

# Model Curriculum

## Quality Control Biologist

**SECTOR: LIFE SCIENCES**  
**SUB-SECTOR: BIOPHARMACEUTICAL**  
**OCCUPATION: QUALITY**  
**REF ID: LFS/Q2301, 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

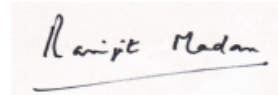
### MODEL CURRICULUM

Complying to National Occupational Standards of  
Job Role/ Qualification Pack: **'Quality Control Biologist'**  
QP No. **'LFS/Q2301,V1.0 NSQF Level 5'**

Date of Issuance: **December 28<sup>th</sup>, 2018**

Valid up to: **December 31<sup>st</sup>, 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 Biologist

## CURRICULUM / SYLLABUS

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

<b>Program Name</b>	<b>Quality Control Chemist</b>		
<b>Qualification Pack Name &amp; Reference ID.</b>	Quality Control Biologist LFS/Q2301, V1.0		
<b>Version No.</b>	1.0	<b>Version Update Date</b>	01-04-2019
<b>Pre-requisites to Training</b>	<b>Minimum qualification</b> - B. Pharma / Graduation in Biotechnology/ B. Sc with Chemistry/ Biology/Microbiology/ Biochemistry as major subject (Preferable) <b>Experience</b> – 0-2 Years		
<b>Training Outcomes</b>	<b>After completing this programme, participants will be able to:</b> <ul style="list-style-type: none"> <li>• Define life sciences industry, legal and regulatory framework and pharmacopeia to enable him/herself for establishing the industry standards in his/her performance.</li> <li>• Maintain a healthy, safe and secure working environment at the pharmaceutical manufacturing shop floor, laboratory and area around in conformance with environmental health and safety (EHS) rules.</li> <li>• Apply scientific knowledge about biological product and process in quality control analysis of bio-pharmaceutical products.</li> <li>• Prepare, preserve and ensure stability of biological samples as per good laboratory practices (GLP) and good manufacturing practices (GMP).</li> <li>• Operate analytical equipment and instruments as per standard operating procedures (SOP) and good laboratory practices (GLP)</li> <li>• Perform routine analysis of biopharmaceuticals in lab in compliance with good manufacturing practices (GMP) and good laboratory practices (GLP).</li> <li>• Conduct quality check for bio-pharmaceutical samples in conformance of acceptance limits as per standard operating procedures (SOP).</li> <li>• Apply good documentation practice (GDP) and data integrity while reporting and documentation as per standard operating procedures (SOP) and good laboratory practices (GLP).</li> <li>• Work effectively in a team.</li> <li>• Respond to audit queries by citing evidence of work done.</li> <li>• Apply core communication skills and professional skills such as planning and organizing, problem solving, analytical and critical skills, decision making and customer centricity at work.</li> </ul>		

This course encompasses 6 out of 6 Compulsory NOS (National Occupational Standards) of “Quality Control Biologist” Qualification Pack issued by “Life Sciences Sector Skill Development Council”.

