

QUALIFICATIONS PACK - OCCUPATIONAL STANDARDS FOR LIFE SCIENCES INDUSTRY



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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 - Quality Assurance Chemist

SECTOR: LIFE SCIENCES

SUB-SECTOR: CONTRACT RESEARCH, PHARMACEUTICAL AND BIOPHARMACEUTICAL

OCCUPATION: QUALITY ASSURANCE

REFERENCE ID: LFS/Q0302

ALIGNED TO: NCO-2004/2113.0901

A **Quality Assurance Chemist** is responsible for ensuring compliance with regulations and standard operating procedures and quality of products.

Brief Job Description: A **Quality Assurance Chemist** performs physical checks, conducts document verification exercise, ensures compliance to systems and procedures, undertakes risk control assessment, conducts/participates in internal/external audits and also carries out in-process sampling, finished product sampling activities.

Personal Attributes: The individual should have good knowledge of in-process checks and Quality Assurance systems. He/she must also have exposure of regulatory audits.

Qualifications Pack For
Quality Assurance Chemist

Qualifications Pack Code	LFS/Q0302		
Job Role	Quality Assurance Chemist		
Credits(NSQF)	TBD	Version number	1.0
Sector	Life Sciences	Drafted on	23/06/14
Sub-sector	Contract Research, Pharmaceutical and Biopharmaceutical	Last reviewed on	01/06/16
Occupation	Quality Assurance	Next review date	01/06/19
NSQC Clearance On	18/06/2015		

Job Role	Quality Assurance Chemist
Role Description	Responsible for ensuring compliance with regulations and standard operating procedures & quality of products
NSQF level	5
Minimum Educational Qualifications	B. Pharma (Preferable)/ B. Tech in Biotechnology (Preferable for Bio Pharmaceutical)/ B. Sc. in Microbiology (Preferable for Bio Pharmaceutical)/ B.Sc. in chemistry
Maximum Educational Qualifications	M. Pharma (Preferable)/ M. Tech in Biotechnology (Preferable for Bio Pharmaceutical)/ M.Sc. in Microbiology (Preferable for Bio Pharmaceutical)/ M.Sc. in chemistry
Training (Suggested but not mandatory)	On the job training (1 year of training for entry level chemist is mandatory), GXP (GLP, GDP, GMP) (Mandatory)
Minimum Job Entry Age	19 Years
Experience	2-4 year in Production/ Quality Control in case of B. Pharma./ B.Sc./ MSc./ B. Tech.; In case of M. Pharma./ M. Tech- Biotechnology - no prior experience required Quality Assurance certification, ISO certification
Applicable National Occupational Standards (OS)	<p>Compulsory:</p> <ol style="list-style-type: none"> LFS/N0303 Perform Quality Checks LFS/N0101 Maintain a healthy, safe and secure working environment in the life sciences facility LFS/N0104 Coordinate with Supervisor and team members

Qualifications Pack For
Quality Assurance Chemist

Job Details

	<p>Optional: N.A.</p>
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*Qualifications Pack For
Quality Assurance Chemist*



