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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

Contact Us:
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Contents

Introduction

Qualifications Pack - Licensing Manager – Life Sciences

SECTOR: LIFE SCIENCES

SUB-SECTOR: PHARMACEUTICAL AND BIOPHARMACEUTICAL

OCCUPATION: SUPPLY CHAIN MANAGEMENT

REFERENCE ID: LFS/Q0609

ALIGNED TO: NCO-2004/NIL

Licensing Manager manages the work of the licensing team in order to ensure that the appropriate licenses are in place for carrying out the life sciences facility's operations. The role holder liaisons with the licensing authorities to ensure appropriate documents and licenses are available at the time of selling/imports/exports.

Brief Job Description: Licensing Manager manages the work of the licensing team in order to ensure that the company is protected by the required inbound and outbound contracting and licensing of the manufactured products.

Personal Attributes: The individual should have good knowledge of the Pharmaceutical industry as well as knowledge of licensing procedures and requirements. He/ she should have an analytical bent of mind and should be able to deal with different kinds of people so as to liaise with people across the departments.

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Qualifications Pack For Licensing Manager - Life Sciences

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Job Details

Qualifications Pack Code	**LFS/Q0609**
Job Role	**Licensing Manager – Life Sciences**

Credits(NSQF)	TBD	**Version number**	1.0
Industry	Life Sciences	**Drafted on**	15/12/14
Sub-sector	Pharmaceutical and Biopharmaceutical	**Last reviewed on**	01/08/16
Occupation	Supply Chain Management	**Next review date**	01/08/19
NSQC Clearance on	20/07/2015		

Job Role	Licensing Manager – Life Sciences
Role Description	Responsible for managing the work of the licensing team in order to ensure that the company is protected by the required inbound and outbound contracting and licensing of the manufactured products
NSQF level	6
Minimum Educational Qualifications	B.Pharma /Graduate in any field / LLB
Maximum Educational Qualifications	M. Pharma/ M.Sc/ LLM/ Management Degree with law background (Preferable)
Training (Suggested but not mandatory)	On the job training
Minimum Job Entry Age	25 Years
Experience	5-6 years of experience in the related field
Applicable National Occupational Standards (NOS)	**Compulsory:** 1 LFS/N0622: Regulatory compliance and exchange of information for licensing activities 2 LFS/N0613: Provide analytical support for supply chain management 3 LFS/N0623: Manage, coordinate and interact with people to effectively control licensing operations 4 LFS/N0102: Carry out reporting and documentation

	Optional: N.A.
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.

Definitions

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

Acronyms

National Occupational Standards

Overview

This Occupational Standard describes the knowledge, understanding and skills required of a Licensing manager to manage and regulate all the activities related to licensing and exchange relevant information.

LFS/N0622 : Regulatory compliance and exchange of information for licensing activities

<table>
<tr><td rowspan="21" style="writing-mode: vertical-lr;">National Occupational Standard</td><td colspan="2">**Unit Code**</td></tr>
</table>

Unit Code	**LFS/N0622**	
Unit Title (Task)	**Regulatory Compliance and exchange of information for licensing activities**	
Description	The NOS is about a Licensing manager regulating and exchanging information for licensing activities.	
Scope	The unit/ task covers the following: • Manage regulation and legislation needs for licensing activities • Ensure regulatory compliance • Exchange of information	

Performance Criteria (PC) w.r.t. the Scope

Element	Performance Criteria
Manage regulation and legislation needs for licensing activities	To be competent, the user/individual on the job must be able to: PC1. identify and evaluate all regulations and legislations needs for licensing activities PC2. design all compliance strategies for all businesses, including strategy for addressing issues PC3. ensure appropriate licensing activities implementation for various business groups i.e. ensure timely application and approval of licenses and monitor validity & expiry of all licensing documents which are required to carry out export/import operations PC4. maintain knowledge on all compliance trends and recommend changes for all related company processes PC5. prepare required reports for all product forms and manage all communications with licensors and perform audit PC6. evaluate the relevant licensing agreements for all license partners and liason transmit all reports for maintaining database and reconciling the same PC7. maintain and update all distribution lists and manage all correspondence with licensed partners.
Ensure regulatory compliance	PC8. review SAP periodic reports to carry out the departmental checks in compliance with rules and regulations and other statutory requirements PC9. review updates on cost impacts, cost estimates, stock management, feasibility analysis to carry out the departmental functions in compliance with rules and regulations and other statutory requirements PC10. identify variation from the regulatory guidelines and advice for correction of the same
Exchange of Information	PC11. ensure communication of updated information on regulatory and licensing needs to different businesses and stakeholders in a timely manner PC12. obtain the necessary information from across teams and businesses needed to confirm adherence to compliances PC13. establish protocol for sharing of regulatory/statutory-related information for licensing to prevent risk issues PC14. maintain confidentiality of strategic information

Knowledge and Understanding (K)

LFS/N0622 : Regulatory compliance and exchange of information for licensing activities

| A. **Organisational Context** (Knowledge of the Company/ Organisation and its processes)	The user/individual on the job needs to know and understand: KA1. organization's compliance policies and procedures KA2. organization's documentation policies, templates, software used KA3. company defined procedure for reporting compliance risks and occurrences KA4. organization's range of products and licensing needs associated with them KA5. relationships of the organization with all licensors and licensed partners KA6. organization's communication protocols
B. **Technical Knowledge**	The user/individual on the job needs to know and understand: KA7. strong knowledge of regulatory compliances for licensing and legal language KA8. strong hold on legal and contracting procedures KA9. sound knowledge of supply chain management, operations and business KA10. knowledge of contracts, tariffs and governments import/export regulation policy KA11. risk and impact of not complying to defined regulations KA12. knowledge of supply chain best practices
Skills (S)	
A. **Core Skills/ Generic Skills**	**Writing Skills**
	The user/ individual on the job needs to know and understand how to: SA1. record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail SA2. good report writing and documentation skills SA3. prepare status and progress reports
	Reading skills
	The user/individual on the job needs to know and understand how to: SA4. read and understand manuals, SOPs, health and safety instructions, memos, reports, job cards etc.
	Oral Communication (Listening and Speaking skills)
	The user/individual on the job needs to know and understand how to: SA5. communication with upstream and downstream teams SA6. disclose information only to those who have the right and need to know it SA7. communicate confidential and sensitive information discretely to authorized person as per SOP SA8. communicate with people in a form and manner and using language that is open and respectful SA9. ability to effectively negotiate the quality, quantity and price SA10.
	Customer Centricity