Sr. No.	Module	Key Learning Outcomes	Equipment Required
1	<p><b>Life Sciences Industry and Quality related regulations</b></p> <p><b>Theory Duration</b> (hh:mm) 08:00</p> <p><b>Practical Duration</b> (hh:mm) 00:00</p> <p><b>Corresponding NOS Code</b> Bridge Module</p>	<ul style="list-style-type: none"> <li>Explain the overview of Life Sciences industry and its sub sectors</li> <li>Summarize various regulatory authorities and their rules &amp; regulations for manufacturing</li> <li>Recall detailed norms pertaining to good manufacturing practices (GMP), good documentation practices (GDP), and 5S guidelines</li> <li>Explain the organizational structure and employment benefits in life sciences industry</li> <li>Outline the role and responsibilities of a Quality Control Biologist</li> </ul>	<p>Computer system, LCD Projector &amp; Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts</p>
2	<p><b>GLP guidelines and production overview</b></p> <p><b>Theory Duration</b> (hh:mm) 04:00</p> <p><b>Practical Duration</b> (hh:mm) 16:00</p> <p><b>Corresponding NOS Code</b> LFS/N0338</p>	<ul style="list-style-type: none"> <li>Recall the guidelines of GLP, Pharmacopeia and how to read them</li> <li>Identify the instruments used in bio-pharmaceutical testing</li> <li>Recall active pharmaceutical ingredient (API) production and formulation process</li> <li>Explain critical quality attributes (CQA), critical process parameters (CPP) and critical process controls (CPC).</li> <li>Interpret basics of formulation like route of drug administration, dosage forms and their relevant benefits</li> <li>Describe quality management system for quality control in Life Sciences industry</li> </ul>	<p>Computer system, LCD Projector &amp; Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts, Flask, Petri plates, Spreader, Laminar Air flow chamber, Incubator</p>
3	<p><b>Health and safety</b></p> <p><b>Theory Duration</b> (hh:mm) 08:00</p> <p><b>Practical Duration</b> (hh:mm) 16:00</p> <p><b>Corresponding NOS Code</b> LFS/N0101</p>	<ul style="list-style-type: none"> <li>Select appropriate personal protection equipment (PPEs) while performing quality control test and analysis</li> <li>Explain the concepts of safety including hazards, accidents, safety signs and signals</li> <li>Explain the clean room classifications and requirements</li> <li>Perform environmental monitoring and follow clean room behaviour practices</li> <li>Interpret material safety data sheet (MSDS) and follow the process of safety analysis</li> <li>Explain the guidelines to be followed for handling and storage of hazardous material</li> <li>Explain EHS rules and Heinrich pyramid at shop floor</li> <li>Explain the fire safety concepts in case of fire emergency in quality control lab</li> </ul>	<p>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<sub>2</sub> type Fire Extinguisher, ABC Type Fire Extinguisher</p>

		<ul style="list-style-type: none"> <li>Describe the process for reporting critical information to concerned team members and supervisor</li> <li>Demonstrate emergency and first aid measures</li> <li>Practice core and professional skills such as planning and organizing, problem solving, objection handling, and critical thinking</li> </ul>	
4	<p><b>Workplace cleanliness</b></p> <p><b>Theory Duration</b> (hh:mm) 08:00</p> <p><b>Practical Duration</b> (hh:mm) 16:00</p> <p><b>Corresponding NOS Code</b> LFS/N0103</p>	<ul style="list-style-type: none"> <li>Describe the steps to level of hygiene in QC laboratory</li> <li>Explain measures to be taken in case of spillage of chemicals, media, culture etc</li> <li>Carry out disposal methods for waste, used/ unused solutions according to SOP</li> <li>Describe the use of health and safety, environmental and other relevant regulations and guidelines followed at work</li> <li>Explain how to assess any out of control situation and report to supervisor</li> <li>Demonstrate the ways to clean all equipment as per SOP and manufacturer instructions</li> <li>Examine lab area to ensure cleaning of various surfaces and equipment</li> <li>Explain correct methods as per GMP for various types of soiling and surface</li> <li>Explain GMP protocol and workplace SOPs related to accidental damage</li> </ul>	<p>Computer system, LCD Projector &amp; Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts, Formats of sample Lab Notebook, sample Logbooks</p>
5	<p><b>Sample Preparation, preservation and Storage</b></p> <p><b>Theory Duration</b> (hh:mm) 08:00</p> <p><b>Practical Duration</b> (hh:mm) 40:00</p> <p><b>Corresponding NOS Code</b> LFS/N0338</p>	<ul style="list-style-type: none"> <li>Explain standards and guidelines for sample handling in Life Science industry</li> <li>Explain guidelines for weighing of samples</li> <li>Demonstrate the good storage practices (GSP) for storage of samples</li> <li>Discuss the application of sampling plans for raw materials, biological materials, tissue culture sampling etc.</li> <li>Demonstrate the procedure for sample handling and preparation of biological samples</li> <li>Explain stability of sample and the process of sample stabilization</li> <li>Identify and report nonconformity of the sample as per SOP</li> </ul>	<p>Computer system, LCD Projector &amp; Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts, Sample Brochure of Pharma Products, role play skirts/ write ups, 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</p>
6	<p><b>Test and analysis of Biological samples for Plant/ Animal/Human cell culture</b></p> <p><b>Theory Duration</b> (hh:mm)</p>	<ul style="list-style-type: none"> <li>Explain the clean room classifications and requirements as laid in GMP</li> <li>Demonstrate preparation of all reagents (including stock solutions), media, diluents and other suspending fluids</li> <li>Define the labelling procedure as per SOP to indicate the identity, concentration,</li> </ul>	<p>Computer system, LCD Projector &amp; Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts, Manufacturing Equipment models/ diagrams (API &amp;</p>