Performance Criteria	As described in the relevant NOS units

Qualifications Pack For
Quality Assurance Chemist

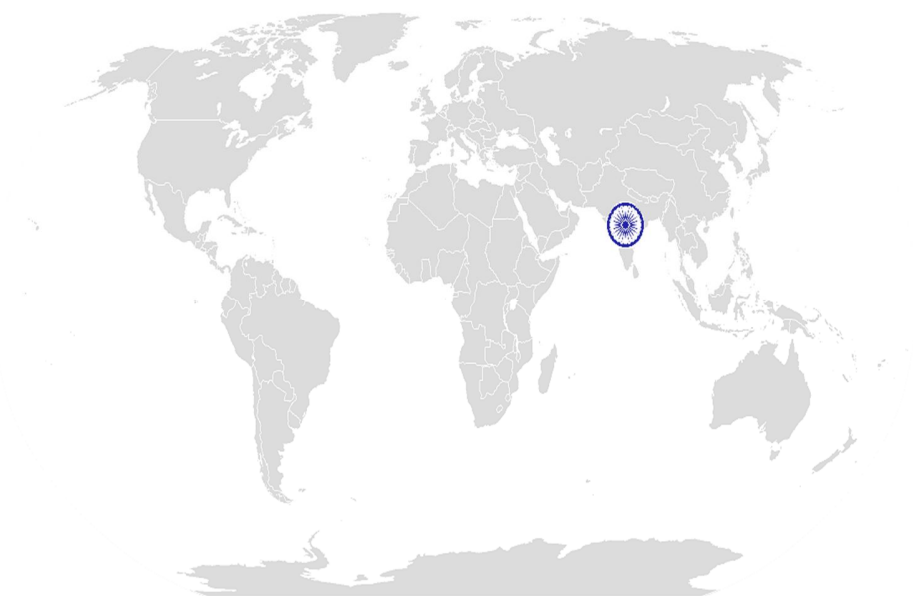
Definitions

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.
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
CAPA	Corrective and Preventive Actions
OOS	Out of Specification

LFS/N0303 : Perform Quality Checks

National Occupational Standard



Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Quality Assurance Chemist to perform in-process and post-production quality checks

LFS/N0303 : Perform Quality Checks

National Occupational Standard	Unit Code	LFS/N0303
	Unit Title (Task)	Perform Quality Checks
	Description	This OS is about a Quality Assurance Chemist performing pre-production checks, documentation activities, in-process quality checks and post production quality checks and activities to ensure compliance with regulatory standards and procedures
	Scope	<p>Pre-production checks/Documentary activities</p> <ul style="list-style-type: none"> • identify and determine appropriate quality monitoring arrangements for the processes and procedures of manufacturing, quality control, warehouse and engineering documents • self-Inspections • as per regulatory guidelines and standard operating procedures, monitor all documents and data control (issuance, retrieval, destruction and archival) for all the process • monitor the validation and qualification activities of machines as per validation master plan for compliances with regulatory guidelines. • ensure qualification activities during installation of new equipment and other analytical instruments <p>In-Process checks/activities</p> <ul style="list-style-type: none"> • ensure in-process checks are conducted at relevant processing stages and have met the requisite acceptance criteria / specifications. • verify adherence to cleaning SoPs and cleanliness of equipment and area used for production to ensure there is no contamination of next product from the previous product traces • perform material verification to check if the right material, in right quantity for the batch has been issued or not • check the quality management system (QMS) elements such as change control, incident management, CAPA management are adhered to on the shop floor • check if the manufacturing facility (area & process) is meeting the basic GMP requirements (e.g. facility upkeep, labeling policy, environmental conditions, cross contamination guidelines, segregation of materials) • carry out investigations related to complaints, batch failures, Out of Specification (OOS) incidents and report monthly and year-to-date comparisons. <p>Post-production checks/activities</p> <ul style="list-style-type: none"> • monitor and ensure review of batch manufacturing and packing documents • monitor adherence to various good manufacturing practices activities and laid down procedures in receipt, storage, testing, processing and dispatch of products • review batch manufacturing/batch processing, packaging and analytical records, equipment logs etc. before batch release

