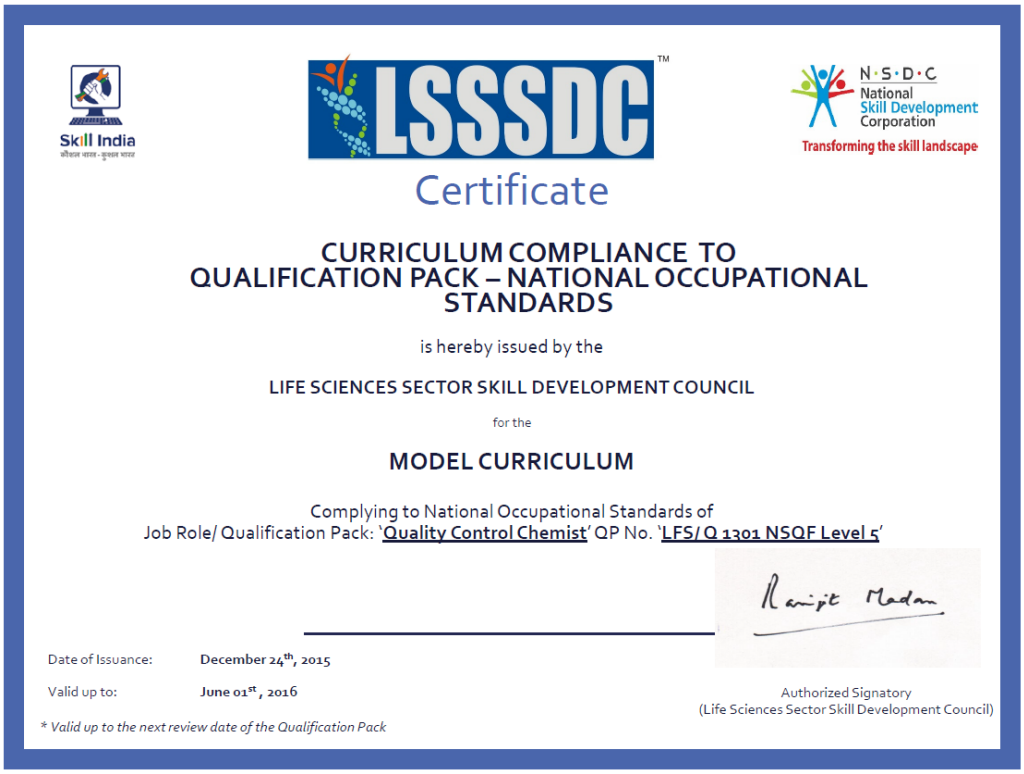
Model Curriculum

Quality Control Chemist

SECTOR: LIFE SCIENCES
SUB-SECTOR: PHARMACEUTICAL
OCCUPATION: QUALITY
REF ID: LFS/ Q 1301 Ver1.0
NSQF LEVEL: 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 Control Chemist' QP No. 'LFS/ Q 1301 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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Quality Control Chemist

CURRICULUM / SYLLABUS

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

Program Name	**Quality Control Chemist**		
Qualification Pack Name & Reference ID.	Quality Control Chemist LFS/ Q 1301 Ver1.0		
Version No.	1.0	**Version Update Date**	24–12 – 2015
Pre-requisites to Training	B. Pharma / B. Sc. with Chemistry major subject or Analytical Chemistry (Preferable)		
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 application of Basics of Chemistry, chromatography and separation science in instrumental analysis of Pharmaceutical Products as well as gain Procedural Knowledge and Quality skills for Sample Preparation and Sample Handling and Skills to perform Quality Check (Inspection and Analysis), to enable him/herself able to perform routine analysis in lab while ensuring 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 QC results in lab while ensuring compliance with GDP, GMP & GLP and organizational SOP • Operate analytical Equipment and Instruments like Gas Chromatography (GC), High Performance Liquid Chromatography (HPLC), Fourier Transfer-Infrared (FT-IR), Inductively Coupled Plasma (ICP), Auto-Titration, UV-Visible mass spectrophotometer detection, stability chambers, BOD incubators, Photoflourometer • Perform routine analysis in lab while ensuring compliance with GMP & GLP and carry out Quality Checks in the Quality Control process • Follow 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 QMS for Quality Control, norms for global standards like cGMP, ISO, GLP, GDP. Skills to operate a Laboratory Management Information System • Carryout reporting and documentation as per quality standards and SoPs		