B. Professional Skills	The user/individual on the job needs to know and understand how to:
	SB1. establish and nurture relationships with multiple stakeholders
	SB2. effectively interact with the various stakeholders to complete assigned tasks
	Analytical Thinking
	The user/individual on the job needs to know and understand how to:
	SB3. pursue detail orientation
	SB4. use the specific data/ facts to arrive at conclusions
	Plan and Organize
	The user/individual on the job needs to know and understand how to:
	SB5. work effectively within demanding timelines
	SB6. organize, plan and prioritize activities to multi task
	SB7. effectively assign / delegate work to subordinates
	SB8. take responsibility for completing one's own work assignment
	SB9. capacity to learn from experience in a range of settings and scenarios and the
	SB10. open to new ways of doing things
	SB11. build an environment of trust and a shared goal for the team
	SB12. effectively schedule activities amongst team members
	Decision Making
	The user/individual on the job needs to know and understand how to:
	SB13. collaborate with others when making decisions
	Critical Thinking
	The user/individual on the job needs to know and understand how to:
	SB14. identify bottlenecks and suggest improvements for overcoming them
	Problem Solving
	NA

<u>NOS Version Control</u>

NOS Code		LFS/N0622	
Credits(NSQF)	TBD	**Version number**	1.0
Industry	Life Sciences	**Drafted on**	15/12/14
Industry Sub-sector	Pharmaceutical and Biopharmaceutical	**Last reviewed on**	01/08/16
Occupation	Supply Chain Management	**Next review date**	01/08/19

National Occupational Standards
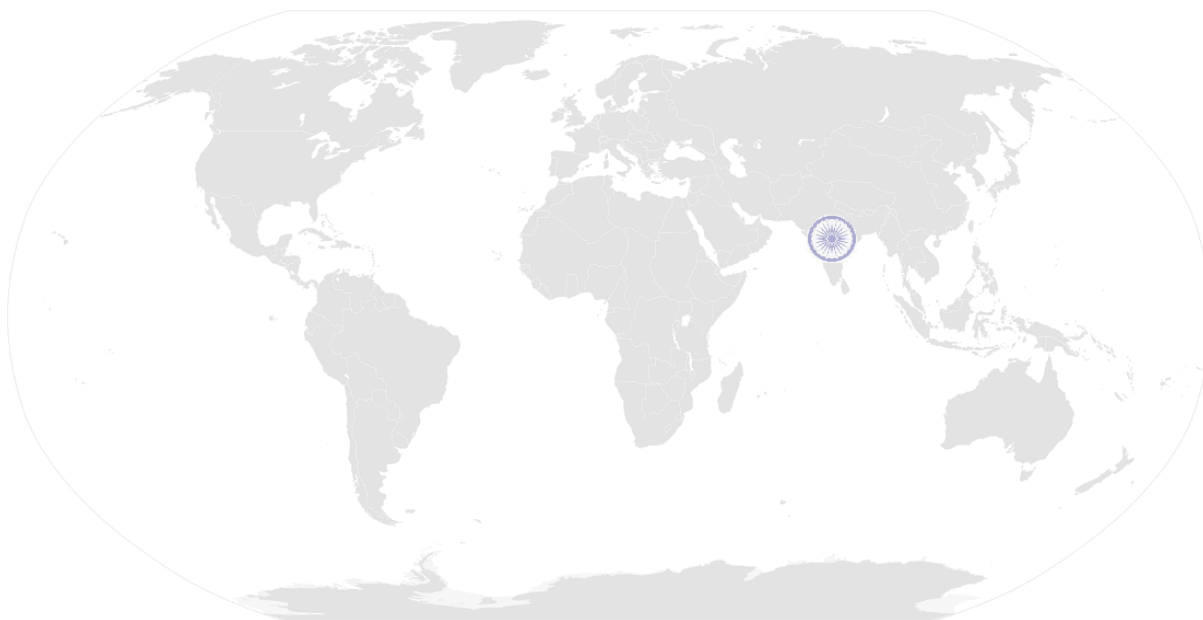
<u>**Overview**</u>

This Occupational Standard describes the knowledge, understanding and skills required of a Licensing manager to provide analytical support for supply chain management processes with the help of data collected and suggest changes.

