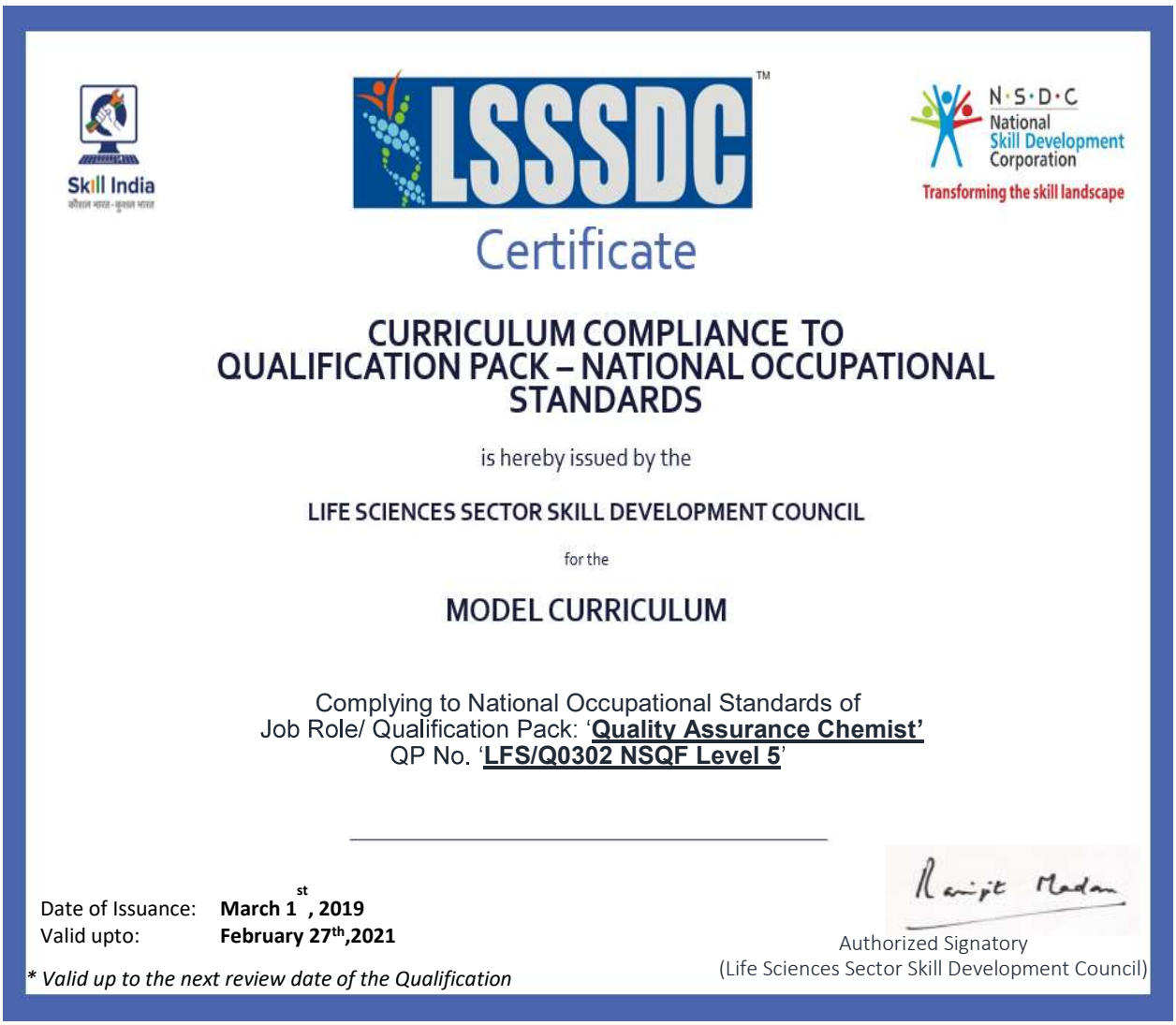
Model Curriculum

Quality Assurance Chemist

SECTOR:	**LIFE SCIENCES**
SUB-SECTOR:	**CONTRACT RESEARCH, PHARMACEUTICAL AND BIOPHARMACEUTICAL**
OCCUPATION:	**QUALITY**
REF ID:	**LFS/Q0302, V1.0**
NSQF LEVEL:	**5**