Program Name	Quality Control Chemist
	• Participate in audits as a QC team member and generate the responses for audit queries. Ability to deal with potential risks and challenges for quality and data integrity. • 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. He/ she become capable of managing emergency procedures. • Ensure routine maintenance and cleanliness at work area. • Coordinate and support with Supervisor, cross functional teams and within the team for various functional activities • Practice Professional Skills at work; like Decision Making, Planning & Organizing, Customer Centricity, Problem Solving (including trouble shooting), Analytical Thinking, Critical Thinking

This course encompasses Six (6) out of Six (6) National Occupational Standards (NOS) of "Quality Control Chemist- Life Sciences (LFS/Q 1301 Ver1.0)" Qualification Pack issued by "Life Sciences Sector Skill Development Council, India".

Sr. No.	Module	Key Learning Outcomes	Equipment Required
1	**Orientation Module** **Theory Duration** (hh:mm) 10:00 **Practical Duration** (hh:mm) 00:00 **Corresponding NOS Code** LFS/N0301, LFS/N0314 LFS/N0302	• Understand Brief outline of Life Sciences Industry, its sub-sectors • Gain knowledge of Regulatory Authorities and Government Policies, rules and Regulations and their impact on manufacturing in Life Sciences Industry • Know the Standards for Manufacturing in Life Sciences like CGMP, ISO, GLP, GDP etc. Gain orientation with Pharmacopeia and how to read them • Know about Existing Organisation in Life Sciences Industry (in context of Large/Medium/ Small Enterprises): Their Organization Structure and Benefits. Orientation on typical manufacturing and Quality function in a Life Sciences organization. • Know about Role of a Quality Control Chemist and required skills and knowledge (As per Qualification Pack) and its Career Path	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 for Life Sciences Industry** **Theory Duration** (hh:mm) 10:00 **Practical Duration** (hh:mm) 06:00 **Corresponding NOS Code** LFS/N0301, LFS/N0302, LFS/N0320 LFS/N0314	• Know about Fundamental Science in API Production including Size Separation, Mixing and homogenization Process, Mass Transfer, Fluid Flow, Heat Transfer, Size Reduction, 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 about 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, Assay calculation procedure and assay role in formulation, Standard weight procedure or standard quantity effect in formulation. • Know 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 o quality control	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, Manufacturing Equipment models/ diagrams (API & Formulations)
3.	**Fundamentals of Instrumental Analysis for Life Sciences Industry**	• Learn and apply Basics of Pharmaceutical Science and Chemistry inclusive of Organic Nomenclature System, Organic Reaction Mechanism, and Basic Analytical Chemistry	Participant Manual, Power point presentation, Case Studies, Computer system, LCD Projector & Screen/

