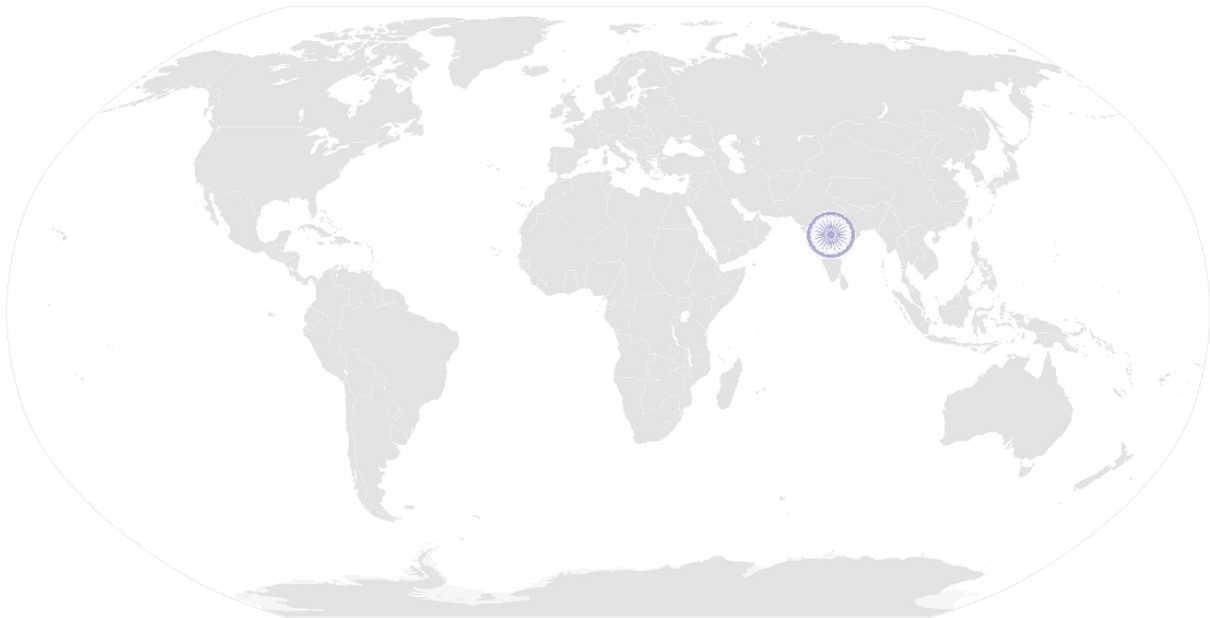
NOS Version Control

NOS Code	LFS/N0536		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	15/01/15
Industry Sub-sector	Pharmaceutical, Bio Pharmaceutical, Contract Research	Last reviewed on	01/08/16
Occupation	R&D	Next review date	01/08/19



LFS/N0302 : Coordinate with Supervisors and colleagues within and outside the department

National Occupational Standard



Overview

This Occupational Standard describes the knowledge, understanding and skills required of a Data Entry Operator to work as a team member and multi-task in order to achieve production on schedule and meeting the quality requirements.

LFS/N0302 : Coordinate with Supervisors and colleagues within and outside the department

