Model Curriculum

Quality Control Chemist-Microbiology

SECTOR: LIFE SCIENCES
SUB-SECTOR: PHARMACEUTICAL AND BIOPHARMACEUTICAL
OCCUPATION: QUALITY
REF ID: LFS/Q0308, 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 Control Chemist-Microbiology,V1.0**'
QP No. 'LFS/Q0308 NSQF Level 5'

Date of Issuance: **April 25th , 2019**
Valid up to: **March 30th , 2020**

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

Authorized Signatory
(Life Sciences Sector Skill Development Council)

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Quality Control Chemist-Microbiology

CURRICULUM / SYLLABUS

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

Program Name	**Quality Control Chemist-Microbiology**		
Qualification Pack Name & Reference ID.	Quality Control Chemist LFS/Q0308, V1.0		
Version No.	1.0	**Version Update Date**	25-04-2019
Pre-requisites to Training	**Minimum qualification -** B.Sc. in a relevant subject such as biochemistry, biology, chemistry, immunology, biomedical science, biotechnology, microbiology (Preferable) **Experience** – 0-2 Years		
Training Outcomes	**After completing this programme, participants will be able to:** • Define life sciences industry, legal and regulatory framework and pharmacopeia to enable him/herself for establishing the industry standards in his/her performance • Operate analytical equipment and instruments for test and analysis of samples as per standard operating procedures (SOP) • Perform routine analysis in lab in line with good manufacturing practices (GMP) and good laboratory practices (GLP) • Carry out quality checks in the quality control process • Perform statistical analysis of QC results in lab as per SOPs • Follow good documentation practices (GDP) guidelines for documentation to meet the quality standards • Participate in audits as a QC team member and generate the responses for audit queries • Coordinate with supervisor, cross functional teams and within the team for various functional activities • Carry out reporting and documentation as per GDP • Maintain a healthy, safe and secure working environment in the life sciences facility by learning managing emergency situations and their results • Practice core communication skills and professional skills at the workplace such as planning and organizing, problem-solving, decision-making, using analytical and critical skills		

This course encompasses 7 out of 7 Compulsory NOS (National Occupational Standards) of "Quality Control Chemist-Microbiology" Qualification Pack issued by "Life Sciences Sector Skill Development Council".

Sr. No.	Module	Key Learning Outcomes	Equipment Required
1	**Life Sciences Industry and Quality related regulations** **Theory Duration** (hh:mm) 04:00 **Practical Duration** (hh:mm) 00:00 **Corresponding NOS Code** Bridge Module	• Explain the overview of life sciences industry and its sub sectors • Summarize various regulatory authorities and their rules & regulations for manufacturing • Recall detailed norms pertaining to good manufacturing practices (GMP), good laboratory practices (GLP), good documentation practices (GDP), and 5S guidelines • Explain the organizational structure and employment benefits in life sciences industry • Outline the role and responsibilities of a quality control chemist-microbiology	
2	**GLP guidelines and production overview** **Theory Duration** (hh:mm) 04:00 **Practical Duration** (hh:mm) 16:00 **Corresponding NOS Code** LFS/N0321	• Recall the guidelines of GLP, pharmacopeia and how to read them • Explain the instruments used in microbiological testing • Recall API production and formulation process and identify critical quality attributes (CQA), critical process parameters (CPP) and critical process controls (CPC). • Interpret basics of formulation like route of drug administration, dosage forms and their relevant benefits • Describe quality management system for quality control in life sciences industry	Flask, Petri plates, Spreader, Laminar Air flow chamber, Incubator
3	**Health and safety** **Theory Duration** (hh:mm) 06:00 **Practical Duration** (hh:mm) 16:00 **Corresponding NOS Code** LFS/N0101	• Select appropriate personal protection equipment (PPEs) while performing quality control test and analysis • Explain the concepts of safety including hazards, accidents, safety signs and signals • Explain the clean room classifications and requirements • Perform environmental monitoring and follow clean room behaviour practices • Interpret material safety data sheet (MSDS) and follow the process of safety analysis • Explain the guidelines to be followed for handling and storage of hazardous material • Explain EHS rules and Heinrich pyramid at shop floor • Explain the fire safety concepts in case of fire emergency in microbiology lab	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