Sr. No.	Module	Key Learning Outcomes	Equipment Required
	Theory Duration (hh:mm) 10:00 **Practical Duration** (hh:mm) 02:00 **Corresponding NOS Code** LFS/N0301, LFS/N0320	fundamentals including balancing chemical equations, chemical equilibria, acid and base chemistry, stoichiometric calculations, reduction and oxidation chemistry and interaction of light with matter. • Know and apply the detailed understanding of basic principles of Separation Sciences, critical system parameters and their Industrial use in Quality Control analysis for Life Sciences Industry	LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts, Periodic Table of Elements, Chemistry lab equipment and glassware, gloves, half face mask, apron
4.	**Sample Preparation, preservation and Storage** **Theory Duration** (hh:mm) 07:00 **Practical Duration** (hh:mm) 04:00 **Corresponding NOS Code** LFS/N0301, LFS/N0103	• Know and apply the basics of Sample Preparation, preservation and storage, Handling Glassware in Laboratory, Calibration of Glassware. Guidelines for Weighing and measuring the samples, safety precautions while handling sample and understanding the toxicity and carcinogenicity while handling critical samples. • Know about Standards and guidelines for sample handling in Pharmaceutical and Biopharmaceutical Industry and perform sample handling and preparation. • Gain detailed knowledge of Good Storage Practice, how to know stability of sample and process of sample stabilization, before storage of sample and apply the learned practices while sample storage.	Syringes (2ml, 5ml, 10ml), Mortor and Pessel (Type: Silica, SS-316L, Agate, Granite), Halogen Moisture Analyzer, Seive Shaker, Seive meshes (All grade levels like 100, 150, 200, 250 etc,..), Motor grinder, Muffle Furnace, Silica & Platinum Crucibles, Muffle Furnace, Loss on Drying Machine with Vaccum, pressure gauge meter, Refractometer, 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, Labeling Machine, Laboratory Microscopes(40X and 100X), Barcode scanner, Torque tester, Induction cap sealer, Bursting strength, Pin hole tester, Differential scanning calorimeter, Analytical balance with printer,

Sr. No.	Module	Key Learning Outcomes	Equipment Required
			Pipettes (1mL, 2mL, 5 ml/10 ml), Sonicators, Hot air oven, Rotary shaker water bath, Glassware drying oven, Cleaning agents (soap/alconox etc), Centrifuge , Centrifuge tubes, pH meter , conductivity meter, Scale, Magnetic stirrers, Hot plate with magnetic stirrer, LOD bottles Desicattor, Droppers, Vortex mixer, Lab equipped with Fume Hoods, Glassware for Lab, Burrette stand with white tile
5.	**Operating Knowledge of Analytical Instruments** **Theory Duration** (hh:mm) 34:00 **Practical Duration** (hh:mm) 34:00 **Corresponding NOS Code** LFS/N0301	• Gain detailed knowledge about Molecular, Atomic near Infrared spectroscopy and Vibrational spectroscopy and the analysis of metals and apply leraning while operating analytical instruments. • Gain Conceptual Scientific Knowledge and skills and operate analytical Equipment and Machinery like Fourier Transfer-Infrared (FT-IR), Inductively Coupled Plasma (ICP), Auto-Titration, UV-Visible mass spectrophotometer detector, pH meter. • Gain knowledge and skills about Chromatography including Basic principles of chromatography, Thin Layer Chromatography, Gas Chromatography and Liquid Chromatography, High performance Liquid Chromatography, Preparatory, High performance Liquid Chromatography. • Operate analytical Equipment and Instruments like Gas Chromatography (GC), High Performance Liquid Chromatography (HPLC).	UV Analyser (Make: Perkin elmer/shimadzu/Thermo), FT-IR (Make: Shimadzu/Thermo), HPLC (Make: Agilent/Waters/Shimadzu), Mobile phase filteration kit with filters (MilliQ) with vaccum motor, Milli-Q / TKA water for HPLC, Syringe Filters (6,6-Nylon,PVTF, PVDFE, PTFE etc..), Specific optical rotation Analyser (Make: Rudolph Autopol V/ Jasco 2000 or 3000), HPLC vials, Crimpers, Dissolution filters (1 micron), Gas chromatographer , GC vials, GC injection needle, hplc columns, gc columns, Dissolution Apparatus, DT Apparatus
6.	**Perform Quality Checks in Quality Control Process** **Theory Duration** (hh:mm) 14:00	• Learn and Perform Quality Check (Inspection and Analysis) in QC, compare results with statistical limits, Calibrations, IQ, OQ, PQ and techniques for improving instrumental analysis. Handle Exceptions. Operate the instruments like stability chambers, BOD incubators and Photo flouro meter. Knowledge of QC analysis Checklist for all relative instruments.	Syringes (2ml, 5ml, 10ml), UV Analyser (Make: Perkin elmer/shimadzu/Thermo), FT-IR (Make: Shimadzu/Thermo), Mortor and Pessel (Type: Silica, SS-316L, Agate, Granite), Halogen Moisture Analyzer, Seive Shaker, Seive meshes (All grade levels like 100,