Certificate

CURRICULUM COMPLIANCE TO QUALIFICATION PACK – NATIONAL OCCUPATIONAL STANDARDS

is hereby issued by the

LIFE SCIENCES SECTOR SKILL DEVELOPMENT COUNCIL

for the

MODEL CURRICULUM

Complying to National Occupational Standards of
Job Role/ Qualification Pack: '**Quality Assurance Chemist'**
QP No. '**LFS/Q0302 NSQF Level 5**'

Date of Issuance: **March 1st, 2019**
Valid upto: **February 27th,2021**

** Valid up to the next review date of the Qualification*

Authorized Signatory
(Life Sciences Sector Skill Development Council)

TABLE OF CONTENTS

Quality Assurance Chemist

CURRICULUM / SYLLABUS

This program is aimed at training candidates for the job of a "Quality Assurance Chemist", in the "Life Sciences" Sector/Industry and aims at building the following key competencies amongst the learner

Program Name	**Quality Assurance Chemist**		
Qualification Pack Name & Reference ID.	Quality Assurance Chemist LFS/Q0302, V1.0		
Version No.	1.0	**Version Update Date**	01-03-2019
Pre-requisites to Training	**Minimum qualification -** B. Pharma (Preferable)/ B. Tech in Biotechnology (Preferable for Bio Pharmaceutical)/ B. Sc. in Microbiology (Preferable for Bio Pharmaceutical)/ B.Sc. in chemistry **Maximum qualification-** M. Pharma (Preferable)/ M. Tech in Biotechnology (Preferable for Bio Pharmaceutical)/ M.Sc. in Microbiology (Preferable for Bio Pharmaceutical)/ M.Sc. in chemistry **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		
Training Outcomes	**After completing this programme, participants will be able to:** • Explain the salient aspects of the life sciences industry and its pertinent regulations in order to demonstrate performance that is in line with industry standards. • Explain manufacturing and packing operations of pharmaceutical products, analytical awareness, handling of complaints, product returns and recalls, vendor management, engineering ability skills. • Practice sample management system and sample handling and skills to perform quality checks (Inspection/ Audits) to demonstrate internal quality audits in manufacturing, engineering, QC and other cross functions to ensure compliance with good manufacturing practices (GMP), good laboratory practices (GLP), good documentation practices (GDP) guidelines and organizational standard operating procedure (SOP) • Recall basic statistics and various statistical tools and techniques to perform statistical analysis of manufacturing, packing, QC, engineering and product distribution controls in manufacturing operation while ensuring compliance with GDP, GMP, GLP and organizational SOP • Verify and approve all manufacturing and analytical equipment and instruments to ensure compliance with GMP and GLP • Follow and verify the norms of GDP, online documentation system, various SOP's and reporting formats, GMP/ GLP guidelines relating to the required information capturing, reporting and documentation to meet the quality standards • Recall CQA, CPP, QMS for quality control, norms for global standards as cGMP, ISO, GLP, GDP and verify Laboratory Information Management System (LIMS) • Conduct quality assurance audits and generate reports for audit and close the audit queries.		

	• Act as per the environment, health and safety (EHS) norms and maintain a healthy, safe, and secure working environment in the pharmaceutical manufacturing area and the surrounding area • Assist supervisor and coordinate with cross functional teams and within the team for various functional activities • Practice professional skills at workplace such as decision making, planning and organizing, customer centricity, problem solving, objection handling, analytical thinking, critical thinking.