LFS/N0303 : Perform Quality Checks

	<ul style="list-style-type: none"> present the results of the work done to the appropriate people, in accordance with departmental and organizational procedures manage activities such as audits, regulatory agency inspections, or product recalls communicate regulatory information to multiple departments and ensure that information is interpreted correctly develop and maintain standard operating procedures or local working practices
Performance Criteria (PC) w.r.t. the Scope	
Element	Performance Criteria
Pre-production checks/Documentary activities	<p>To be competent, the user/individual on the job must be able to:</p> <p>PC1. formulate and implement regulatory policies and procedures</p> <p>PC2. keep oneself abreast with the current knowledge of relevant regulations</p> <p>PC3. train staff in regulatory policies or procedures</p> <p>PC4. to plan and participate self-inspections for various departments on the site as per predefined schedules and coordinate with cross functional teams</p> <p>PC5. compile statistical data and writes narrative reports summarizing quality assurance findings, along with review of documents</p> <p>PC6. assist in continuous improvement initiatives to enhance product quality, compliance, drive efficiencies and cost effectiveness of Quality Assurance team</p>
In-Process checks/activities	<p>PC7. carry out sampling activities for quality assurance audit across stages</p> <p>PC8. assess repetitive incidences of OOS and OOT. Prepare and evaluate the trend of OOS and OOT investigation periodically</p> <p>PC9. provide document support to regulatory departments for compilation of various regulatory documents, including verification of in-process quality check documentation</p> <p>PC10. collaborate with the production/packaging teams for providing line clearance</p>
Post-production checks/activities	<p>PC11. support / assign personnel to support internal and external audit activities</p> <p>PC12. provide requisite information, documents, clarifications to supervisors during actual audits</p> <p>PC13. check storage and disposal of samples during and after analysis</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. quality policy of the company</p> <p>KA2. standard operating procedures of the production unit</p> <p>KA3. policies and procedures for conducting/participating in audits</p> <p>KA4. legal and regulatory frameworks relevant to the production work</p> <p>KA5. quality assurance methods approved by the company</p> <p>KA6. format of presenting the information captured during quality checks</p> <p>KA7. composition/requirements of the product manufactured</p>

LFS/N0303 : Perform Quality Checks

<p>B. Technical Knowledge</p>	<p>The user/individual on the job needs to know and understand:</p> <p>KB1. knowledge of pharmacopeia</p> <p>KB2. good manufacturing practices, good laboratory practices and good documentation practices and ISO guidelines</p> <p>KB3. packaging specifications for different products</p> <p>KB4. engineering skills for QA like concept for engineering, HVAC, AHU, water systems, compressed air, electricity, and facility requirements, documentation in various process like reporting defects/problem/ incidents/quality issues/test results</p> <p>KB5. knowledge on Critical Quality Attributes (CQA), Critical Process Parameters (CPP) and Critical Process Controls(CPC) and acceptance criteria</p> <p>KB6. qualification & validation procedures like compilation of stability data and its verification, addressing the Quality impacting and non-impacting incidents, deviations, OOS, OOT, CAPA follow-up and closure, stability protocol certification of commercial and validation batches</p> <p>KB7. knowledge of instrument management and calibration procedures</p> <p>KB8. knowledge of QA procedures and schedules</p> <p>KB9. quality management systems and documentation activities like control, issuance, archiving and distribution of records/ reports/ filing, art works, packing standards, protocols, drug calculations, uploading and maintenance of batch documents in database and SAP, monitoring of documents and their controls, control and issuance of SOP/STP/ Protocols/work sheets/BMR/BPR and record of analysis, designing of training matrix</p> <p>KB10. fundamental Science in API and Formulation Production and Packaging including review skills in PAS/X activities, potency calculation for active materials, basics of Pharmaceutical Science and Chemistry inclusive of Organic Nomenclature System, Organic Reaction Mechanism, and Basic Analytical Chemistry fundamentals like including balancing chemical equations, chemical equilibria, acid and base chemistry, stoichiometric calculations, reduction and oxidation chemistry and interaction of light with matter</p>
<p>Skills (S)</p>	
<p>A. Core Skills/ Generic Skills</p>	<p>Writing skills</p> <p>The user/ individual on the job needs to know and understand how to:</p> <p>SA1. make legible entries online/offline</p> <p>SA2. write detailed reports for investigation</p> <p>SA3. pay attention to detail while recording production parameters</p> <p>SA4. use computer application, such as Microsoft Office</p> <p>Reading skills</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SA5. read important documents, reports and procedures accurately, including those pertaining to deviations, incidents etc.</p>