National Occupational Standard

Unit Code	LFS/N0613
Unit Title (Task)	**Provide analytical support for supply chain management**
Description	This NOS is about the Licensing Manager providing analytical support for supply chain management processes with the help of data collected and suggest changes.
Scope	The unit\ task covers the following: • Analyze the supply chain management processes • Data collection and analysis

Performance Criteria (PC) w.r.t. the Scope	
Element	**Performance Criteria**
Analyze the supply chain management processes	To be competent, the user/individual on the job must be able to: PC1. analyze and recommend improvements to all internal procedures and implement same PC2. establish role and responsibilities in providing analytical support for supply chain management process PC3. obtain confirmation from relevant employees and define the objective of the study
Data collection and analysis	PC4. access suitable sources of data PC5. sort and collate relevant data for the analysis PC6. usage of appropriate analysis methods and procedures PC7. identify potential and actual glitches and the causes for the same

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. organizational coding system of finished material, compounds and company manual KA2. different quality management systems (ISO-9000, ISO-14001, OHSAS-18000), good laboratory and manufacturing practices KA3. material disposal procedure, importance of appropriate disposal of material and implications of not following the material disposal procedure KA4. importance of identifying non-conforming products and storage of the same KA5. implications (impact on internal/external customers) of defective products, materials or components KA6. the reason and impact of the occurrence of problems KA7. measures, steps and possible solutions that have been taken/identified to address the previous problems
B. Technical Knowledge	The user/individual on the job needs to know and understand: KB1. knowledge and understanding of supply chain concepts and application (e.g., just in time, material requirement planning) KB2. knowledge of supply chain best practices

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LFS/N0613 : Provide analytical support for supply chain management

Skills (S)		
A. Core Skills/ Generic Skills	**Writing Skills**	
	The user/ individual on the job needs to know and understand how to: SA1. maintain proper and concise records as per given format SA2. record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail	
	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 images, graphs and diagrams	
	Oral Communication (Listening and Speaking skills)	
	The user/individual on the job needs to know and understand how to: SA5. communication with upstream and downstream teams SA6. communicate with job owners like sample originating section, supplier etc. SA7. work in a team and other behavioural skills required to support the small group activities (E.g. Quality Circle, Cross Functional Team, Suggestion Scheme) SA8. maintain confidentiality of information and data SA9. communicate with people in a form and manner and using language that is open and respectful SA10. demonstrate ability to establish rapport and effective working relationships with business partners, department leadership and peers	
B. Professional Skills	**Decision Making**	
	The user/individual on the job needs to know and understand how to: SB1. act objectively , rather than impulsively or emotionally when faced with difficult/stressful or emotional situations SB2. deal with a colleague individually, depending on the type of concern	
	Plan and Organise	
	The user/individual on the job needs to know and understand how to: SB3. develop specific goals and plans to priorities SB4. organize and accomplish work SB5. follow up with other members to evaluate progress, give constructive feedback and praise to other for work well done SB6. effective delegation and leading without authority	
	Problem Solving	
	The user/individual on the job needs to know and understand how to: SB7. resolve any difficulties in relationships with colleagues , in a way that preserves goodwill and trust SB8. must possess good presentation skills SB9. ability to communicate, solve conflicts, negotiate on behalf of the team and company	
	Critical Thinking	

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National Occupational Standards

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LFS/N0613 : Provide analytical support for supply chain management

|	The user/individual on the job needs to know and understand how to: SB10. spot and communicate potential areas of disruptions to work process and report the same
	Analytical Thinking

	The user/individual on the job needs to know and understand how to:
	  SB11. attention to detail
	  SB12. use the existing data to arrive at specific conclusions/ data points
	  SB13. use the existing data points to generate required reports for business

	Customer Centricity
	NA
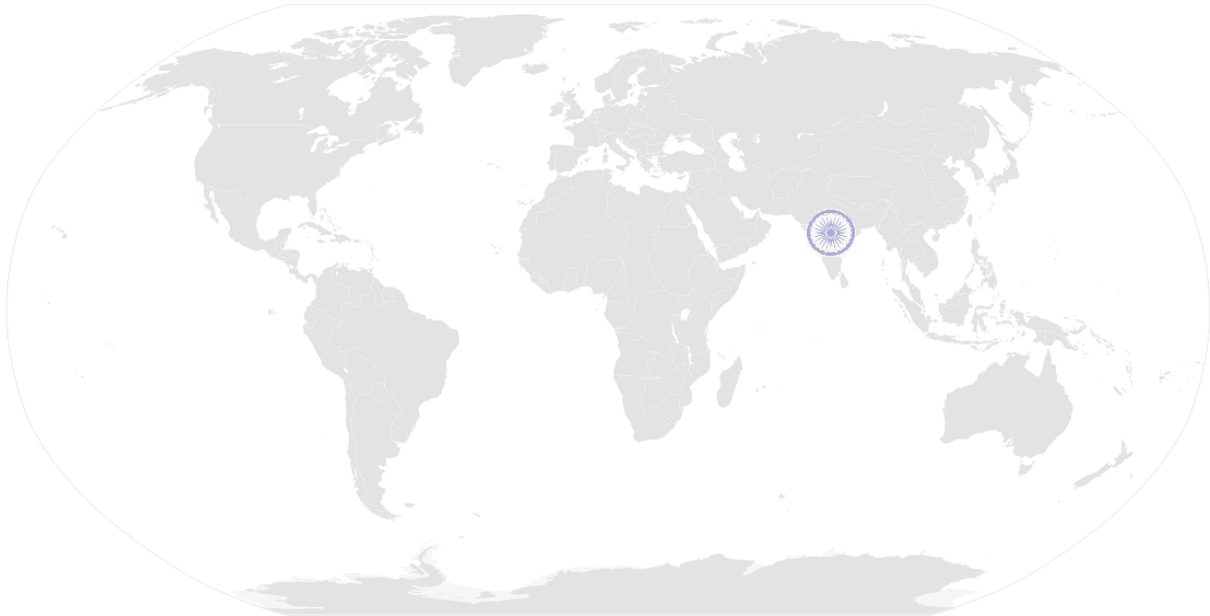
NOS Version Control