National Occupational Standard

Unit Code	LFS/N0302
Unit Title (Task)	Coordinate with Supervisors and colleagues within and outside the department
Description	This NOS unit is about the Data Entry Operator coordinating with supervisors and colleagues within and outside the department
Scope	The unit/ task covers the following: <ul style="list-style-type: none"> Supervisors Team management
Performance Criteria (PC) w.r.t. the Scope	
Element	Performance Criteria
Supervisor	To be competent, the user/individual on the job must be able to: <ul style="list-style-type: none"> PC1. receive work instructions from reporting supervisor PC2. communicate to reporting supervisor about process-flow improvements, production defects received from previous process, repairs and maintenance of equipment as required PC3. communicate deviations in the production process to reporting supervisor PC4. communicate any potential hazards or expected process disruptions PC5. handover completed work to supervisor
Team Management	<ul style="list-style-type: none"> PC6. work as a team with colleagues and share work as per their or own work load and skills PC7. work and support colleagues of other departments PC8. train line or reporting staff if needed PC9. communicate and discuss work flow related difficulties in order to find solutions with mutual agreement PC10. explain what information means and how it can be used to team members PC11. document all the control steps undertaken or recommended to be followed as per the standards PC12. interview team members and colleagues to collect data to be recorded in log books and batch documents if needed
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: <ul style="list-style-type: none"> KA1. company's policies on: preferred language of communication, reporting and escalation policy, quality delivery standards, and personnel management KA2. reporting structure
B. Technical Knowledge	The user/individual on the job needs to know and understand: <ul style="list-style-type: none"> KB1. communicate effectively

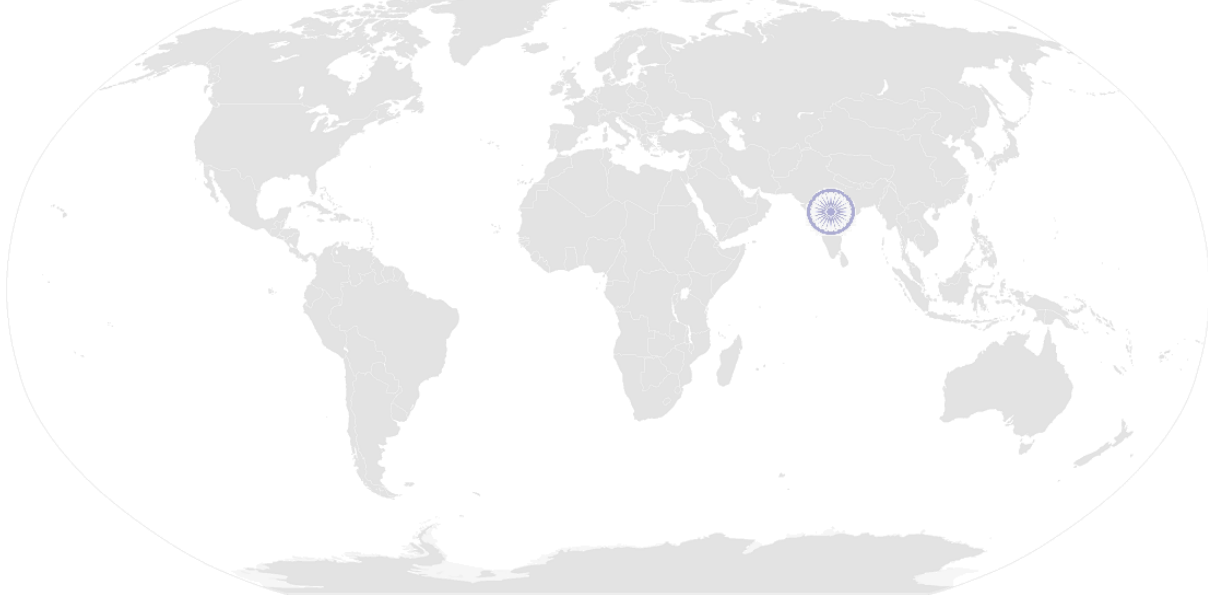
LFS/N0302 : Coordinate with Supervisors and colleagues within and outside the department

	KB2. build team coordination
Skills (S)	
A. Core Skills/ Generic Skills	Writing skills
	The user/ individual on the job needs to know and understand how to: SA1. read job sheets and interpret technical details mentioned in the jobsheet
	Reading skills
	The user/individual on the job needs to know and understand how to: SA2. read notes/comments from the supervisor
	Oral Communication (Listening and Speaking skills)
	The user/individual on the job needs to know and understand how to: SA3. interact with team members to work efficiently
B. Professional Skills	Decision Making
	The user/individual on the job needs to know and understand how to: SB1. spot and communicate potential areas of disruptions to work process and report the same SB2. when to report to supervisor and when to deal with a colleague individually, depending on the type of concern
	Critical 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 work processes by interacting with others and adopting best practices
	Analytical Thinking
	NA
	Plan and Organize
	NA
Problem Solving	
NA	
Customer Centricity	
NA	