LFS/N0303 : Perform Quality Checks

	SA6. read and understand SOPs and company policies
	Oral Communication (Listening and Speaking skills)
	The user/individual on the job needs to know and understand how to: SA7. interact with people to effectively gather information SA8. listen effectively and orally communicate technical information accurately SA9. build and maintain positive and effective relationships with colleagues and customers
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
	Plan and Organise
	The user/individual on the job needs to know and understand how to:
	SB2. plan work in an effective and balanced manner, as well as undertake regular trend analysis of the same
	SB3. plan work assigned on a daily basis and provide estimates of time required for each piece of work
	SB4. understand one's role and responsibilities and make submissions as per the agreed deadlines
	SB5. work with functional, departmental boundaries to harness synergies and realize organizational vision
	Problem Solving
	The user/individual on the job needs to know and understand how to:
	SB6. seek clarification on problems from others SB7. use effective problem solving techniques depending on the rating and context of the problem SB8. address issues with minimum or nil impact on product quality as well as reduced deviations
Analytical Thinking	
The user/individual on the job needs to know and understand how to:	
SB9. analyse data and activities to assess risks SB10. pass on relevant information to others	
Critical thinking	
The user/individual on the job needs to know and understand how to:	
SB11. provide opinions on work in a detailed and constructive way SB12. apply balanced judgments to different approaches	
Customer Centricity	

LFS/N0303 : Perform Quality Checks

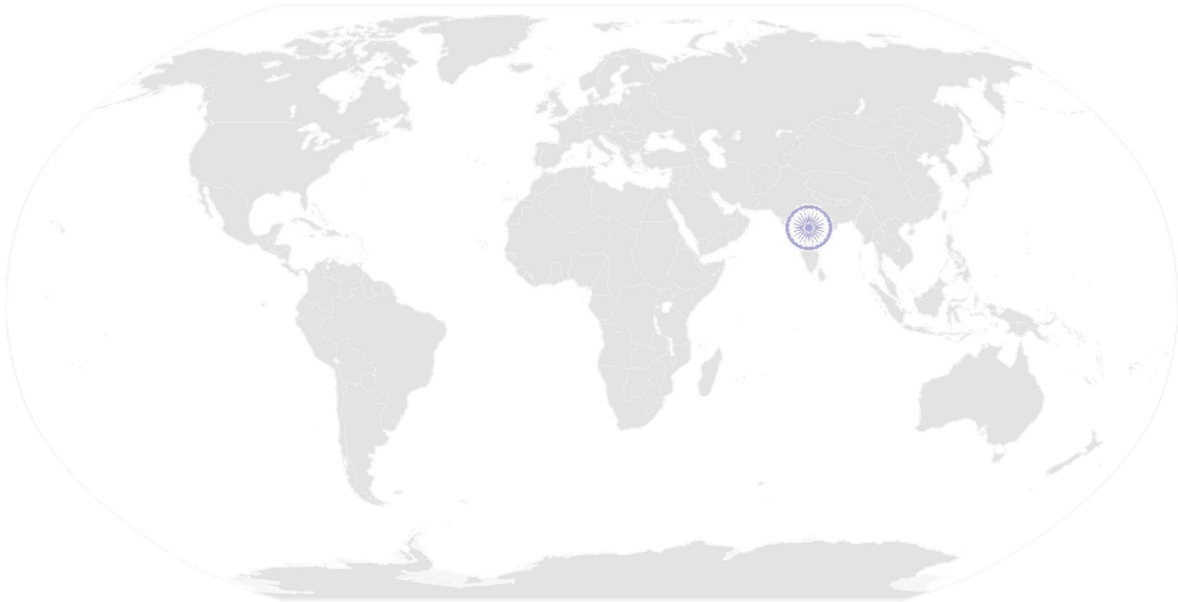
	<p>The user/individual on the job needs to know and understand how to:</p> <p>SB13. visualize the needed specifications and SLA while carrying out any QA activity and show zero tolerance for any deviation</p>
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NOS Code	LFS/N0303		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	23/06/14
Industry Sub-sector	CR, Pharmaceutical and Biopharmaceutical	Last reviewed on	01/06/16
Occupation	Quality	Next review date	01/06/19

NOS Version Control

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

National Occupational Standard



Overview

This Occupational Standard is about the knowledge, understanding and skills required by a Quality Assurance Chemist 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 Quality Assurance Chemist 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	<p>This unit / task covers the following:</p> <p>Ensuring healthy, safe and secure working environment:</p> <ul style="list-style-type: none"> 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 <p>Managing emergency procedures:</p> <ul style="list-style-type: none"> 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	<p>To be competent, the user/individual on the job must be able to:</p> <p>PC1. observe and comply with the 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 the individual can deal with safely, competently and within the limits of their 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>	
Managing emergency procedures	<p>PC9. report any hazards that the individual is not competent to deal with to the relevant person in line with organizational procedures and warn other people who may be affected</p> <p>PC10. follow the company's emergency procedures promptly, calmly, and efficiently</p>	