Sr. No.	Module	Key Learning Outcomes	Equipment Required
	Practical Duration (hh:mm) 06:00 **Corresponding NOS Code** LFS/N0320, LFS/N0314	• Know about and Productivity norms and calculate the overall equipment efficiency (OEE), practice Techniques of improving productivity (Lean and 6 sigma), Techniques to control the rejects. Learn and apply Techniques to control the breakdown, Handling of market complaints, Deviation, incident and change control procedure and Required Documentation practices by QMS, CGMP. • Carry out Statistical Analysis of Laboratory data: Gain Knowledge of Calculations and Use of QC Statistics like Levey-Jennings Charts & Westgard Rules, CV, Comparative Evaluations, CVR, SDI. • Learn and apply Fundamentals of Advance QC approaches like Quality by Design and Process Analytical Technology, Method Transfer Process and how to manage the Quality Risk. • Practice Practical problem solving/ trouble shooting in QC Analysis.	150, 200, 250 etc,..), Motor grinder, Muffle Furnace, Silica & Platinum Crucibles, Muffle Furnace, Loss on Drying Machine with Vaccum, pressure gauge meter, Refractometer, 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, Labeling Machine, Laboratory Microscopes(40X and 100X), Barcode scanner, Torque tester, Induction cap sealer, Bursting strength, Pin hole tester, Differential scanning calorimeter, Analytical balance with printer, Pipettes (1mL, 2mL, 5 ml/10 ml), Sonicators, Hot air oven, Rotary shaker water bath, Glassware drying oven, Cleaning agents (soap/alconox etc), Centrifuge , Centrifuge tubes, pH meter , conductivity meter, Scale, Magnetic stirrers, Hot plate with magnetic stirrer, LOD bottles Desicattor, Droppers, Vortex mixer, Lab equipped with Fume Hoods, Glassware for Lab, Burrette stand with white tile, HPLC (Make: Agilent/Waters/Shimadzu), Mobile phase filteration kit with filters (MilliQ) with

Sr. No.	Module	Key Learning Outcomes	Equipment Required
			vaccum motor, Milli-Q / TKA water for HPLC, Syringe Filters (6,6-Nylon,PVTF, PVDFE, PTFE etc..), Specific optical rotation Analyser (Make: Rudolph Autopol V/ Jasco 2000 or 3000), HPLC vials, Crimpers, Dissolution filters (1 micron), Gas chromatographer , GC vials, GC injection needle, hplc columns, gc columns, Dissolution Apparatus, DT Apparatus
7.	**Documentation for Quality Control** **Theory Duration** (hh:mm) 12:00 **Practical Duration** (hh:mm) 10:00 **Corresponding NOS Code** LFS/N0301, LFS/N0302, LFS/N0314, LFS/N0320	• Learn the concept and practical skills for Work Planning of Quality Control and required documentation in various Quality Control Process like reporting defects/problem/incidents/quality issues/test results considering Data integrity aspects and follow the learnings while documentation for quality control. • Learn and follow the detailed concepts of Good Documentation Practices and Knowledge about importance of Data Integrity and how to complete documentation in line with Good Laboratory Practices and Good Manufacturing Practices. • Provide a detailed response to an audit / process related query from any cross-functional team and Quality assurance team. • Know and follow generic Organizational Policy & various internal Process relevant for QC Chemist like reporting unresolved issues, hazards, escalations, test point recording requirements etc. • Learn and practice Related Core Skills and Professional Skills: Reading, writing, listening and speaking, Critical thinking, problem solving, decision making, customer centricity, plan and organizing, Analytical thinking.	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, Formats of Lab Notebook, Log books, sample of graphs and analytical reports
8.	**Maintain a healthy, safe and secure working environment in the pharmaceutical manufacturing facility and laboratory** **Theory Duration**	• Learn and follow the Basic Concepts of Safety including Hazards, Accidents, Safety Signs and Signals and Henriech Pyramid and use the PPE and safety tools like eye shower etc. • Know about Water Systems at Plant, Engineering related tools and techniques to operate the machine safely.	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,