NOS Code	LFS/N0613		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	15/12/14
Industry Sub-sector	Pharmaceutical and Biopharmaceutical	Last reviewed on	01/08/16
Occupation	Supply Chain Management	Next review date	01/08/19
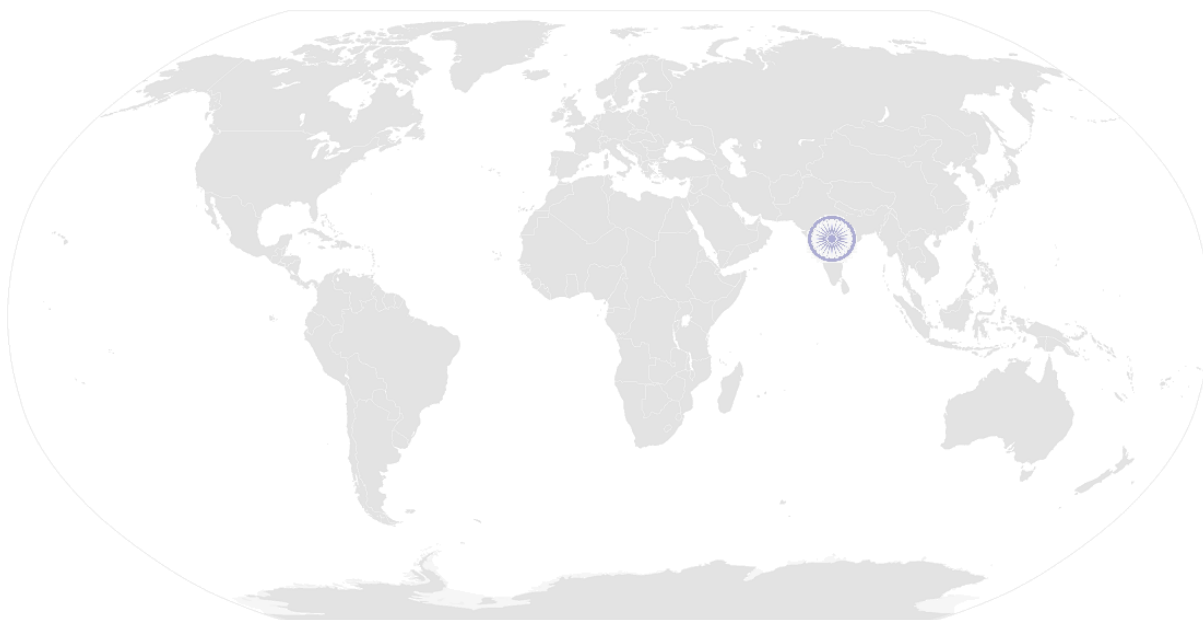
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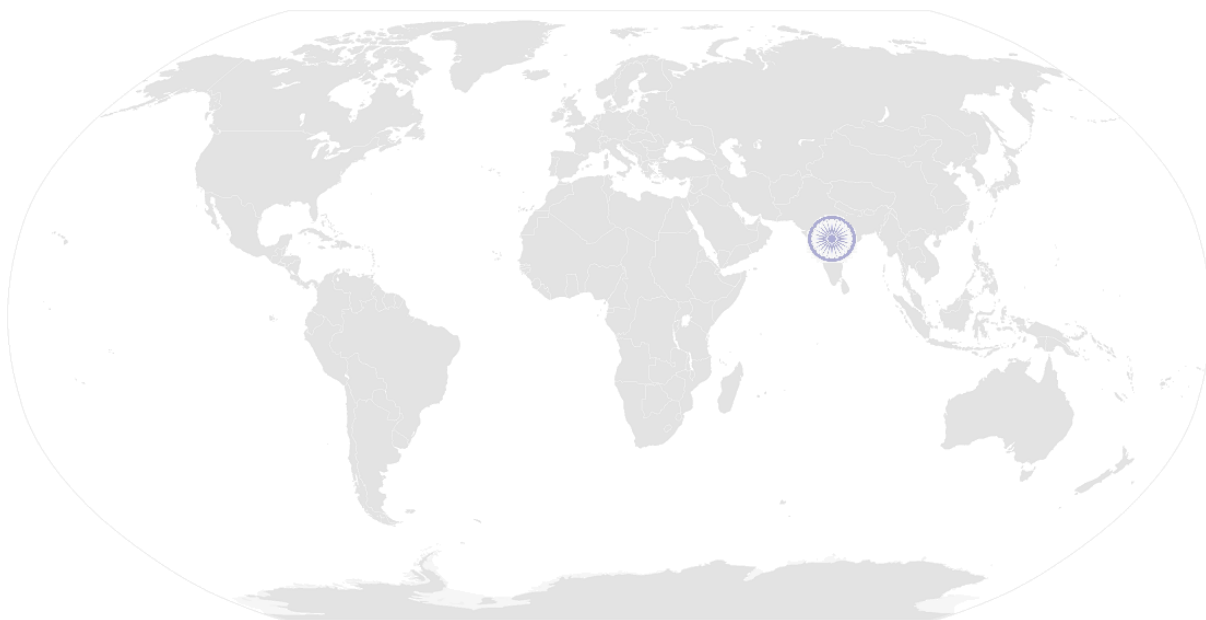
Overview

This Occupational Standard describes the knowledge, understanding and skills required of a Licensing manager to manage, coordinate and interact with people to effectively control licensing operations.