	<p>22:00</p> <p><b>Practical Duration</b> (hh:mm) 40:00</p> <p><b>Corresponding NOS Code</b> LFS/N0338</p>	<p>storage conditions, preparation date, validated expiry date and/or recommended storage period</p> <ul style="list-style-type: none"> <li>• Explain the procedure for preparation and maintenance of standard cultures/medias to conduct quality analysis on the samples</li> <li>• Demonstrate techniques and methodologies used in quality assessment of plant tissue culture</li> <li>• Explain qualitative and quantitative test for biopharmaceuticals and biologicals samples</li> <li>• Describe the assay validation and calibration activity</li> <li>• Demonstrate a variety of identification methods, like molecular testing to test samples</li> <li>• Define Out of Trend (OOT) and Out of Specification (OOS) samples</li> <li>• Describe the process for addressing audit queries from QA team, internal auditor and external auditor</li> </ul>	<p>Formulations), 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, 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</p>
7	<p><b>Inspection of samples</b></p> <p><b>Theory Duration</b> (hh:mm) 32:00</p> <p><b>Practical Duration</b> (hh:mm) 56:00</p> <p><b>Corresponding NOS Code</b> LFS/N0338</p>	<ul style="list-style-type: none"> <li>• Explain different types of medias for bioanalytical quality test</li> <li>• Describe culture and sub-cultures, its handling and maintenance</li> <li>• Explain in vitro and in vivo potency tests on biologicals and biopharmaceuticals as per SOP</li> <li>• Identify and classify microorganisms in every incoming sample like in water, drugs, specimen extracted from humans, plants, animals, environment etc</li> <li>• Explain the growth and development of horticultural and agronomic crop plants, current management practices, and factors that influence yield, aesthetics, and end-use quality</li> <li>• Describe bacterial cell structure and cytoplasmic organelle and their functions</li> <li>• Perform biochemical characterization of microbes by Gram stain and biochemical cards</li> <li>• Describe the importance of cleaning and sterilization of the samples through various sterilization techniques</li> </ul>	<p>Computer system, LCD Projector &amp; Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts, Sample Brochure of Pharma Products, role play skits/ write ups, 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, GC vials Petri plates, Inserts</p>
8	<p><b>Instrumentation in Biological Analysis</b></p> <p><b>Theory Duration</b> (hh:mm) 08:00</p> <p><b>Practical Duration</b> (hh:mm) 30:00</p>	<ul style="list-style-type: none"> <li>• Describe operation of analytical instrument and equipment for analysis of test sample</li> <li>• Summarize the basic application of analytical instruments</li> <li>• Explain basic principles of analytical instruments</li> <li>• Explain plant tissue culture techniques and their applications</li> <li>• Assess the equipment status for calibration, validation and cleaning</li> </ul>	<p>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,</p>