Sr. No.	Module	Key Learning Outcomes	Equipment Required
	(hh:mm) 16:00 **Practical Duration** (hh:mm) 10:00 **Corresponding NOS Code** LFS/N0101	• Use Material Data Safety Sheet, follow the Process of Safety Analysis, Handle Hazardous Material in Lab, know and follow Fire Safety concepts and how to act in case of Fire Emergency at shop floor. Know about various PPEs used in different production operations and do Job Safety Analysis for Various production machines/ equipment. • Learn and follow the Basic Concepts and practical skills for managing Emergency Procedures and how to do first aid. • Practice Related Core Skills and Professional Skills: Reading, writing, listening, speaking, Plan and organize, Critical thinking, problem solving, decision making, customer centricity.	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
9.	**Ensure Cleanliness in the work area.** **Theory Duration** (hh:mm) 08:00 **Practical Duration** (hh:mm) 08:00 **Corresponding NOS Code** LFS/N0103	• Gain Knowledge of different Material, chemicals and equipment and their cleaning procedure as per manufacturer's guide. • Gain Knowledge about Electronic and Optical Sensors in laboratory equipment and their operations as per the manual. • Know and Follow 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 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: Reading, writing, listening, speaking, Plan and organize, Critical thinking, problem solving, decision making, customer centricity.	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
10.	**Coordinate with Supervisor, within team and cross functional the teams.** **Theory Duration** (hh:mm) 16:00 **Practical Duration**	• Manage Supervisor- Reportee Relationship including identify Partnering Opportunities at work; Know and follow General reporting process, protocol and escalation policy and Importance of reports and communication with Supervisor. • Apply techniques for Collaborating with Other Groups and Divisions. • Learn and follow the conceptual and practical skills required by QC Chemist in Audits: • Importance of CGMP/ GLP/ GDP/QMS/ SOP related documentation	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	Key Learning Outcomes	Equipment Required
	(hh:mm) 10:00 **Corresponding NOS Code** LFS/N0302, LFS/N0314	• Method to Respond to Audit Queries How to Face Internal Audit Interactions • Use of IT in communication and coordination. • Practice Related Core Skills and Professional Skills: Reading, writing, listening, speaking, Analytical thinking, problem solving, decision making, customer centricity.	
11	**Information Technology Skills** **Theory Duration** (hh:mm) 16:00 **Practical Duration** (hh:mm) 20:00 **Corresponding NOS Code** LFS/N0314	• Apply Basic Computer Skills (Ms Office, Internet)+ Typing Practice at Work. • Handle different software's used to operate the QC instruments. • Gain and apply Knowledge about 21 CFR Part 11 compliance system and its requirements.	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
12.	**Internship** **Theory Duration** (hh:mm) 00:00 **Practical Duration** (hh:mm) 200:00 **Corresponding NOS Code** LFS/N0301 LFS/N0320, LFS/N0101, LFS/N0103 LFS/N0302 LFS/N0314	• Sample Preparation and sample handling. • Instrument handling for Quality Control and how to maintain the work area clean. • Maintain a healthy, safe and secure working environment in the pharmaceutical facility of manufacturing /testing/ analysis / research laboratory. • Coordinate with Shift Supervisor, cross functional teams especially QA, Production, Maintenance and SCM and within the team. • Carryout reporting and documentation to meet quality standards.	Internship Monitoring Report
	Total Duration	**Unique Equipment Required:** 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, Manufacturing Equipment models/ diagrams (API & Formulations), Periodic Table of Elements, Chemistry lab	

