Model Curriculum

Quality Assurance Chemist

Quality Assurance Chemist

SECTOR: **LIFE SCIENCES**
SUB-SECTOR: **CONTRACT RESEARCH, PHARMACEUTICAL, BIOPHARMACEUTICAL**
OCCUPATION: **QUALITY**
REFERENCE ID: **LFS/Q0302 Ver1.0**
NSQF LEVEL: **LEVEL 5**

LSSSDC

N·S·D·C National Skill Development Corporation
Transforming the skill landscape

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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 Ver1.0		
Version No.	1.0	**Version Update Date**	24–12 – 2015
Pre-requisites to Training	B. Pharma (Preferable)/ B. Tech in Biotechnology (Preferable for Bio Pharmaceutical)/ B. Sc. in Microbiology (Preferable for Bio Pharmaceutical)/ B.Sc. in chemistry		
Training Outcomes	**After completing this programme, participants will be able to:** • Gain Knowledge about Life Sciences Industry, Legal and Regulatory framework and Pharmacopeia to enable him/herself for establishing the Industry Standards in his/her performance • Gain scientific knowledge and skills about Manufacturing and packing operations of Pharmaceutical Products, Analytical awareness, Handling of complaints, product returns and recalls, vendor management, engineering ability skills. • Learn Procedural Knowledge, Quality skills for Sample management system and Sample Handling and Skills to perform Quality Checks (Inspection/ Audits), to enable him/herself able to perform internal quality audits in manufacturing, engineering, QC and other cross functions to ensure compliance with GDP, GMP & GLP and organizational SOP • Gain Knowledge of basic statistics and hands on Knowledge of 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 enable him/herself while ensuring compliance with GMP & GLP • Follow and verify the norms of Good Documentation Practice, 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 • Gain Knowledge of CQA, CPP, QMS for Quality Control, norms for global standards like cGMP, ISO, GLP, GDP. Capable to verify a Laboratory Information Management System (LIMS) • Conduct quality assurance audits and generate the reports for audit and close the audit queries. • Maintain a healthy, safe and secure working environment at the pharmaceutical manufacturing shop floor, Laboratory and area around as per EHS requirement and Industrial practices and ability to ensure routine maintenance and cleanliness at work area. Manage emergency procedures.		

	• Coordinate and support with Supervisor, cross functional teams and within the team for various functional activities • Practice Professional Skills at work like Communication skills (read, write, listen and speak), Decision Making, Planning & Organizing, Customer Centricity, Problem Solving, Objection Handling, Analytical Thinking, and Critical Thinking.

This course encompasses Three (3) out of Three (3) National Occupational Standards (NOS) of "Quality Assurance Chemist LFS/Q0302 Ver1.0" Qualification Pack issued by "Life Sciences Sector Skill Development Council".

Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
1	Orientation Module	10:00	00:00	• Understand Brief outline of Life Sciences Industry, its sub-sectors • Know about Regulatory Authorities and Government Policies, rules and Regulations and their impact on manufacturing in Life Sciences Industry • Understand the Standards for Manufacturing in Life Sciences like cGMP, ISO, GLP, GDP etc. Orientation of Pharmacopeia • Know about the Existing Organization in Life Sciences Industry (in context of Large/Medium/ Small Enterprises): Their Organization Structure and Benefits. Orientation on typical manufacturing function in a Life Sciences organization. • Know and Perform the Role of a Quality Assurance Chemist and required skills and knowledge (As per Qualification Pack) and its Career Path	LFS/N0303, LFS/N0101, LFS/ N0104	Participant Manual, Power point presentation, Case Studies, Computer system, LCD Projector & Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts
2	Overview of Production Process & Packaging operation for	10:00	06:00	• Learn and Apply the Fundamental Science in API and Formulation Production, packaging including review skills in PAS/X activities,	LFS/N0303	Compression Machine prototype, Coating Machine Prototype, FBE Prototype, Hardness Tester, DT

Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
	Life Sciences Industry			potency calculation for active materials, procedures and initiate the changes where ever applicable. Co-ordination for self-inspection audit. Addressing of incidents, investigations, CAPA follow-up and closure. Review and approval of Operational specification, UAT, Master batch records, executed batch report and executed dispensing report in PAS/X. Role of API in typical Pharmaceutical Manufacturing and role of API particle size in formulations, Knowledge on Critical Quality Attributes (CQA), Critical Process Parameters (CPP) and Critical Process Controls(CPC). • Know and apply the Basics of Formulations including Route of Drug Administration and Various Dosage Forms like Oral Solid Dosage, Liquid Oral Dosage, Sterile Dosage, Dermatological Dosage and their relevant benefits, line clearance of various manufacturing and packing operations, routine sampling of in-process and its checks, validation and finished product samples. Collection of stability and control samples during packing operations. Know pack stock checks, batch documents, control on OSD, review and trending of Annual Product Quality Reviews.		Apparatus, Multimill, SA9 Capsule Filling Prototype, Airjet Cleaning Machine, Filter Press, Inline homogeniser Cum Mixer, Automatic Filling Machine , Planetary mixer(jackatted with electrical heating facility), Preparation vessel, reactor (Not required) & Storage Tank, Agitator- Stirrer, Colloid Mill, Vacuum Homogenizer Mixer, Skid CIP-WIP System, Weighing balance (1.2kg, 6.0kg with printer), Rapid mixer granulator (table top 1/5 L capacity), Double cone blender (5L Capacity), Remi stirrers, Semi-Automatic Cap Sealing Machine, On Line Inspection, Turn Table , Labelling machine, Induction machine, Dose mono filling machine Prototype, Induction Sealing Machine Prototype, Cap Sealing Machine Prototype, Semi-Automatic Ropp Cap Sealing Machine & Screw Capping Machine, Glove box isolators for potent drugs, Autoclave,

Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				• Gain Knowledge about Quality Management System for Production in Life Sciences Industry including its introduction and importance, QC and QA Systems, Detail aspects of cGMP, GLP, ISO with reference of quality assurance, On the Job Training, material verification, in-process labelling and status of material, release, process validation and stability protocols/reports, with drawl of reserve and stability samples from the production shop floor. Review of SOP, following safety, health and environmental procedures and practices.		Climatic chambers (300 L capacity), Monoblock Rotary Dry Powder Filling & Sealing Machine, Single Dose Filling Machine, Automatic(Liquid) Filling Machine , Tube Filling Machines For Laminated / Plastic Tubes, Multicolumn, Rectangular Steriliser, Tube Filling Machine Prototype, Preparation vessel, reactor & Storage Tank, Dispo Homogenizer, Inline Homogenizer, Barcode scanner, Torque tester, Bursting strength, Pin hole tester, Differential scanning calorimeter
3	Fundamentals of Analytical to Quality Assurance personnel for Life Sciences Industry	20:00	08:00	• Know and apply the 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. • Gain and apply knowledge of compilation of stability data and its verification, addressing the Quality	LFS/N0303	UV Analyser (Make: Perkin elmer/shimadzu/Thermo), FT-IR (Make: Shimadzu/Thermo), Halogen Moisture Analyzer, Seive Shaker & Mesh sizes, Polarimeter, Auto titrator, Melting point , Capillary tubes, TLC chamber, Brookfiled Viscometer, Black particle size analyzer, Density meter, Bulk density and Tapped density tester, Friabilator, Vernier calipers, Micrometer screw gauge, Karl Fisher Apparatus

Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				impacting and non-impacting incidents, deviations, OOS, OOT, CAPA follow-up and closure, stability protocol certification of commercial and validation batches, ensuring the GMP compliance and control of data integrity issues in QC, analytical reports, knowledge on SAP, verification of standard operating procedures/ standard testing procedures/work sheets/ Analytical report before approval. • Gain and apply the knowledge of release process of Certificate of analysis for blend, API & finished products, vendor specifications for trending of Out of Trending (OOT) results, notification closures, Quality management systems, stability master data, pulls & maintenance. Knowledge on in-process checks during manufacturing and packing operations. • 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.		(Make: Metrom), Particle Size Analyzer (Make: Malvern Master 2000), Hardness Tester, Laboratory Microscopes(40X and 100X), HPLC (Make: Agilent/Waters/Shimadzu), Specific optical rotation Analyser (Make: Rudolph Autopol V/ Jasco 2000 or 3000), Gas chromatographer, Dissolution Apparatus, DT Apparatus, Analytical balance with printer, Centrifuge , pH meter with ATC Probe/ Glass electrode, conductivity meter

Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				• Learn and apply practical skill for Complex and Non-Complex Techniques.		
4	Process Validation and Exhibit staging for Quality Assurance	06:00	05:00	• Gain and apply the knowledge on hold time data, SHE report availability, compliance in master production records, vendor status of raw material prior to start of new product and before validation batch start, method transfer, method validation and calibration reports. • Review and approve Master production records, change controls, bill of material, performance qualification protocols and reports, analytical reports related to exhibit/ submission batches, regulatory dossiers of various markets. • Gain and apply knowledge on R&D development strategy, technology transfer, production and manufacturing assurance for execution of process performance qualification and verification of batches, Quality impacting and non-impacting incidents, deviations, OOS, OOT, CAPA follow-up and closure, detail aspects like cGMP, GLP compliance.	LFS/N0303	Participant Manual, Power point presentation, Case Studies, Computer system, LCD Projector & Screen/ LCD Monitor, Mike, 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,
5	Documentation for Quality Assurance	34:00	34:00	• Control, issue, archive and distribute records/ reports/ filing, art works, packing standards, protocols, drug calculations, upload and	LFS/N0303	Participant Manual, Power point presentation, Case Studies, Computer system, LCD Projector

Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				maintain batch documents in database and SAP, 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. • Handle vendor & market complaints, provide justification or clarification for customer queries, change controls, internal & external audits.		& Screen/ LCD Monitor, Mike, 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
6	Engineering Skills for Quality Assurance	06:00	06:00	• Learn and apply 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. • Follow the detailed concepts and guidelines of Good Documentation Practices and documentation requirement for Good Manufacturing Practices,	LFS/N0303	Participant Manual, Power point presentation, Case Studies, 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 and change control records,

Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				building management systems, environment management systems etc • Give an audit justification given for wrong entry done in qualification documents, response to production team and conduct audits for facility, equipment and utilities on periodic basis, understanding on action plans and sticking to the time lines. • Rreview and approve Qualification protocols and calibration schedules of equipment and facility, preventive maintenance procedures, design qualification, SOP/URS/Standard control practices, layouts, cleaning validation documents.		sample job cards, log books, sample calibration schedule, sample engineering layouts
7	Ensure Cleanliness in the work area	08:00	04:00	• Gain and apply knowledge of different Material, chemicals and equipment and their cleaning procedure as per manufacturer's guide • Gain and apply Knowledge about Electronic and Optical Sensors in laboratory equipment • Follow the methodology for storage area inspection with methods and materials required for cleaning variety of surfaces and equipment, methods to check the treated surface and equipment on completion of cleaning, disposal methods	LFS/N0303	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/

Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				for waste, used/ unused solutions and relevant SOP, Procedures for reporting any unidentified soiling and Escalation procedures for soils or stains that could not be removed • Practice Related Core Skills and Professional Skills at work like; Reading, writing, listening and speaking, Critical thinking, problem solving, decision making, customer centricity, plan and organizing.		Manual bottle eye washer, Co2 type Fire Extinguisher, ABC Type Fire Extinguisher
8	Maintain a healthy, safe and secure working environment in the pharmaceutical manufacturing facility and laboratory	16:00	10:00	• Learn and apply the Basic Concepts of Safety including Hazards, Accidents, Safety Signs and Signals and Henriech Pyramid • Know about Water Systems at Plant, Engineering related tools and techniques to operate the machine safely • Use Material Data Safety Sheet, follow Process of Safety Analysis. Learn and apply Fire Safety concepts and act in case of Fire Emergency at shop floor. Use various PPEs in different production operations and to do Job Safety Analysis for Various production machines/ equipment • Learn and apply the Basic Concepts and practical skills for managing Emergency Procedures and how to do first aid	LFS/N0101	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/ Manual bottle eye washer, Co2 type Fire Extinguisher, ABC Type Fire Extinguisher

Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				• Practice Related Core Skills and Professional Skills at work like: Reading, writing, listening, speaking, Plan and organize, Critical thinking, problem solving, decision making, customer centricity		
9	Coordinate with Supervisor, within team and cross functional the teams	18:00	18:00	• Manage Supervisor-Reportee Relationship including identify Partnering Opportunities at work; orientation on General reporting process, protocol and escalation policy and Importance of reports and communication with Supervisor • Interact with cross functional teams while conducting internal audits and communicate the audit observations • Use the techniques for Collaborating with Other Groups and Divisions • Apply the conceptual and practical skills required by QC Chemist in Audits • Know about Importance of cGMP/ GLP/ GDP/QMS/ SOP/ regulatory requirements related documentation • Follow the Method to Respond to Audit Queries • Face Internal Audit Interactions • Use IT in communication and coordination • Practice Related Core Skills and Professional Skills at	LFS/N0104	Power point presentation, Case Studies, Computer system, LCD Projector & Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts, Sample Audit Report and Sample Responses

Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				work : Reading, writing, listening, speaking, Analytical thinking, problem solving, decision making, customer centricity		
10	Information Technology Skills	18:00	18:00	• Use Basic Computer Skills (Ms Office, Internet)+ Typing at Work • Handle different software's used to operate the QC instruments • Apply the knowledge on 21 CFR Part 11 compliance system and its requirements	LFS/N0303, LFS/N0104	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
11	Internship	00:00	191:00	• Perform the Quality Checks • Maintain a healthy, safe and secure working environment in the pharmaceutical facility of manufacturing /testing/ analysis / research laboratory • Coordinate with Supervisor and within team members	LFS/N0303 LFS/N0101 LFS/N0104	Internship Monitoring Report
	Total Duration	**146:00**	**300:00**	**Unique Equipment Required:** Compression Machine prototype, Coating Machine Prototype, FBE Prototype, Hardness Tester, DT Apparatus, Multimill, SA9 Capsule Filling Prototype, Airjet Cleaning Machine, Filter Press, Inline homogeniser Cum Mixer, Automatic Filling Machine , Planetary mixer(jackatted with electrical heating facility), Preparation vessel, reactor (Not required) & Storage Tank, Agitator- Stirrer, Colloid Mill, Vacuum Homogenizer Mixer, Skid CIP-WIP System, Weighing balance (1.2kg, 6.0kg with printer), Rapid mixer granulator (table top 1/5 L capacity), Double cone blender (5L Capacity), Remi stirrers, Semi-Automatic Cap Sealing Machine, On Line Inspection, Turn Table , Labelling machine, Induction machine, Dose mono filling machine Prototype, Induction Sealing Machine Prototype, Cap Sealing Machine Prototype, Semi-Automatic Ropp Cap Sealing Machine & Screw Capping Machine, Glove box isolators for potent drugs, Autoclave, Climatic chambers (300 L capacity), Monoblock Rotary Dry		

Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				Powder Filling & Sealing Machine, Single Dose Filling Machine, Automatic(Liquid) Filling Machine , Tube Filling Machines For Laminated / Plastic Tubes, Multicolumn, Rectangular Steriliser, Tube Filling Machine Prototype, Preparation vessel, reactor & Storage Tank, Dispo Homogenizer, Inline Homogenizer, Barcode scanner, Torque tester, Bursting strength, Pin hole tester, Differential scanning calorimeter, UV Analyser (Make: Perkin elmer/shimadzu/Thermo), FT-IR (Make: Shimadzu/Thermo), Halogen Moisture Analyzer, Seive Shaker & Mesh sizes, Polarimeter, Auto titrator, Melting point , Capillary tubes, TLC chamber, Brookfiled Viscometer, Black particle size analyzer, Density meter, Bulk density and Tapped density tester, Friabilator, Vernier calipers, Micrometer screw gauge, Karl Fisher Apparatus (Make: Metrom), Particle Size Analyzer (Make: Malvern Master 2000), Hardness Tester, Laboratory Microscopes(40X and 100X), HPLC (Make: Agilent/Waters/Shimadzu), Specific optical rotation Analyser (Make: Rudolph Autopol V/ Jasco 2000 or 3000), Gas chromatographer, Dissolution Apparatus, DT Apparatus, Analytical balance with printer, Centrifuge , pH meter with ATC Probe/ Glass electrode, conductivity meter, Participant Manual, Power point presentation, Case Studies, Computer system, LCD Projector & Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts, Computer Lab, Internship Monitoring Report, 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/ Manual bottle eye washer, Co2 type Fire Extinguisher, ABC Type Fire Extinguisher		

Grand Total Course Duration: **_446_ Hours _00__ Minutes**

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

Annexure1: Assessment Criteria

Assessment Criteria for Quality Assurance Chemist	
Job Role	**Quality Assurance Chemist**
Qualification Pack	**LFS/ Q 0302 Ver1.0**
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 laid out in Qualification Pack)
4	Individual assessment agencies will create unique evaluations for skill practical for every student at each examination/training centre based on the assessment criteria laid out in qualification pack
5	To pass the Qualification Pack , every trainee should score a minimum of 70% aggregate in all NOS and a minimum of 50% 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	
		Total Marks (300)	**Out Of**	**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,		8	4	4

	compliance, drive efficiencies and cost effectiveness of Quality Assurance team				
	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**	**49**	**51**
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 records legibly and accurately		10	4	6
	PC9. report any hazards that the individual is not competent to deal with to the relevant		10	4	6

	person in line with organizational procedures and warn other people who may be affected				
	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**
Grand Total		**300**	**300**	**143**	**157**
Percentage Weightage				**48%**	**52%**
Minimum Pass Percentage to Qualify				**70%**	

Annexure2: Trainer Prerequisites for Job role: "Quality Assurance Chemist" mapped to Qualification Pack: "LFS/ Q 0302 Ver1.0"

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 Ver1.0".
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-organized and focused, eager to learn and keep oneself updated with the latest in the mentioned field.
3	**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
4a	**Domain Certification**	Certified for Job Role: "Quality Assurance Chemist" mapped to QP: "LFS/Q 0302 Ver1.0". 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: "SSC/1402". Minimum accepted score is 80% as per LSSSDC guidelines.
5	**Experience**	Preferably Minimum Five (5) years' experience in life sciences (Pharmaceutical/ Biopharmaceutical) Quality occupation for non-trained and non-qualified talent Or Minimum Two (2) years' experience with Quality Assurance Chemist Level-5 qualified

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/ Q 0302 NSQF Level 5**'

Date of Issuance: **December 24th, 2015**

Valid up to: **June 01st, 2016**

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

Authorized Signatory
(Life Sciences Sector Skill Development Council)

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