Unit Code	LFS/N0623
Unit Title (Task)	Manage, coordinate and interact with people to effectively control licensing operations
Description	The NOS is about a Licensing manager managing, coordinating and interacting with internal and external stakeholders to effectively control licensing operations.
Scope	The unit/ task covers the following: • Managing teams • Interacting with internal stakeholders • Interacting with external stakeholders

Performance Criteria (PC) w.r.t. the Scope

Element	Performance Criteria
Managing teams	To be competent, the user/individual on the job must be able to: PC1. ensure that the licensing team is on-board with the organizational strategies PC2. communicate licensing department objectives and provide leadership direction to achieve targets/goals PC3. manage and support recruitment PC4. ensure appropriate delegation of responsibility amongst team members PC5. set KRA's for direct reports, monitor overall team's KRA's, conduct performance appraisal, ensure clarity PC6. facilitate the development of subordinates through constant on and off the job learning, job rotation etc. PC7. guide, motivate and develop the sub-ordinates. PC8. oversee staff deployment and drive motivation levels of the team PC9. monitor staff welfare and facilitate complaint resolution PC10. manage efficiency levels and drive timely delivery of all operational targets
Interacting with internal stakeholders	PC11. collaborate with compliance manager and prepare presentations to be presented in all meeting and committees PC12. collaborate to ensure the effectiveness of existing processes and to incorporate improvements PC13. collaborate with SAP Cell, Stores, Dispatch, PPC (Production, Planning & Control), Support- Materials, Total Cost Management Control to gather critical information, facts and data
Interacting with external stakeholders	PC14. coordinate with suppliers, contractors and vendors, for continuous evaluation and maintaining long term relationships and ensuring all company policies and procedures are followed

Knowledge and Understanding (K)

National Occupational Standard

LFS/N0623 : Manage, coordinate and interact with people to effectively control licensing operations

|	
A. Organisational Context (Knowledge of the Company/ Organisation and its processes)	The user/individual on the job needs to know and understand: KA13. organization strategy KA14. organization's compliance policies and procedures KA15. company defined procedure for reporting compliance risks and occurrences KA16. organization's range of products and licensing needs associated with them KA17. relationships of the organization with external stakeholders associated with licensing activities KA18. organization's communication protocols
B. Technical Knowledge	The user/individual on the job needs to know and understand: KA19. strong knowledge of regulatory compliances for licensing and legal language KA20. strong hold on legal and contracting procedures KA21. sound knowledge of supply chain management, operations and business KA22. knowledge of contracts, tariffs and governments import/export regulation policy KA23. risk and impact of not complying to defined regulations KA24. knowledge of supply chain best practices
Skills (S)	
A. Core Skills/ Generic Skills	**Writing skills**
	The user/ individual on the job needs to know and understand how to: SA1. record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail SA2. maintain proper and concise records as per given formal
	Reading skills
	The user/individual on the job needs to know and understand how to: SA3. read and understand manuals, SOPs, health and safety instructions, memo SA4. read images, graphs, diagrams SA5. understand the various coding systems as per company norms
	Oral Communication (Listening and Speaking skills)
	The user/individual on the job needs to know and understand how to: SA6. communication with upstream and downstream teams SA7. communicate with job owners like sample originating section, supplier etc. SA8. maintain confidentiality of information and data SA9. communicate with people in a form and manner and using language that is open and respectful SA10. clear and timely communication for trust building
	Decision Making

B. Professional Skills	The user/individual on the job needs to know and understand how to:
	SB1. strong emotional intelligence and communication skills that facilitate decision making and execution
	SB2. appropriate skill to analyse the available information and take timely decisions to improve coordination and increase business
	Plan and Organise
	The user/individual on the job needs to know and understand how to:
	SB3. develop specific goals and plans to priorities
	SB4. organize and accomplish work
	SB5. follow up with other members to evaluate progress, give constructive feedback and praise to other for work well done
	SB6. take responsibility for completing one's own work assignment
	SB7. take initiative to enhance/learn skills in one's area of work
	SB8. capacity to learn from experience in a range of settings and scenarios and the capacity to reflect on and analyze one's learning
	SB9. open to new ways of doing things
	SB10. effective delegation and leading without authority
	Problem Solving
	The user/individual on the job needs to know and understand how to:
	SB11. act objectively , rather than impulsively or emotionally when faced with difficult/stressful or emotional situations
	SB12. resolve any difficulties in relationships with colleagues , in a way that preserves goodwill and trust
	SB13. ability to communicate, solve conflicts, negotiate on behalf of the team and company
	Analytical Thinking
	NA
	Critical Thinking
	NA
	Customer Centricity
	NA