<p><b>Corresponding NOS Code</b> LFS/N0338</p>	<ul style="list-style-type: none"> <li>Describe calibration and validation of analytical instrument as per SOP and manual</li> <li>Discuss maintenance procedure for instruments as per SOP</li> </ul>	<p>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, Needle burner, Hygrometer, Heat sealing machine, Glass slides, 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<sub>2</sub> 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</p>
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			Duster, White Board Marker, Flip Charts, Laser Pointer, sterile Surgical Gloves
9	<p><b>Quality Analysis</b></p> <p><b>Theory Duration</b> (hh:mm) 08:00</p> <p><b>Practical Duration</b> (hh:mm) 40:00</p> <p><b>Corresponding NOS Code</b> LFS/N0320</p>	<ul style="list-style-type: none"> <li>Explain quality check in QC lab and interpretation of results using statistical limits</li> <li>Identify instruments used for QC analysis as per checklist</li> <li>Explain specialised computer software for biological sample analysis and lab management system</li> <li>Describe the ways to handle equipment malfunction and report faults during the equipment breakdown as appropriate</li> <li>Discuss statistical analysis of laboratory data</li> <li>Explain advance QC approaches like quality by design and process analytical technology and method transfer process</li> <li>Identify critical quality attributes (CQA), critical process parameters (CPP) and critical process controls (CPC)</li> <li>Describe quality management system</li> </ul>	<p>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<sub>2</sub> 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)</p>
10	<p><b>Reporting and Documentation</b></p> <p><b>Theory Duration</b> (hh:mm) 12:00</p> <p><b>Practical Duration</b> (hh:mm) 16:00</p> <p><b>Corresponding NOS Code</b> LFS/N0314</p>	<ul style="list-style-type: none"> <li>Prepare reports in pre-decided format as per SOPs</li> <li>Describe how to select the correct method of documentation as per SOPs and GMP protocols</li> <li>Explain the importance of timely reporting of incident</li> <li>Discuss document validation process as per GMP protocols</li> <li>Explain the procedure for Identification and reporting of incidents where SOP are not followed</li> <li>Describe escalation matrix where the instructions are not defined in SOP</li> <li>Explain efficient and clear communication methods for reporting the incidents and communication with team</li> </ul>	<p>Computer system, LCD Projector &amp; Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts</p>

		<ul style="list-style-type: none"> <li>• Demonstrate proficiency in IT tools for data entry in e-documents wherever needed</li> <li>• Discuss the importance of confidentiality of the data and internal processes</li> <li>• Explain different software to operate the QC instruments</li> <li>• Discuss the importance of maintaining information security while using e-mail and other official communication channels</li> </ul>	
11	<p><b>Coordinate with Supervisor, within team and cross functional the teams</b></p> <p><b>Theory Duration</b> (hh:mm) 16:00</p> <p><b>Practical Duration</b> (hh:mm) 08:00</p> <p><b>Corresponding NOS Code</b> LFS/N0302</p>	<ul style="list-style-type: none"> <li>• Explain general reporting process, protocol and escalation policy</li> <li>• Summarise reports and testing related documents as per SOP</li> <li>• Discuss techniques for collaborating with other groups and divisions in order to achieve organizational goals</li> <li>• Explain the importance of cGMP/QMS/ SOP related documentation</li> <li>• Explain how to report deviations to the reporting supervisor</li> <li>• Demonstrate proficiency in IT tools for communication and coordination</li> <li>• Practice core communication skills and professional skills to meet the work output requirements</li> </ul>	<p>Computer system, LCD Projector &amp; Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts</p>
12	<p><b>Information Technology Skills at work</b></p> <p><b>Theory Duration</b> (hh:mm) 16:00</p> <p><b>Practical Duration</b> (hh:mm) 32:00</p> <p><b>Corresponding NOS Code</b> LFS/N0314</p>	<ul style="list-style-type: none"> <li>• Use IT tools for data entry in e-documents wherever needed</li> <li>• Use different software (such as MIDI software, etc) to operate the QC instruments</li> <li>• Discuss the requirements of 21 CFR Part 11 and data integrity rules</li> <li>• Describe how to maintain the confidentiality of the data and internal processes</li> <li>• Explain the procedure for maintaining online records</li> <li>• Apply software program such as LIMS to analyse the samples</li> </ul>	<p>Computer system, LCD Projector &amp; Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts, Sherlock MIDI Software</p>
13	<p><b>On the Job Training</b></p> <p><b>Theory Duration</b> (hh:mm) 00:00</p> <p><b>Practical Duration</b> (hh:mm) 00:00</p> <p><b>OJT Duration</b> (hh:mm) 100:00</p>	<ul style="list-style-type: none"> <li>• Perform sample preparation and analysis of incoming materials</li> <li>• Assist in research work to support the development of new products</li> <li>• Carry out test procedures using correct testing equipment as per SOP</li> <li>• Maintain a healthy, safe and secure working environment in the life sciences facility</li> <li>• Coordinate with shift supervisor, cross functional teams and within the team</li> <li>• Carry out reporting and documentation to meet quality standards</li> </ul>	<p>On the job training monitoring report</p>