This course encompasses 3 out of 3 compulsory NOS (National Occupational Standards) of "Quality Assurance Chemist" Qualification Pack issued by "Life Sciences Sector Skill Development Council".

Sr. No.	Module	Key Learning Outcomes	Equipment Required
1	**Orientation Module** **Theory Duration** (hh:mm) 08:00 **Practical Duration** (hh:mm) 00:00 **Corresponding NOS Code** Bridge Module	• Explain life sciences industry and its sub-sectors • Summarize regulatory authorities rules and regulations for manufacturing • Recall detailed norms pertaining to GMP, Current Good Manufacturing Practises (cGMP), ISO, GLP, GDP and guidelines of Pharmacopeia • Summarize regulatory authorities rules and regulations for manufacturing • Outline the role of a Quality Assurance Chemist and practice the required skills (as per Qualification Pack)	Participant Manual, Power point presentation, Computer system, LCD Projector & Screen/ LCD Monitor, Mic, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts
2	**GxP Quality Assurance** **Theory Duration** (hh:mm) 16:00 **Practical Duration** (hh:mm) 40:00 **Corresponding NOS Code** LFS/N0303	• Recall aspects of current good manufacturing practices (cGMP), good laboratory practices (GLP), good documentation practices (GDP), Good Clinical practices (GCP) guidelines and standard operating procedure (SOP) • Prepare, approve and monitor the implementation of quality policy and objectives, quality manual, master validation plan (MVP) • Explain quality management system (QMS) for quality assurance in Life Sciences industry • Maintain training documents for trainings imparted • Explain and summarize complaints and product recall as per SOP • Carry out investigation of deviations and out of specifications (OOS) • Participate in internal quality audit and quality review	Guidelines for good manufacturing practices (cGMP), good laboratory practices (GLP), good documentation practices (GDP), Good Clinical practices (GCP), standard operating procedure (SOP), sample Quality manual, sample quality policy, sample master validation plan
3	**Engineering Skills for Quality Assurance** **Theory Duration** (hh:mm) 16:00 **Practical Duration** (hh:mm) 44:00 **Corresponding NOS Code** LFS/N0303	• Implement the concept and practical skills 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 • Approve equipment and critical utilities qualification calendar for HVAC, water, gas and power distribution systems calibration, qualification and maintenance schedule • Ensure that all equipments and instruments are qualified, calibrated before use and documentation for same is complete • Participate in internal audits for facility, equipment and utilities on periodic basis	Participant Manual, Power point presentation, Computer system, LCD Projector & Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts, diagrams of Engineering instruments, sample calibration record and change control records, sample job cards, log books, sample calibration schedule, sample engineering layouts

		• Prepare compliance report for audits observations • Review and approve qualification protocols and calibration schedules of equipment and facility • Explain the concept and need of preventive maintenance procedures, design qualification, SOP/URS/Standard control practices, layouts and cleaning validation	
4	**Quality Assurance for Production** **Theory Duration** (hh:mm) 16:00 **Practical Duration** (hh:mm) 60:00 **Corresponding NOS Code** LFS/N0303	• Recall API production and formulation process and identify critical quality attributes (CQA), critical process parameters (CPP) and critical process controls (CPC) • Explain basics of formulation like route of drug administration, dosage forms and their relevant benefits • Coordinate with the manufacturing department in controlling their process and products at every stage of manufacturing to meet specification through testing, auditing and reporting • Explain in-process checks during manufacturing and packing operations • Carry out issuance of operational specification, master formula records, batch manufacturing records (BMR) and batch packing records (BPR) • Co-ordination for internal audit for addressing of incidents, investigations, CAPA follow-up and closure • Follow line clearance of various manufacturing and packing operations, routine sampling of in-process and its checks, validation and finished product samples • Review and approve master production records, change controls, bill of material, performance qualification protocols and reports, analytical reports related to exhibit/ submission batches • Perform material verification, in-process labelling and status of material, release, process validation and stability protocols/reports	Participant Manual, Power point presentation, Computer system, LCD Projector & Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts, manufacturing equipment models/ diagrams (API & Formulations), sample production plan, sample log books, sample BMR and BPR
5	**Quality Assurance for Quality Control** **Theory Duration** (hh:mm) 16:00 **Practical Duration** (hh:mm) 60:00	• Explain release process of certificate of analysis (COA) for blend, API and finished products • Investigation of deviations and out of specifications • Conduct internal quality audit and quality review • Review collection of stability and control samples during packing operations • Verify the GMP compliance and control of data integrity issues in QC, analytical reports, verification of standard operating	Participant Manual, Power point presentation, Computer system, LCD Projector & Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts, QC Equipment models/ diagrams, sample SOPs, sample log books, sample analytical sheets