		• Describe the process for reporting critical information to concerned team members and supervisor • Demonstrate emergency and first aid measures • Practice core and professional skills such as planning and organizing, problem solving, objection handling, and critical thinking	
4	**Workplace cleanliness** **Theory Duration** (hh:mm) 04:00 **Practical Duration** (hh:mm) 16:00 **Corresponding NOS Code** LFS/N0103	• Describe the steps to level of hygiene in QC microbiology laboratory • Explain measures to be taken in case of spillage of biological strains and samples, chemicals, media, culture etc • Carry out disposal methods for waste, used/ unused solutions according to SOP • Describe the use of health and safety, environmental and other relevant regulations and guidelines followed at work • Explain how to assess any out of control situation and report to supervisor • Demonstrate the ways to clean all equipment as per SOP and manufacturer instructions • Examine lab area to ensure cleaning of various surfaces and equipment • Explain correct methods as per GMP for various types of soiling and surface • Explain GMP protocol and workplace SOPs related to accidental damage	Formats of Lab Notebook, Logbooks
5	**Instrumentation in microbiology** **Theory Duration** (hh:mm) 08:00 **Practical Duration** (hh:mm) 32:00 **Corresponding NOS Code** LFS/N0321	• Explain the procedure and use of various equipment used in microbiological analysis • Summarize the basic application of analytical instruments • Explain basic principles of analytical instruments • Demonstrate the use of analytical instrument and equipment for analysis of test sample • Describe how to perform calibration and validation of analytical instrument as per SOP and manual • Explain the maintenance procedure for instruments as per SOP	Glassware Washing Machine ,Autoclave, Laboratory Microscopes(40X and 100X),pH meter ,Hot plate with magnetic stirrer, analytical balance with printer (of different capacity and sensitivity 0.001 mg, 0.01 mg,0.1 mg,1 mg sensitivity),water bath, Computer (including Monitor, CPU, Keyboard, typewriter, UPS),Microsoft Office Version 2007 and above (including Ms. Word, Ms Excel, Ms Power point, Ms Outlook),Computer work desk with LAN,LCD Projector, White Screen, White Board, Sound System with Mike, Lab Management Information System (demonstration), Syringes (2 ml),Syringes (5 ml), Syringes (10 ml), Milli-Q / TKA water for HPLC, Centrifuge, Centrifuge Tubes (10ml) Centrifuge Tubes (25ml), Centrifuge Tubes (50ml), Conductivity Meter, Vortex Mixer, Micropipette (20 to 200

			microlitre), Micropipette (100 to 1000 microlitre),Micropipette (0.5 ml to 5 ml) , Chemical Resistant Cabinet, Biosafety Cabinet, Laminar air flow (Vertical), Tube heating block, Water Filtration assembly (multihead), Vacuum pump, Hot Plate, Dry Heat Air Oven, Depyrogenation oven, Refrigerator, Deep freezer, Microbial identification system, Laboratory incubator for different temperature range, Anaerobic jar, Gas burner, Gas lighter, LPG cylinder, Shaker incubator, Garment cubicle, Sterility test apparatus (Closed system), Needle burner, Hygrometer, Heat sealing machine, Glass slides, TOC analyser, Air sampler, Particle counter, TOC Tubes, Half Face Mask, Full Face Mask, Various Cartridges, Safety Goggles, Safety Shoes, Gum Boots, Chemical Absorbent Roll, Self Contained Breathing Apparatus, PVC Apron, Gloves (Nitrile), Gloves ({Heat, acid, chemical} resistant) Gloves(washing), Lab Coat, Non sterile Surgical Gloves (in Microbiology), Eye washer with sprinkler, CO_2 type Fire Extinguisher, ABC Type Fire Extinguisher, Material Safety Data Sheet, Formats of Log Books, GLP Guidelines, Format of lab Note Book, Format of Sample preservation / processing record sheet, Glassware for Lab, White Board Duster, White Board Marker, Flip Charts, Laser Pointer, sterile Surgical Gloves (in Microbiology)
6	**Test and analysis of incoming materials** **Theory Duration** (hh:mm) 12:00 **Practical Duration** (hh:mm)	• Explain the procedure for qualitative and quantitative microbial test • Demonstrate sampling for conducting microbial test according to SOP • Discuss about basic techniques used in microbiology e.g. colony colonies, plate pouring, serial dilutions, etc. • Discuss the labelling requirement to check all reagents (including stock solutions), media, diluents and other suspending fluids • Demonstrate how to prepare medias to conduct quality analysis on the samples	Lab Management Information System (Demonstration), Vortex Mixer, Micropipette (20 to 200 microlitre), Micropipette (100 to 1000 microlitre),Micropipette (0.5 ml to 5 ml), Biosafety Cabinet, Laminar air flow (Vertical), Tube heating block, Water Filtration assembly (multihead), Vacuum pump, Hot Plate, Dry Heat Air Oven, Depyrogenation oven,