LFS/N0302 : Coordinate with Supervisors and colleagues within and outside the department

NOS Version Control

NOS Code	LFS/N0302		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	15/12/14
Industry Sub-sector	Pharmaceutical and Bio Pharmaceuticals	Last reviewed on	01/08/16
Occupation	R&D and Quality	Next review date	01/08/19



Qualifications Pack For
Data Entry Operator/ Documentation Officer
Annexure

Nomenclature for QP and NOS

Qualifications Pack

9 characters

LFS/ Q 0101

LFS



QP Number (2 numbers)

Q denoting Qualification Pack

Occupation (2 numbers)

Occupational Standard

An example of NOS with 'N'

9 characters

LFS/ N 0101

LFS



OS Number (2 numbers)

N denoting National Occupational Standard

Occupation (2 numbers)

Qualifications Pack For
Data Entry Operator/ Documentation Officer

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

**Qualifications Pack For
Data Entry Operator/ Documentation Officer**

Job Role Data Entry Operator/Documentation Officer
Qualification Pack LFS/Q0510
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 Outcomes	Total Marks (300)	Out Of	Marks Allocation	
				Theory	Skills Practical
LFS/N0535 (Enter, update and maintain R&D data in the system)	PC1. prioritize service requests according to organizational guidelines	100	6	3	3
	PC2. fill and process mandated forms for receiving, processing, or tracking data		6	3	3
	PC3. enter data from source documents (such as patient report, test report etc.) or case report forms into computer application following standard sequence and coding protocols		14	6	8
	PC4. scan source documents in accordance with specific instructions		8	3	5
	PC5. verify data entered with source documents, checks for compliance with composition codes and style rules and corrects all typographical errors and missing or repeated data as per the source document only		8	2	6

Qualifications Pack For
Data Entry Operator/ Documentation Officer

	PC6. maintain files of source documents or other information related to data entered		8	3	5
	PC7. investigate and confirm data that is unclear before entering		8	3	5
	PC8. generate reports of data entry, store completed work in designated locations and perform backup operations		8	3	5
	PC9. update database information to reflect most current source information, such as patient profiles		14	6	8
	PC10. assist in the filing and storage of security and back up data files		14	6	8
	PC11. respond to requests for information and access relevant files		6	2	4
	Total		100	40	60
LFS/N0536 (Maintain associated data entry terminals)	PC1. maintain logbooks or records for data entry job runs on the terminal	100	12	4	8
	PC2. operate the terminal as per the defined organization procedures		18	6	12
	PC3. be attentive for error lights and indicators and highlight the same to the concerned authority		14	6	8
	PC4. correctly load files onto storage media of the system		14	6	8
	PC5. check for network and servers functioning prior to job commencement		16	6	10
	PC6. clear the terminal surrounding at the end of the jobs		10	2	8
	PC7. notify the appropriate authority of malfunctions		16	4	12
	Total		100	34	66
LFS/N0302 (Coordinate with Supervisors and colleagues within and outside the department)	PC1. understand the work output requirements	100	10	5	5
	PC2. proactively inform supervisor on issues requiring intervention		10	5	5
	PC3. comply with company policy and rule		10	5	5
	PC4. deliver quality work on time and report any anticipated reasons for delays		16	8	8
	PC5. put team over individual goals		10	5	5

Qualifications Pack For
Data Entry Operator/ Documentation Officer

	PC6. be able to resolve conflicts		10	5	5
	PC7. learn how to multi-task relevant activities		10	5	5
	PC8. provide guidance and direction to subordinates, including setting performance standards and monitoring performance		12	5	7
	PC9. Impart training to team members/cross-function team members		12	5	7
	Total		100	48	52