	Corresponding NOS Code LFS/N0303	procedures/ standard testing procedures/work sheets/ Analytical report before approval • Conduct verification of material damage report, review knowledge on Raw material/In-process/Finished products/ Packing materials/ Stability specifications before approval, detail aspects like cGMP, GLP, ISO with reference of quality assurance • Demonstrate practical skill for complex and non-complex techniques	
6	**Information Technology Skills at work** **Theory Duration** (hh:mm) 16:00 **Practical Duration** (hh:mm) 24:00 **Corresponding NOS Code** LFS/N0303	• Use IT tools for data entry in e-documents wherever needed • Maintain the confidentiality of the data and internal processes • Comply with the requirements of 21 CFR Part 11 rules • Maintain information security while using e-mail and other official communication channels • Maintain online records as per SOP • Maintain electronic signatures, Date and Time stamps • Follow data Integrity	Participant Manual, Power point presentation, Computer Lab, LCD Projector & Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster
7	**Documentation and reporting** **Theory Duration** (hh:mm) 16:00 **Practical Duration** (hh:mm) 24:00 **Corresponding NOS Code** LFS/N0303	• Control, issue, archive and distribute records/ reports/ filing, art works, packing standards, protocols, drug calculations as per guidelines • Upload and maintain batch documents in database • Monitor the documents and their controls, control and issue SOP/STP/ Protocols/work sheets/BMR/BPR and record of analysis, design training matrix • Prepare, compile and approve annual product quality review as per schedule, evaluate control charts for API, In-process and finished product • Conduct incidents, deviations, OOS, OOT, CAPA follow-up and closure, detail aspects like cGMP, Good Documentation Practice compliance. • Perform documentation for market returns, reprocessing (for API batches) or destruction (for finished batches), and informing regulatory authorities about defects found after distribution • Handle vendor and market complaints, provide justification or clarification for customer queries, change controls, internal and external audits • Review and maintain training records of on-the-job and induction trainings according to the schedule	Participant Manual, Power point presentation, Computer system, LCD Projector & Screen/ LCD Monitor, Mic, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts, Sample Validation Reports, Sample BMR/BPR, Sample Lab notebook, Sample Production plan, sample formats of method transfer, method validation and calibration reports, GMP and GLP guidelines, sample labels, sample audit reports, and sample audit responses