	32:00 **Corresponding NOS Code** LFS/N0321	• Explain how to prepare and maintain standard cultures • Describe assay validation procedure • Summarize the importance and procedure of calibration • Discuss how to monitor and assess samples from a range of sources like raw material sampling(microbiology), microbiological analysis of water for purified water and raw water for MCT • Explain the procedure for bacterial endotoxin test (BET)/ Sterility test • Demonstrate a variety of identification methods, like molecular testing to test samples • Explain the procedure to identify the reason for unwanted growth of microorganisms • Discuss about out of trend (OOT) and out of specification (OOS) samples • Define alert and action limits and discuss how to maintain positive and negative controls during testing	Refrigerator, Deep freezer, Microbial identification system, Laboratory incubator for different temperature range, Anaerobic jar, Gas burner, Gas lighter, LPG cylinder, Shaker incubator, Garment cubicle, Sterility test apparatus (closed system)
7	**Sample Preparation, preservation and Storage** **Theory Duration** (hh:mm) 08:00 **Practical Duration** (hh:mm) 32:00 **Corresponding NOS Code** LFS/N0321	• Discuss standards and guidelines for sample handling in life science industry • Perform sampling procedures as per SOP's by utilizing appropriate sampling tools • Describe sampling plans for microbiological sampling • Demonstrate sample handling and preparation of microbial samples • Explain guidelines for weighing of samples • Demonstrate the use of good storage practices (GSP) guidelines for storage of samples • Explain stability of sample and process of sample stabilization • Discuss how to identify and report nonconformity of the sample as per SOP	Flask, Petri plates, Spreader, Laminar Air flow chamber, Incubator, Apron, gloves face mask, Petri plates, flasks, pH meter, Spreader, Laminar Air flow chamber, Hot air oven, Incubator, glassware, gloves, half face mask, apron, Autoclave, chemicals, Pipettes, Test tubes, Hot air oven, extraction tubes cotton, Petri plates, Inserts
8	**Inspection of samples** **Theory Duration** (hh:mm) 16:00 **Practical Duration** (hh:mm) 55:00 **Corresponding NOS Code** LFS/N0321	• Explain and prepare different types of medias for specific microorganisms • Summarize how to verify cleaning and sterilization of the samples through various sterilization techniques • Demonstrate media preparation and culturing of media with microorganism. • Demonstrate the preparation of broth and agar plate (streaking and spread plate procedures) • Discuss how to identify and classify microorganisms in incoming sample (water, drugs, specimen extracted from humans, plants animals or environment) • Explain dynamic techniques (FAME) and static techniques • Elaborate bacterial cell structure and cytoplasmic organelle and their functions	Flask, Petri plates, Spreader, Laminar Air flow chamber, Incubator, Apron, gloves face mask, Petri plates, flasks, pH meter, Spreader, Laminar Air flow chamber, Hot air oven, Incubator, glassware, gloves, half face mask, apron, Autoclave, chemicals, Pipettes, Test tubes, Hot air oven, Extraction tubes cotton,Petri plates