Sr. No.	Module	Key Learning Outcomes	Equipment Required
	Theory Duration (hh:mm) 153:00 **Practical Duration** (hh:mm) 310:00	equipment and glassware, gloves, half face mask, apron, Syringes (2ml, 5ml, 10ml), Mortor and Pessel (Type: Silica, SS-316L, Agate, Granite), Halogen Moisture Analyzer, Seive Shaker, Seive meshes (All grade levels like 100, 150, 200, 250 etc,..), Motor grinder, Muffle Furnace, Silica & Platinum Crucibles, Muffle Furnace, Loss on Drying Machine with Vaccum, pressure gauge meter, Refractometer, 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, Labeling Machine, Laboratory Microscopes(40X and 100X), Barcode scanner, Torque tester, Induction cap sealer, Bursting strength, Pin hole tester, Differential scanning calorimeter, Analytical balance with printer, Pipettes (1mL, 2mL, 5 ml/10 ml), Sonicators, Hot air oven, Rotary shakerwater bath, Glassware drying oven, Cleaning agents (soap/alconox etc), Centrifuge , Centrifuge tubes, pH meter , conductivity meter, Scale, Magnetic stirrers, Hot plate with magnetic stirrer, LOD bottlesDesicattor, Droppers, Vortex mixer, Lab equipped with Fume Hoods, Glassware for Lab, Burrette stand with white tile, UV Analyser (Make: Perkin elmer/shimadzu/Thermo), FT-IR (Make: Shimadzu/Thermo), HPLC (Make: Agilent/Waters/Shimadzu), Mobile phase filteration kit with filters (MilliQ) with vaccum motor, Milli-Q / TKA water for HPLC, Syringe Filters (6,6-Nylon,PVTF, PVDFE, PTFE etc..), Specific optical rotation Analyser (Make: Rudolph Autopol V/ Jasco 2000 or 3000), HPLC vials, Crimpers, Dissolution filters (1 micron), Gas chromatographer , GC vials, GC injection needle, hplc columns, gc columns, Dissolution Apparatus, DT Apparatus, Formats of Lab Notebook, Log books, sample of graphs and analytical reports, 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, Sample Audit Report and Sample Responses, Computer Lab, Internship Monitoring Report	

Grand Total Course Duration: 463Hours 00 Minutes

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

Trainer Prerequisites for Job role: "Quality Control Chemist" mapped to Qualification Pack: "LFS/ Q 1301 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/Q1301 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-organised and focused, eager to learn and keep oneself updated with the latest in the mentioned field.
3	**Minimum Educational Qualifications**	B. Pharma / B. Sc. with Chemistry major subject or Analytical Chemistry (Preferable)
4a	**Domain Certification**	Certified for Job Role: "Quality Control Chemist" mapped to QP: "LFS/Q 1301 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/Q1402". Minimum accepted score is 80% as per LSSSDC guidelines.
5	**Experience**	Preferably Minimum Four (4) years' experience in life sciences (Pharmaceutical/ Biopharmaceutical) Quality occupation for non-trained and non-qualified talent Or Minimum Two (2) years' experience with Quality Control Chemist Level-5 qualified