		• Ensure that planned/unplanned changes or deviations are documented, reviewed and analysed	
8	**Workplace Cleanliness** **Theory Duration** (hh:mm) 10:00 **Practical Duration** (hh:mm) 16:00 **Corresponding NOS Code** LFS/N0303	• Maintain level of hygiene in all the areas such as manufacturing, laboratory, storage • Check all types of working environment conditions (ventilation, temperature) • Recall methodology for area inspection with methods and materials required for cleaning variety of surfaces and equipments • Recall all types of stains and cleaning material required to remove the specific stain • Describe all types of accidental damage at the time of work • Assess any out of control situation and report to supervisor • Examine the shop floor for cleanliness after every batch manufacturing operation and update the cleaning status • Examine the area after cleaning activity for residue of oily substance and scrap material • Use personal protective equipment and after use put them at neat and clean place • Verify disposal of waste and scrap as per SOP • Verify cleaning of all equipments as per SOP	Various types of cleaning material, chemicals, cleaning equipment, half face mask, full face mask, various cartridges, safety goggles, safety shoes, gum boots, chemical absorbent, self-contained breathing apparatus, PVC apron, gloves(Nitrile, {Heat, acid, chemical} resistant, washing etc..), lab coat, surgical gloves (in microbiology), eye washer with sprinkler, CO_2 type fire extinguisher, ABC type fire extinguisher
9	**Health and Safety** **Theory Duration** (hh:mm) 16:00 **Practical Duration** (hh:mm) 16:00 **Corresponding NOS Code** LFS/N0101	• Explain the concepts of safety including hazards, accidents, safety signs and signals • Follow EHS rules and Heinrich pyramid at shop floor • Recall the use of the water systems at plant and engineering related tools • Follow the clean room classifications and requirements • Perform environmental monitoring and follow clean room behaviour practices • Use material safety data sheet (MSDS) and follow the process of safety analysis • Follow the fire safety concepts and prepare oneself to act in case of fire emergency at shop floor • Use personal protection equipment (PPEs) in different production operations • Follow the emergency procedures and perform first aid as and when needed • Practice core and professional skills such as planning and organizing, problem solving, objection handling, and critical thinking	half face mask, full face mask, various cartridges, safety goggles, safety shoes, gum boots, chemical absorbent, self-contained breathing apparatus, PVC apron, gloves (Nitrile, {Heat, acid, chemical} resistant, washing etc..), lab coat, surgical gloves (in microbiology), eye washer with sprinkler, CO_2 type fire extinguisher, ABC type fire extinguisher
10	**Coordinate with Supervisor and cross functional the teams**	• Follow general reporting process, protocol and escalation policy • Interact with cross functional teams while conducting internal audits, vendor audits and communicate the audit observations	Power point presentation, computer system, LCD Projector & screen/ LCD monitor, mike, sound system, laser pointer, white/ black board, white board

	Theory Duration (hh:mm) 16:00 **Practical Duration** (hh:mm) 16:00 **Corresponding NOS Code** LFS/N0104	• Use efficient and clear communication methods for reporting the incidents/ deviations and communication with team • Use the techniques for collaborating with other groups and divisions • Demostrate the conceptual and practical skills required by QA Chemist in Audits • Explain the importance of data integrity cGMP/QMS/ regulatory requirements SOP related documentation • Follow the method to respond to audit queries • Face internal audit interactions • Use IT tools in communication and coordination • Practice core communication skills and professional skills to meet the work output requirements	marker/ chalk, duster, flip charts, sample audit report and sample responses
11	**On the Job Training** **Theory Duration** (hh:mm) 00:00 **Practical Duration** (hh:mm) 00:00 **OJT Duration** (hh:mm) 80:00 **Corresponding NOS Code** LFS/N0303	• Perform quality assurance procedures for production and quality control • Upload and maintain batch documents in database • Preform in-process checks during manufacturing and packing operations • Issue documents to departments as per the requisition raised by respective department • Maintain a healthy, safe and secure working environment in the life sciences facility • Coordinate with shift supervisor, cross functional teams and within the team • Carry out reporting and documentation to meet quality standards	On the job training monitoring report
	Total Duration **Theory Duration** 146:00 **Practical Duration** **300**:00 **OJT Duration** 80:00	**Unique Equipment Required:** Participant Manual, Power point presentation, Computer system, LCD Projector & Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts, Computer Lab, Sample Validation Reports, Sample BMR/BPR, Sample Lab notebook, Sample Production plan, sample formats of method transfer, method validation and calibration reports, GMP and GLP guidelines, sample labels, sample audit reports, and sample audit responses, Diagrams of engineering instruments, sample calibration and change control records, sample job cards, log books, sample calibration schedule, sample engineering layouts, various types of cleaning material, chemicals, cleaning equipment, half face mask, full face mask, various cartridges, safety goggles, safety shoes, gum boots, Chemical Absorbent, Self-Contained Breathing Apparatus, PVC Apron, Gloves(Nitrile, {Heat, acid, chemical} resistant, washing etc..), Lab Coat, Surgical Gloves (in Microbiology), Eye washer with sprinkler, CO_2 type Fire Extinguisher, ABC Type Fire Extinguisher	