		• Explain biochemical characterization of microbes by Gram stain and biochemical cards • Identify microbes using phenotypic and genotypic methods • Demonstration harvesting procedure and processing of cells for the extraction of fatty acids, saponification and trans-esterification reactions • Explain the procedure for preparation of FAME compounds • Demonstration extraction procedure of fatty acids and conversion into FAMEs	
9	**Quality Checks in Quality Control** **Theory Duration** (hh:mm) 08:00 **Practical Duration** (hh:mm) 24:00 **Corresponding NOS Code** LFS/N0320	• Perform quality check in QC lab and compare results with statistical limits • Verify checklist for instruments used for QC analysis • Operate specialised computer software for microbiological sample analysis and lab management system • Describe the ways to handle equipment malfunction and report faults during the equipment breakdown as appropriate • Discuss statistical analysis of laboratory data • Explain advance QC approaches like quality by design and process analytical technology and method transfer process • Identify critical quality attributes (CQA), critical process parameters (CPP) and critical process controls (CPC) • Describe quality management system	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, CO_2 type Fire Extinguisher, ABC Type Fire Extinguisher, Lab Management Information System (Demonstration), Vortex Mixer, Micropipette (20 to 200 microlitre), Micropipette (100 to 1000 microlitre),Micropipette (0.5 ml to 5 ml), Biosafety Cabinet, Laminar air flow (Vertical), Tube heating block, Water Filtration assembly (multihead), Vacuum pump, Hot Plate, Dry Heat Air Oven, Depyrogenation oven, Refrigerator, Deep freezer, Microbial identification system, Laboratory incubator for different temperature range, Anaerobic jar, Gas burner, Gas lighter, LPG cylinder, Shaker incubator, Garment cubicle, Sterility test apparatus (Closed system)
10	**Reporting and Documentation** **Theory Duration** (hh:mm) 08:00	• Prepare reports in pre-decided format as per SOPs • Describe how to select the correct method of documentation as per SOPs, GLP and GMP protocols • Explain prototypic report, polyphasic report and comprehensive reports	

	Practical Duration (hh:mm) 16:00 **Corresponding NOS Code** LFS/N0314	• Explain MIDI extraction procedure, MIS chromatogram ,2D Clustering • Explain report generation of 2D plot, histogram, dendrogram, phylogenetic tree from samples, neighbour joining tree • Report in time about each incident • Adapt validation process of document as per GMP protocols • Record and describe the work done in local language and/ or English • Explain efficient and clear communication methods for reporting the incidents and communication with team • Demonstrate proficiency in IT tools for data entry in e-documents wherever needed • Discuss the importance of confidentiality of the data and internal processes • Explain different software to operate the QC instruments • Discuss the importance of maintaining information security while using e-mail and other official communication channels	
11	**Research for development of New products** **Theory Duration** (hh:mm) 06:00 **Practical Duration** (hh:mm) 16:00 **Corresponding NOS Code** LFS/N0322	• Explain the procedure to grow different strains of bacteria in various conditions for their molecular and cellular characterization • Explain identification procedure of different biomarkers • Explain applications of rapid microbial identification system (RMIS), FAME from different sources • Discuss the working principle and procedure of laboratory equipment such as autoclave, Laminar airflow, Biosafety cabinet, sterility test apparatus, incubator etc • Discuss in detail about collation of new articles published on research newsletters	
12	**Coordination with cross functional teams** **Theory Duration** (hh:mm) 08:00 **Practical Duration** (hh:mm) 08:00 **Corresponding NOS Code** LFS/N0104	• Explain general reporting process, protocol and escalation policy • Submit the reports and testing related documents as per SOP • Discuss techniques for collaborating with other groups and divisions in order to achieve organizational goals • Explain the importance of cGMP/QMS/ SOP related documentation • Describe the process for addressing audit queries from QA team, internal auditor and external auditor • Demonstrate proficiency in IT tools for communication and coordination • Practice core communication skills and professional skills to meet the work output requirements	