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

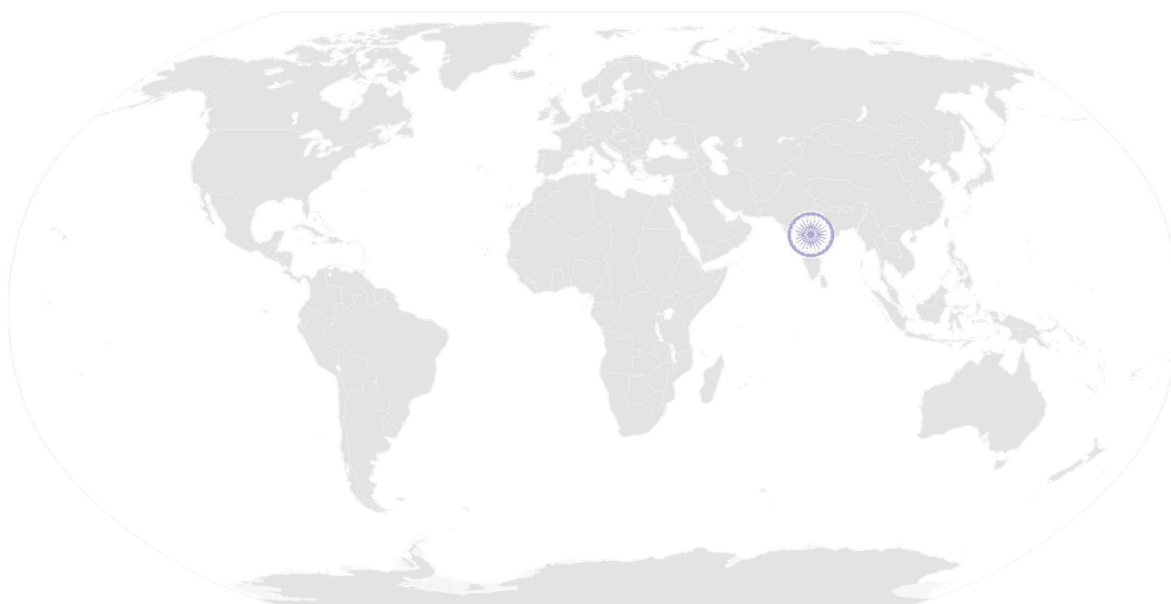
Knowledge and Understanding (K)	
A. Organisational Context (Knowledge of the Company/ Organisation and its processes)	<p>The user/ individual on the job needs to know and understand:</p> <p>KA1. legislative requirements and company's procedures for health, safety and security and individual's role and 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 individual responsibility for dealing with hazards</p> <p>KA5. the 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>
B Technical Knowledge	<p>The user/ individual on the job needs 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)	
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. complete accurate, well written work with attention to detail</p>
	<p>Reading skills</p> <p>The user/ individual on the job needs to know and understand how to:</p> <p>SA2. read instructions, guidelines, procedures, rules and service level agreements</p>
	<p>Oral Communication (Listening and Speaking skills)</p> <p>The user/ individual on the job needs to know and understand how to:</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. Professional Skills	Decision making
	The user/ individual on the job needs to know and understand how to:
	SB1. make decisions on suitable courses of action
	Plan and Organise
	The user/ individual on the job needs to know and understand how to:
	SB2. plan and organize work to meet health, safety and security requirements
	Problem solving
	The user/ individual on the job needs to know and understand how to:
	SB3. apply problem solving approaches in different situations
	Analytical thinking
	The user/ individual on the job needs to know and understand how to:
	SB4. analyse data and activities
Critical thinking	
The user/ individual on the job needs to know and understand how to:	
SB5. apply balanced judgments to different situations	
Customer Centricity	
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 and Bio Pharmaceuticals	Last reviewed on	01/06/16
Occupation	Manufacturing, Quality, Supply Chain, R&D	Next review date	01/06/19