NOS Version Control

NOS Code	LFS/N0623		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	15/12/14
Industry Sub-sector	Pharmaceutical	Last reviewed on	01/08/16
Occupation	Supply Chain Management	Next review date	01/08/19
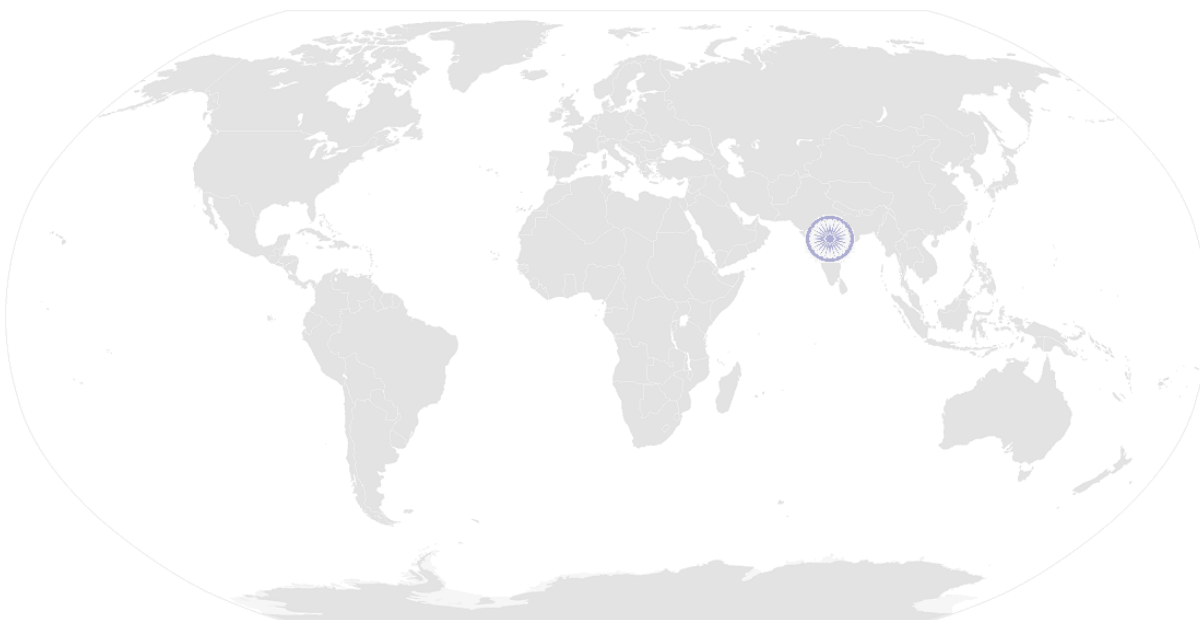
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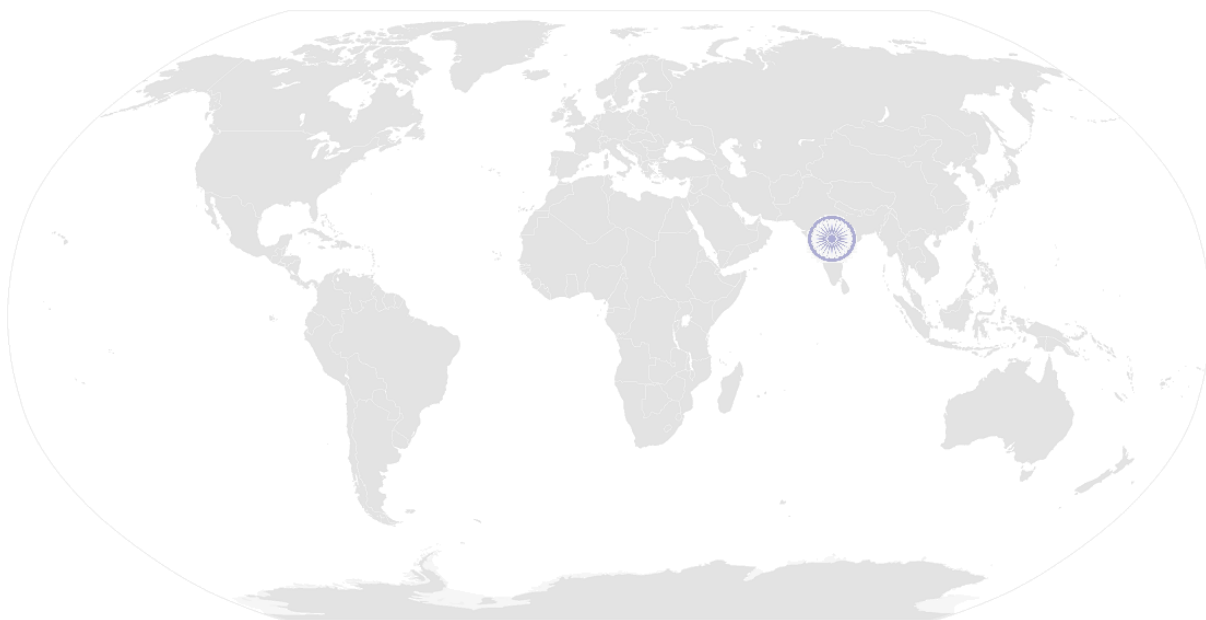
Overview

This Occupational Standard describes the knowledge, understanding and skills required of a Licensing manager for reporting, recording and documentation of data/problem/incidents etc. and to maintain information security.
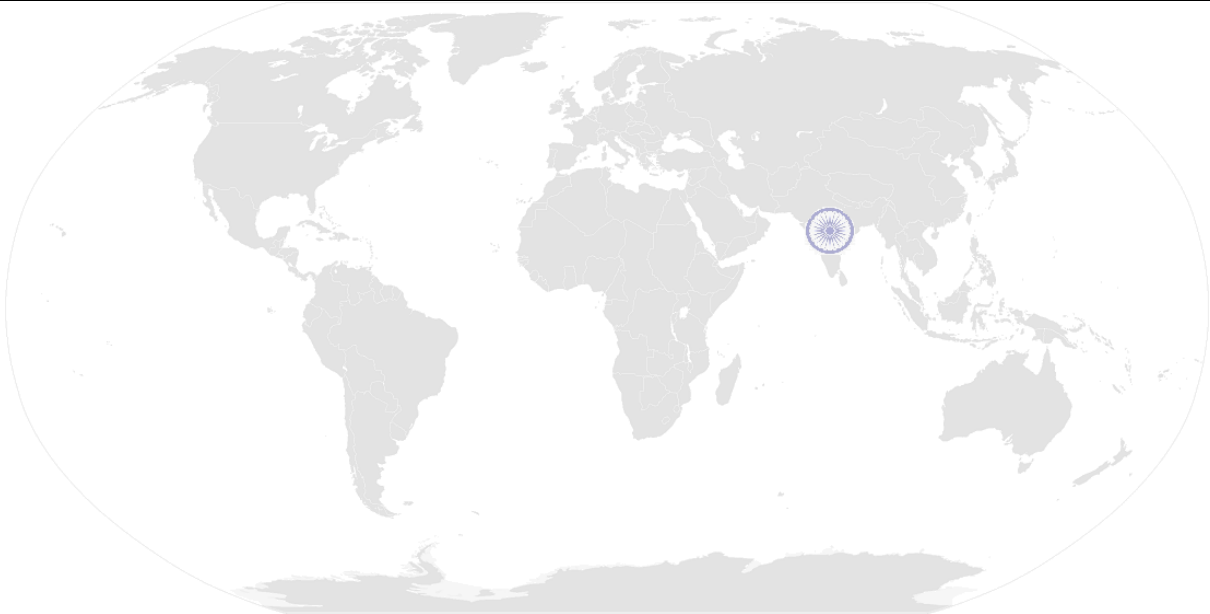
National Occupational Standard