Annexure: Assessment Criteria

Assessment Criteria for Quality Control Chemist	
Job Role	Quality Control Chemist
Qualification Pack	LFS/ Q 1301 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/N0301 (Perform routine analysis in lab while ensuring compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP))	PC1. perform all the routine quality check activities and validations satisfactorily, including checking for sample authenticity, appropriate storage of chemicals/ reagents, maintaining reaction temperatures	100	3	1	2
	PC2. train the line staff effectively to perform quality checks		5	2	3
	PC3. plan and manage manpower efficiently to undertake the needed work/ quality checks, post receiving samples for testing, recording in the specified documents		6	3	3
	PC4. ensure that all work meets applicable QA/QC guidelines and approved within procedures		10	5	5
	PC5. review the data given by analysts and ensure that it is as per the SOP approved within procedures		10	5	5
	PC6. ensure all activities conducted shall meet the quality standards and norms as specified		10	5	5
	PC7. review and update test methods and procedures according to SOP approved within procedures as per schedule or when a regulatory requirement arises according to written procedures		6	3	3
	PC8. fill log book, column, reagent, volumetric solution, working standard, reference standard entries, calibration records, etc and prepare reports for document findings and recommendations on time		6	2	4
	PC9. conduct sampling and analysis on time and as per approved written procedure, along with reagent, reference standard preparation and standardisation		10	5	5
	PC10. coordinate effectively with personnel in other disciplines to integrate findings and recommendations		4	2	2
	PC11. analyse root cause of deviations, OOS/OOT and incidents, take corrective as well preventive actions to avoid future deviations		4	2	2
	PC12. analyse root cause of deviations, OOS/OOT and take corrective actions		4	1	3
	PC13. participate in laboratory investigations and check the validity/ stability of volumetric solutions/pH buffers, standards as part of daily routine and discard expired solutions/standards as per written procedures		4	2	2
	PC14. regular documentation (online/offline) of all the activities		2	1	1
	PC15. conduct regular checks for positioning of all equipment and instrument tags and undertake cleaning procedures for instruments post usage		4	2	2
	PC16. conduct regular checks on equipment and instrument conditions, document calibrations and		4	2	2

				Marks Allocation	
		Total Marks (300)	Out Of	Theory	Skills Practical
	coordinate with maintenance team for preventive maintenance				
	PC17. precision in instrument calibrations as per specified and approved schedule to minimize source of errors		4	2	2
	PC18. maintain instrument maintenance logs and follow preventive maintenance schedules		2	1	1
	PC19. investigate out of calibration if any, and impact of previously analysed products as per approved written procedures		2	1	1
	Total		**100**	**47**	**53**
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 person in line with organizational procedures and warn other people who may be affected		10	4	6
	PC10. follow the company's emergency procedures promptly, calmly, and efficiently		10	5	5
	Total		**100**	**48**	**52**
LFS/N0302 (Coordinate with Supervisors and colleagues within and outside the department)	PC1. receive work instructions from reporting supervisor	100	10	5	5
	PC2. communicate to reporting supervisor about process-flow improvements, production defects received from previous process, repairs and maintenance of equipment as required		10	5	5
	PC3. communicate deviations in the production process to reporting supervisor		10	5	5
	PC4. communicate any potential hazards or		10	4	6

				Marks Allocation	
		Total Marks (300)	Out Of	Theory	Skills Practical
	expected process disruptions				
	PC5. handover completed work to supervisor		10	5	5
	PC6. work as a team with colleagues and share work as per their or own work load and skills		8	4	4
	PC7. work and support colleagues of other departments		8	3	5
	PC8. train line or reporting staff if needed		10	5	5
	PC9. communicate and discuss work flow related difficulties in order to find solutions with mutual agreement		8	4	4
	PC10. explain what information means and how it can be used to team members		8	4	4
	PC11. document all the control steps undertaken or recommended to be followed as per the standards		8	4	4
	Total		**100**	**48**	**52**
LFS/N0320 (To carry out quality checks in the quality control process)	PC1. ensure that total range of checks are regularly and consistently performed	100	16	8	8
	PC2.use appropriate measuring instruments, equipment, tools, accessories etc. ,as required		13	5	8
	PC3.ensure the status and accuracy of instruments used for measurement		10	5	5
	PC4.identify non-conformities to quality assurance standards		13	5	8
	PC5.identify potential causes of non-conformities to quality assurance standards		13	5	8
	PC6.identify impact on final product due to non-conformance to company standards		16	8	8
	PC7.evaluating the need for action to ensure that problems do not recur		6	3	3
	PC8.suggest corrective action to address problem		7	3	4
	PC9.review effectiveness of corrective action		6	3	3
	Total		**100**	**45**	**55**
LFS/N0314 (To carry out reporting and documentation to meet quality standards)	PC1.report defects/problem/incidents/quality issues/test results as applicable in a timely manner	100	10	5	5
	PC2.report to the appropriate authority as laid down by the company		3	1	2
	PC3.follow reporting procedures as prescribed by the company		4	2	2
	PC4.work with production management and Quality Assurance to provide feedback regarding quality standards and issues		4	2	2
	PC5.help other R&D lab staff with any other testing required during the developmental work		4	2	2
	PC6.identify documentation to be completed relating to one's role		7	3	4
	PC7.record details accurately in appropriate format		6	3	3
	PC8.accurately document the results of the inspections and testing		8	4	4
	PC9.maintain all controlled document files and test		10	5	5