LFS/N0104 : Coordinate with Supervisor and team members

National Occupational Standard



Overview

This Occupational Standard describes the knowledge, understanding and skills required of a Quality Assurance Chemist to co-ordinate with manager and team members

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LFS/N0104 : Coordinate with Supervisor and team members

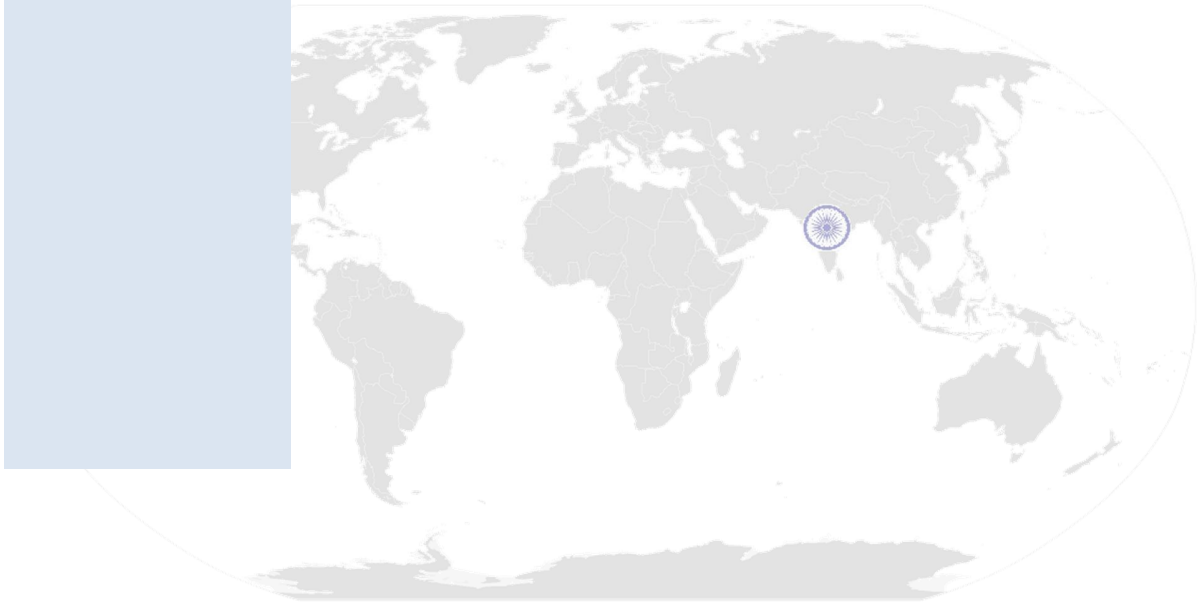
National Occupational Standard	Unit Code	LFS/N0104
	Unit Title (Task)	Coordinate with Supervisor and team members
	Description	This OS unit is about the Quality Assurance Chemist communicating with colleagues and seniors in order to achieve smooth and hazard-free work flow during production
	Scope	<p>This unit/task covers the following:</p> <p>Coordinate with supervisor</p> <ul style="list-style-type: none"> • receive work instructions from reporting supervisor • communicate to reporting supervisor about process-flow improvements, production defects received from previous process, repairs and maintenance of equipment as required • provide support to supervisor for carrying out investigations related to complaints, batch failures, OOS/ OOT, incidents etc. • communicate any potential hazards or expected process disruptions • provide requisite information, documents, clarifications to supervisor during actual audits • handover completed work to supervisor <p>Coordinate with team members</p> <ul style="list-style-type: none"> • work as a team with colleagues and share work as per their or own work load and skills • interview team members and colleagues to collect data to be recorded in log books and batch documents • support/assign personnel/team members to support internal and external audit activities as per instructions of superiors/supervisor • work with colleagues of other departments • communicate and discuss work flow related difficulties in order to find solutions with mutual agreement • provide documented shift handovers to the next person in the shift
Performance Criteria (PC) w.r.t. the Scope		
Element	Performance Criteria	
Coordinate with supervisor	<p>To be competent, the user/individual on the job must be able to:</p> <p>PC1. understand the work output requirements</p> <p>PC2. comply with company policy and rule</p> <p>PC3. proactively inform supervisor on issues requiring intervention</p> <p>PC4. deliver quality work on time and report any anticipated reasons for delays</p>	
Coordinate with team members	<p>To be competent, the user/individual on the job must be able to:</p> <p>PC5. put team over individual goals</p> <p>PC6. be able to resolve conflicts</p> <p>PC7. learn how to multi-task relevant activities</p>	