Unit Code	LFS/N0102
Unit Title (Task)	Carry out reporting and documentation
Description	This NOS unit is about a Production Supervisor reporting data/problem/incidents etc., recording and documentation, information security.
Scope	This unit/task covers the following: • Reporting • Recording and Documentation • Information Security

Performance Criteria (PC) w.r.t the Scope	
Element	**Performance Criteria**
Reporting	To be competent, the user/individual on the job must be able to: PC1. report data/problems/incidents as applicable in a timely manner PC2. report to the appropriate authority as laid down by the company PC3. follow reporting procedures as prescribed by the company
Recording and documentation	PC4. identify documentation to be completed relating to one's role PC5. record details accurately in appropriate format PC6. complete all documentation within stipulated time according to company procedure PC7. ensure that the final document meets regulatory and compliance requirements PC8. make sure documents are available to all appropriate authorities to inspect
Information Security	PC9. respond to requests for information in an appropriate manner whilst following organizational procedures PC10. inform the appropriate authority of requests for information received

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: KA1. types of documentation in organization, importance of maintaining the same and different methods of recording information KA2. reporting incidents where standard operating procedures are not followed KA3. the importance of complete and accurate documentation KA4. knowledge of production workflow sequences and materials demand KA5. escalation matrix for reporting identified issues, hazards and breakage

LFS/N0102: Carry out reporting and documentation

B. Technical Knowledge	The user/individual on the job needs to know and understand: KB1. obtain and interpret records, charts, specifications, equipment manuals, history/technical support reports and other documents

Skills (S)	
C. Core Skills/ Generic Skills	**Writing Skills**
	The user/ individual on the job needs to know and understand how to: SA1. record and communicate details of work done to appropriate people using written/typed report SA2. maintain proper records as per given format
	Reading Skills
	The user/individual on the job needs to know and understand how to: SA3. read and understand manuals, SOPs, health and safety instructions, memos, reports, job cards etc. SA4. ability to read and interpret images, graphs, diagrams for typical product specifications, job sheets, procedures, basic machine control panels, material labels and safety information as provided SA5. understand the various coding systems as per company norms
	Oral Communication (Listening and Speaking skills)
	The user/individual on the job needs to know and understand how to: SA6. disclose information only to those who have the right and need to know it. SA7. communicate confidential and sensitive information discretely to authorized person as per SOP SA8. communicate with people in a form and manner and using language that is open and respectful
B. Professional Skills	**Analytical Thinking**
	The user/individual on the job needs to know and understand how to: SB1. attention to detail SB2. use of automated report writing and documentation technologies
	Critical Thinking
	The user/individual on the job needs to know and understand how to: SB3. suggest improvements(if any) in process based on experience
	Plan and Organise

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LFS/N0102: Carry out reporting and documentation

	The user/individual on the job needs to know and understand how to: SB4. capacity and skill to learn from experience in a range of settings and scenarios and the capacity to reflect on and analyze one's learning.
	Problem Solving
	The user/individual on the job needs to know and understand how to: SB5. act objectively , rather than impulsively or emotionally when faced with difficult/stressful or emotional situations
	Decision Making
	NA
	Customer Centricity
	NA

NOS Version Control

NOS Code		LFS/N0102	
Credits(NSQF)	TBD	**Version number**	1.0
Industry	Life Sciences	**Drafted on**	15/12/14
Industry Sub-sector	Pharmaceutical and Biopharmaceutical	**Last reviewed on**	01/08/16
Occupation	Supply Chain Management	**Next review date**	01/08/19
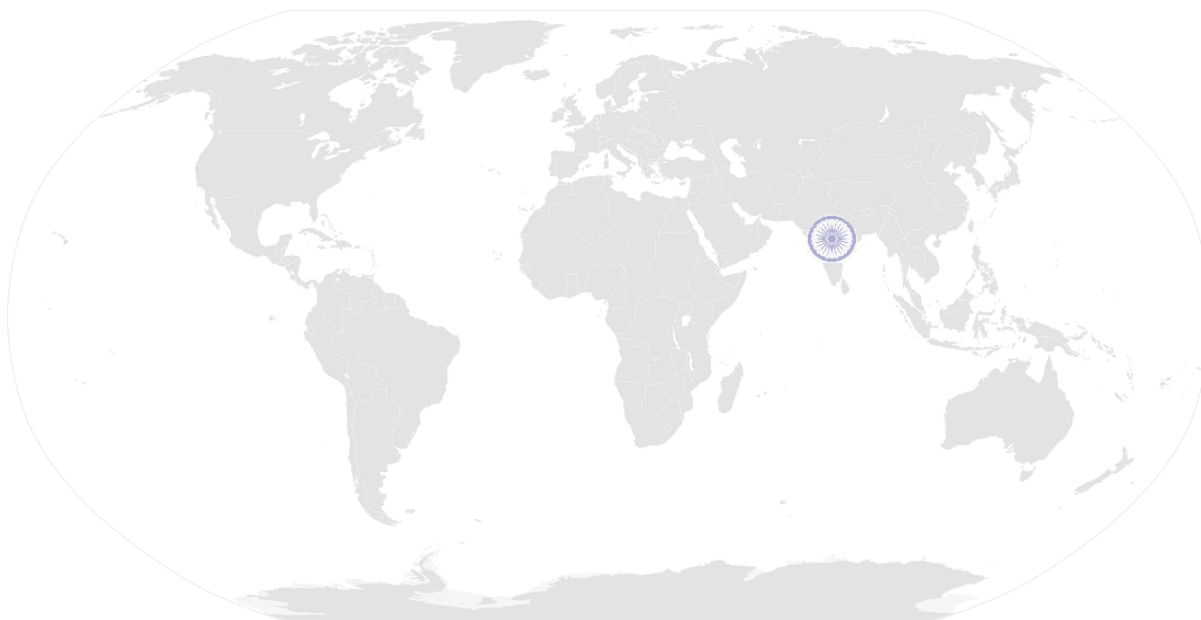
Annexure