13	**Information Technology Skills at work** **Theory Duration** (hh:mm) 08:00 **Practical Duration** (hh:mm) 12:00 **Corresponding NOS Code** LFS/N0314	• Use IT tools for data entry in e-documents wherever needed • Use different softwares (such as MIDI software, etc) to operate the QC instruments • Discuss the requirements of 21 CFR part 11 and data integrity rules • Describe how to maintain the confidentiality of the data and internal processes • Explain how to maintain information security while using e-mail and other official communication channels • Explain the procedure for maintaining online records • Discuss specialised computer software used for studies, research purposes and for analysing the constituents present in the samples • Demonstrate the use of computer applications specific to the microbiological processes carried out in the laboratory	Sherlock MIDI Software
14	**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/N0321	• Perform sample preparation for analysing the samples received in the laboratory • Carry out analysis of incoming materials as per SOPs • Carry out regular observations for the tests performed and maintain records in logbooks • Assist in research work to support the development of new products • Carry out test procedures using correct testing equipment as per SOP • Maintain a healthy, safe and secure working environment in line with organizational procedures and policies • Ensure workplace cleanliness • Coordinate with shift supervisor, cross functional teams and within the team • Follow organizational reporting and documentation procedure	On the job training monitoring report
	Total Duration **Theory Duration** 100:00 **Practical Duration** 275:00 **OJT Duration** 80:00	**Unique Equipment Required:** Manufacturing Equipment models/ diagrams (API and Formulations), Periodic Table of Elements, gloves, half face mask, apron, Glassware Washing Machine ,Autoclave, Laboratory Microscopes(40X and 100X),pH meter ,Hot plate with magnetic stirrer, analytical balance with printer (of different capacity and sensitivity 0.001 mg, 0.01 mg,0.1 mg,1 mg sensitivity),water bath, Computer (including Monitor, CPU, Keyboard, typewriter, UPS),Microsoft Office Version 2007 and above (including Ms. Word, Ms Excel, Ms Power point, Ms Outlook),Computer work desk with LAN,LCD Projector, White Screen, White Board, Sound System with Mike, Lab Management Information System (Demonstration), Syringes (2 ml),Syringes (5 ml), Syringes (10 ml), Milli-Q / TKA water for HPLC, Centrifuge, Centrifuge Tubes (10ml),Centrifuge Tubes (25ml), Centrifuge Tubes (50ml), Conductivity Meter, Vortex Mixer, Micropipette (20 to 200 microlitre), Micropipette (100 to 1000 microlitre),Micropipette (0.5 ml to 5 ml),Chemical Resistant Cabinet, Biosafety Cabinet, Laminar air flow (Vertical), Tube heating block, Water Filtration	

		assembly (multihead), Vacuum pump, Hot Plate, Dry Heat Air Oven, Depyrogenation oven ,Refrigerator, Deep freezer, Microbial identification system, Laboratory incubator for different temperature range, Anaerobic jar, Gas burner, Gas lighter, LPG cylinder, Shaker incubator, Garment cubicle, Sterility test apparatus (Closed system), Needle burner, Hygrometer, Heat sealing machine, Glass slides, TOC analyser, Air sampler, Particle counter, TOC Tubes, Half Face Mask, Full Face Mask, Various Cartridges, Safety Goggles, Safety Shoes, Gum Boots, Chemical Absorbent Roll, Self Contained Breathing Apparatus, PVC Apron, Gloves (Nitrile), Gloves ({Heat, acid, chemical} resistant),Gloves(washing), Lab Coat, Non sterile Surgical Gloves (in Microbiology), Eye washer with sprinkler,CO2 type Fire Extinguisher, ABC Type Fire Extinguisher ,Material Safety Data Sheet, Formats of Log Books, GLP Guidelines, Format of lab Note Book, Format of Sample preservation / processing record sheet, Glassware for Lab, White Board Duster, White Board Marker, Flip Charts, Laser Pointer, sterile Surgical Gloves (in Microbiology)OJT Monitoring Report **Classroom Aids:** Computer (including Monitor, CPU, Keyboard, Printer, UPS), LCD Projector and Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts

Grand Total Course Duration: **455 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 Control Chemist-Microbiology" mapped to Qualification Pack: "LFS/Q0308, 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/Q0308, 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**	B. Sc. with Microbiology major subject or Biochemistry (Preferable)
4a	**Domain Certification**	Certified for Job Role: "Quality Control Chemist-Microbiology" mapped to QP: "LFS/Q0308, 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/Q2601". Minimum accepted score is 80% as per LSSSDC guidelines.
5	**Experience**	Preferably Minimum Four (4) years' experience in life sciences (Pharmaceutical/ Biopharmaceutical) Quality control occupation for non-trained and non-qualified talent with B. Sc.- Microbiology/biochemistry/ B. Tech Biotechnology education qualification Or Preferably Minimum Two (2) years' experience in life sciences (Pharmaceutical/ Biopharmaceutical) Quality control occupation for non-trained and non-qualified talent with M.Sc. Microbiology/Biochemistry Or Minimum Two (2) years' experience in life sciences (Pharmaceutical/ Biopharmaceutical) Quality control occupation with Quality Control Chemist-Microbiology (LFS/Q0308, V1.0) Level-5 qualified

Annexure: Assessment Criteria

Please refer to the QP PDF for the Assessment Criteria.