LFS/N0104 : Coordinate with Supervisor and team members

	PC8. impart training to team members/cross-function team members
Knowledge and Understanding (K)	
A. Organisational Context (Knowledge of the Company/ Organisation and its processes)	The user/individual on the job needs to know and understand: KA1. knowledge of process management. KA2. the correct method for carrying out corrective actions outlined for each problem. KA3. escalation matrix for reporting identified issues KA4. implications of not adhering to quality control procedures (pertaining to call audits by quality analysts for the executives). KA5. company's tie-ups with technical bodies
B. Technical Knowledge	The user/individual on the job needs to know and understand: KB1. domain knowledge pertaining to life sciences industry. KB2. benefits of the product with respect to similar products from other companies KB3. application of basic sciences (chemistry), mathematics KB4. commercial awareness of pharmaceutical products and overall healthcare sector
Skills (S)	
A. Core Skills/ Generic Skills	Writing Skills
	The user/ individual on the job needs to know and understand how to: SA1. report/observation writing skills
	Reading Skills
	The user/individual on the job needs to know and understand how to: SA2. read notes/comments from the supervisor SA3. read job sheets and interpret technical details mentioned in the jobsheet
B. Professional Skills	Oral Communication (Listening and Speaking skills)
	The user/individual on the job needs to know and understand how to: SA3. interact with team members to work efficiently
B. Professional Skills	Decision Making
	The user/individual on the job needs to know and understand how to: SB1. spot and communicate potential areas of disruptions to work process and report the same SB2. when to report to supervisor and when to deal with a colleague individually, depending on the type of concern
	Problem Solving

LFS/N0104 : Coordinate with Supervisor and team members

	The user/individual on the job needs to know and understand how to:
	SB3. improve work processes by interacting with others and adopting best practices
	Critical Thinking
	The user/individual on the job needs to know and understand how to:
	SB4. spot process disruptions and delays and report and communicate with solutions
	Customer Centricity
	NA.
	Plan & Organize
NA.	
Analytical Thinking	
NA.	



LFS/N0104 : Coordinate with Supervisor and team members

NOS Version Control

NOS Code	LFS/N0104		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	23/06/14
Industry Sub-sector	Pharmaceuticals and Bio Pharmaceuticals	Last reviewed on	01/06/16
Occupation	Manufacturing, Quality, Supply Chain, R&D	Next review date	01/06/19