				Marks Allocation	
		Total Marks (300)	Out Of	Theory	Skills Practical
	records in a timely and accurate manner				
	PC10.ensure that the final document meets regulatory and compliance requirements		7	2	5
	PC11.make sure documents are available to all appropriate authorities to inspect		5	2	3
	PC12.evaluate problems and make initial recommendations for possible corrective action to supervise		4	2	2
	PC13.perform review of records and other documentation for compliance to established procedures and Good Documentation Practices		8	4	4
	PC14.write and update the inspection procedures, protocols and checklists		6	2	4
	PC15.prepare inspection reports as per the inspection activity performed		6	2	4
	PC16.respond to requests for information in an appropriate manner whilst following organizational procedures		4	2	2
	PC17.inform the appropriate authority of requests for information received		4	2	2
	Total		**100**	**45**	**55**
LFS/N0103 (To ensure cleanliness in the work area)	PC1.inspect the area while taking into account various surfaces	100	4	2	2
	PC2.identify the material requirements for cleaning the areas inspected, by considering risk, time, efficiency and type of stain		5	2	3
	PC3.ensure that the cleaning equipment is in proper working condition		5	2	3
	PC4.select the suitable alternatives for cleaning the areas in case the appropriate equipment and materials are not available and inform the appropriate person		4	2	2
	PC5.plan the sequence for cleaning the area to avoid re-soiling clean areas and surfaces		4	2	2
	PC6.Inform the affected people about the cleaning activity		4	2	2
	PC7.display the appropriate signage for the work being conducted		4	2	2
	PC8.ensure that there is adequate ventilation for the work being carried out		5	2	3
	PC9.wear the personal protective equipment required for the cleaning method and materials being used		4	2	2
	PC10.use the correct cleaning method for the work area, type of soiling and surface		4	2	2
	PC11.deal with accidental damage, if any, caused while carrying out the work		4	2	2
	PC12.report to the appropriate person any difficulties in carrying out work		4	2	2

				Marks Allocation	
		Total Marks (300)	Out Of	Theory	Skills Practical
	PC13.identify and report to the appropriate person any additional cleaning required that is outside one's responsibility or skill		4	2	2
	PC14.ensure that there is no oily substance on the floor to avoid slippage		4	2	2
	PC15.ensure that no scrap material is lying around		4	2	2
	PC16.maintain and store housekeeping equipment and supplies		4	2	2
	PC17.follow workplace procedures to deal with any accidental damage caused during the cleaning process		4	2	2
	PC18.ensure that, on completion of the work, the area is left clean and dry and meets requirements		4	2	2
	PC19.return the equipment, materials and personal protective equipment that were used to the right places making sure they are clean, safe and securely stored		5	2	3
	PC20.dispose the waste garnered from the activity in an appropriate manner		5	2	3
	PC21.dispose of used and un-used solutions according to manufacturer's instructions, and clean the equipment thoroughly		5	2	3
	PC22.maintain schedules and records for housekeeping duty		5	2	3
	PC23.replenish any necessary supplies or consumables		5	2	3
		Total	**100**	**46**	**54**
Grand Total	**600**	**600**	**279**	**321**	
Percentage Weightage			**46%**	**54%**	
Minimum Pass Percentage to Qualify			**70%**		

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