Grand Total Course Duration: 526 **Hours 00 Minutes (includes 80 hours of Mandatory OJT)**

(This syllabus/ curriculum has been approved by Life Sciences Sector Skill Development Council.)

Trainer Prerequisites for Job role: "Quality Assurance Chemist" mapped to Qualification Pack: "LFS/Q0302, V1.0"

Sr. No.	Area	Details
1	**Job Description**	To deliver accredited training service, mapping to the curriculum detailed above, in accordance with the Qualification Pack "LFS/Q0302, V1.0".
2	**Personal Attributes**	Aptitude for conducting training, and pre/ post work to ensure competent, employable candidates at the end of the training. Strong communication skills, interpersonal skills, ability to work as part of a team; a passion for quality and for developing others; well-organised and focused, eager to learn and keep oneself updated with the latest in the mentioned field.
3	**Minimum Educational Qualifications**	Graduation (B. Sc.- Chemistry/ B. Pharma are preferred)
4a	**Domain Certification**	Certified for Job Role: "Quality Assurance Chemist" mapped to QP: "LFS/Q0302, V1.0". Minimum accepted score is 80% as per LSSSDC guidelines.
4b	**Platform Certification**	Recommended that the Trainer is certified for the Job Role: "Trainer", mapped to the Qualification Pack: "MEP/Q0102". Minimum accepted score is 80% as per LSSSDC guidelines.
5	**Experience**	Preferably Minimum Four (8) years' experience in life sciences (Pharmaceutical/ Biopharmaceutical) Quality Assurance occupation for non-trained and non-qualified talent with B. Sc.- Chemistry/ B. Pharma preferred education qualification Or Preferably Minimum six (6) years' experience in life sciences (Pharmaceutical/ Biopharmaceutical) Quality Assurance occupation for non-trained and non-qualified talent with M.Sc. Chemistry/ M. Pharm preferred education qualification

Annexure: Assessment Criteria

Assessment Criteria	
Job Role	Quality Assurance Chemist
Qualification Pack	LFS/Q0302, V1.0
Sector Skill Council	Life Sciences Sector Skill Development Council

Sr. No.	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 centre (as per assessment criteria below)
4	Individual assessment agencies will create unique evaluations for skill practical for every student at each examination/training centre based on this criteria
5	To pass the qualification pack, every trainee should score a minimum of 70% in every NOS
6	In case of successfully passing only certain number of NOS's, the trainee is eligible to take subsequent assessment on the balance NOS's to pass the Qualification Pack

				Marks Allocation	
Assessment Outcome	**Assessment Criteria of Outcomes**	**Total Marks (300)**	**Out Of**	**Theory**	**Skills Practical**
1. 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
	PC7. carry out sampling activities for quality assurance audit across stages		5	2	3
	PC8. assess repetitive incidences of OOS and OOT. Prepare		6	3	3

		and evaluate the trend of OOS and OOT investigation periodically				
	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	5
2. LFS/N0101 Maintain a healthy, safe and secure working environment in the life sciences facility	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 deal with safely, competently and within the limits of their authority		10	5	5
	PC6.	adhere and comply to storage and handling guidelines for hazardous material		10	5	5
	PC7.	identify and recommend opportunities for improving health, safety, and security to the designated person		10	5	5
	PC8.	complete any health, safety and security activities like safety drills and prepare		10	4	6

		records legibly and accurately				
	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
3. 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