<p><b>Corresponding NOS Code</b> LFS/N0338</p>	
<p><b>Total Duration</b></p> <p><b>Theory Duration</b> 150:00</p> <p><b>Practical Duration</b> 310:00</p> <p><b>OJT Duration</b> 100:00</p>	<p><b>Unique Equipment Required:</b> Glassware Washing Machine, Autoclave, Laboratory Microscopes(40X and 100X), pH meter, Hot plate with magnetic stirrer, analytical balance with printer (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 PowerPoint, 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), Centrifuge, Centrifuge Tubes (10ml,25ml,50ml), 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, CO<sub>2</sub> Incubator ,Laboratory incubator for different temperature range, Anaerobic jar, Gas burner, Gas lighter, LPG cylinder, Shaker incubator, Garment cubicle, Needle burner, Hygrometer, Heat sealing machine, Glass slides, 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<sub>2</sub> 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, Microwave oven, Magnetic stirrer and Stirring bars, Filtration system for filtration of fluids, Scalpel handle, Spatula, Scoop, Forceps, Graduated cylinders(10ml),Graduated cylinders(100ml), Graduated cylinders(1000 ml),Culture Tubes, Culture Dishes, Culture vessel</p>

Grand Total Course Duration: 460 Hours 00 Minutes (100 hours of OJT is Mandatory)

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

## Trainer Prerequisites for Job role: “Quality Control Biologist” mapped to Qualification Pack: “LFS/Q2301, V1.0”

Sr. No.	Area	Details
1	<b>Job Description</b>	To deliver accredited training service, mapping to the curriculum detailed above, in accordance with the Qualification Pack “LFS/Q2301, V1.0”.
2	<b>Personal Attributes</b>	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	<b>Minimum Educational Qualifications</b>	B. Pharma / Graduation in Biotechnology/ B. Sc with Chemistry/ Biology/Microbiology/ Biochemistry as major subject (Preferable)
4a	<b>Domain Certification</b>	Certified for Job Role: “Quality Control Biologist” mapped to QP: “LFS/Q2301, V1.0”. Minimum accepted score is 80% as per LSSSDC guidelines.
4b	<b>Platform Certification</b>	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	<b>Experience</b>	<p>Preferably Minimum Four (4) years’ experience in life sciences (Pharmaceutical/ Biopharmaceutical) Quality control occupation for non-trained and non-qualified talent with B. Pharma / Graduation in Biotechnology/ B. Sc with Chemistry/ Biology/Microbiology/ Biochemistry</p> <p>Or</p> <p>Preferably Minimum Two (2) years’ experience in life sciences (Pharmaceutical/ Biopharmaceutical) Quality control occupation for non-trained and non-qualified talent with M. Pharma/ M.Tech Chemical/Biotechnology/ M.Sc. with Chemistry/ Biology/Microbiology/ Biochemistry</p> <p>Or</p> <p>Minimum Two (2) years’ experience in life sciences (Pharmaceutical/ Biopharmaceutical) Quality control occupation with Quality Control Biologist (LFS/Q2301, V1.0) Level-5 qualified</p>

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[Annexure: Assessment Criteria](#)

**Please refer to the QP PDF for the Assessment Criteria.**