Nomenclature for QP and NOS

Qualifications 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   Licensing Manager – Life Sciences
Qualifications Pack LFS/Q0609
Sector Skill Council Life Sciences Sector Skill Development Council

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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 (500)	Marks Allocation		
			Out of	Theory	Practical
LFS/N0622 (Regulatory compliance and exchange of information for licensing activities**)**	PC1. identify and evaluate all regulations and legislations for licensing activities	**100**	10	5	5
	PC2. design all compliance strategies for all businesses, including strategy for addressing issues		10	5	5
	PC3. ensure appropriate licensing activities implementation for various business groups i.e. ensure timely application and approval of licenses and monitor validity & expiry of all licensing documents which are required to carry out export/import operations		10	5	5
	PC4. maintain knowledge on all compliance trends and recommend changes for all company processes.		10	5	5
	PC5. prepare required reports for all product forms and manage all communications with licensors and perform audit		12	6	6
	PC6. evaluate all licensing agreements for all license partners and liason to transmit all reports and maintain database and reconcile the same		12	6	6

	PC7. maintain and update all distribution lists and manage all correspondence with licensed partners.		6	3	3
	PC8. review SAP periodic reports to carry out the departmental checks in compliance with rules and regulations and other statutory requirements		5	2	3

	PC9. review updates on cost impacts, cost estimates, stock management, feasibility analysis to carry out the departmental functions in compliance with rules and regulations and other statutory requirements		5	2	3
	PC10. identify variation from the regulatory guidelines and correction of the same		5	2	3
	PC11. comply with organization's policies, procedures, guidelines		5	2	3
	PC12. maintain confidentiality of strategic information		5	2	3
	PC13. communicate information to all relevant people in timely manner		5	2	3
	Total		100	47	53
LFS/N0613 (To provide analytical support for supply chain management)	PC1. analyze and recommend improvements to all internal procedures and implement same	**100**	15	7	8
	PC2. establish role and responsibilities in providing analytical support for Supply chain management process		15	5	10
	PC3. obtain confirmation from relevant employees and define the objective of the study		10	5	5
	PC4. access suitable sources of data		15	7	8
	PC5. sort and collate relevant data for the analysis		15	5	10
	PC6. usage of appropriate analysis methods and procedures		15	5	10
	PC7. identify potential and actual glitches and the causes for the same		15	7	8
	Total		100	41	59
LFS/N0623 (Manage, coordinate and interact with people to effectively control licensing operations)	P1. lead the demand planning team through all stages of the process ensuring accurate and actionable volume plans for new service launches.	**100**	10	5	5
	P2. convey organizational strategy to the team		5	2	3
	P3. ensure that the team is onboard with the organizational strategies		5	2	3
	P4. communicate departmental objectives and provide leadership direction to achieve goals		5	2	3

	PC5. manage and support recruitment		5	2	3
	PC6. delineation of individual roles, appropriate delegation of responsibility		5	2	3
	PC7. lead a team of demand planners responsible for integrating POU data into enterprise wide forecasts driving purchasing decisions		5	2	3
	PC8. set KRA's for direct reports, monitor overall team's KRA's, conduct performance appraisal, ensure clarity		5	2	3
	PC9. facilitate the development of subordinates through constant on and off the job learning, job rotation etc.		5	2	3
	PC10. guide, motivate and develop the sub-ordinates.		5	2	3
	PC11. oversee staff deployment and drive motivation levels of the team		5	2	3
	PC12. monitor staff welfare and facilitate complaint resolution		5	2	3
	PC13. manage efficiency levels and drive timely delivery of all operational targets		5	2	3
	PC14. compliance manager- Collaborate with compliance manager and prepare presentations to be presented in all meeting and committees		5	2	3
	PC15. coordinate with senior management and forecast all weekly revenue for same and resolve all complex issues with help from legal and finance teams		5	2	3
	PC16. quality Head – Collaborate to ensure the effectiveness of existing processes and to incorporate improvements		5	2	3
	PC17. department Heads- SAP Cell, Stores, Dispatch, PPC (Production, Planning & Control), Support- Materials, Total Cost Management Control – Collaborate to gather critical information, facts and data from the business		5	2	3
	PC18. stay in touch with ground reality to ensure effective implementation of key business decisions, to ensure		5	2	3

	availability for reviews, and discuss implementation plans				
	PC19. suppliers, contractors and vendors - For continuous evaluation and maintaining long term relationships with the vendors and contractors and ensuring all company policies and procedures are followed		5	2	3
	Total		100	41	59
LFS/N0102 (Carry out reporting and documentation)	PC1. report data/problems/incidents as applicable in a timely manner	**100**	10	5	5
	PC2. report to the appropriate authority as laid down by the company		10	5	5
	PC3. follow reporting procedures as prescribed by the company		10	5	5
	PC4. identify documentation to be completed relating to one's role		10	5	5
	PC5. record details accurately in an appropriate format		10	5	5
	PC6. complete all documentation within stipulated time according to company procedure		10	5	5
	PC7. ensure that the final document meets regulatory and compliance requirements		10	5	5
	PC8. make sure documents are available to all appropriate authorities to inspect		10	5	5
	PC9. respond to requests for information in an appropriate manner whilst following organizational procedures		10	5	5
	PC10. inform the appropriate authority of requests for information received		10	4	6
	Total		100	49	51