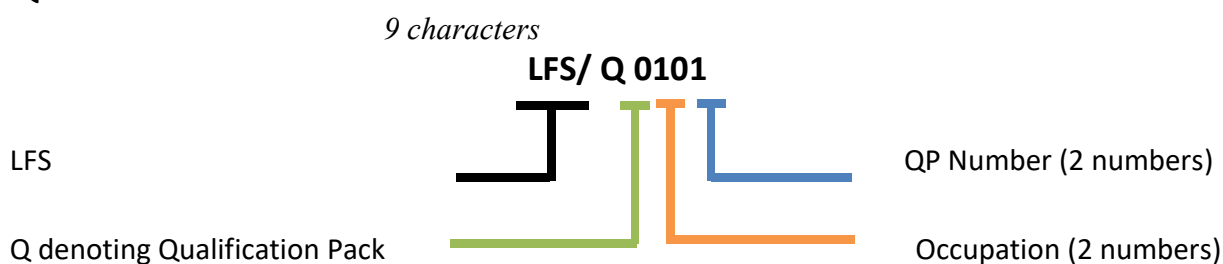


Qualifications Pack - Quality Assurance Chemist

Annexure

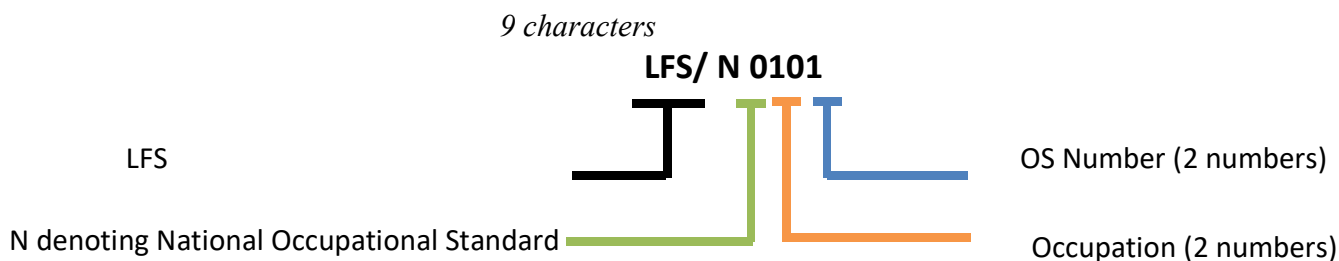
Nomenclature for QP and NOS

Qualification Packs



Occupational Standard

An example of NOS with 'N'



Qualifications Pack - Quality Assurance Chemist

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 - Quality Assurance Chemist

CRITERIA FOR ASSESSMENT OF TRAINEES

Job Role Quality Assurance Chemist

Qualification Pack LFS/Q0302

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/N0303 (Perform Quality Checks)	PC1. formulate and implement regulatory policies and procedures	100	12	6	6
	PC2. keep oneself abreast with the current knowledge of relevant regulations		7	5	2
	PC3. train staff in regulatory policies or procedures		6	2	4
	PC4. to plan and participate self-inspections for various departments on the site as per predefined schedules and coordinate with cross functional teams		6	3	3
	PC5. compiles statistical data and writes narrative reports summarizing quality assurance findings, along with review of documents		10	5	5
	PC6. assist in continuous improvement initiatives to enhance product quality, compliance, drive efficiencies and cost effectiveness of Quality Assurance team		8	4	4

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	PC7. carry out sampling activities for quality assurance audit across stages		5	2	3
	PC8. assess repetitive incidences of OOS and OOT. Prepare and evaluate the trend of OOS and OOT investigation periodically		6	3	3
	PC9. provide document support to regulatory departments for compilation of various regulatory documents, including verifications of in-process quality check documentation		11	5	6
	PC10. collaborate with the production/packaging teams for providing line clearance		4	2	2
	PC11. support / assign personnel to support internal and external audit activities		4	1	3
	PC12. provide requisite information, documents, clarifications to supervisors during actual audits		9	4	5
	PC13. check storage and disposal of samples during and after analysis		12	5	7
	Total		100	47	53
LFS/N0101 (Maintain a healthy, safe and secure working environment in the life	PC1. observe and comply with the 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 the individual can		10	5	5

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sciences facility)	deal with safely, competently and within the limits of their authority				
	PC6. adhere and comply to storage and handling guidelines for hazardous material		10	5	5
	PC7. identify and recommend opportunities for improving health, safety, and security to the designated person		10	5	5
	PC8. complete any health, safety and security activities like safety drills and prepare records legibly and accurately		10	4	6
	PC9. report any hazards that the individual is not competent to deal with to the relevant person in line with organizational procedures and warn other people who may be affected		10	4	6
	PC10. follow the company's emergency procedures promptly, calmly, and efficiently		10	5	5
	Total		100	48	52
LFS/N0104 (Coordinate with Supervisor and team members)	PC1. understand the work output requirements	100	20	10	10
	PC2. comply with company policy and rule		18	8	10
	PC3. proactively inform supervisor on issues requiring intervention		13	5	8
	PC4. deliver quality work on time and report any anticipated reasons for delays		11	5	6
	PC5. put team over individual goals		8	4	4
	PC6. be able to resolve conflicts		8	4	4
	PC7. learn how to multi-task relevant activities		8	4	4
	PC8. Impart training to team members/cross-function team members		14	6	8
	Total		100	46	54