Model Curriculum

Production/ Manufacturing Biologist

SECTOR: LIFE SCIENCES
SUB-SECTOR: BIOPHARMACEUTICAL
OCCUPATION: MANUFACTURING
REF ID: LFS/Q2201, 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: '**Production/ Manufacturing Biologist'**
QP No. 'LFS/Q2201,V1.0 NSQF Level 5'

Date of Issuance: **October 1st , 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)

TABLE OF CONTENTS

Production/Manufacturing Biologist

CURRICULUM / SYLLABUS

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

Program Name	**Production/ Manufacturing Biologist**		
Qualification Pack Name & Reference ID.	Production/ Manufacturing Biologist LFS/Q2201, V1.0		
Version No.	1.0	**Version Update Date**	01-10-2019
Pre-requisites to Training	**Minimum qualification-** B. Pharma /B.Sc./M.Sc. with Chemistry/ Biology/Biochemistry as major subject / Graduation in Biotechnology/ **Experience** – Fresher, No prior experience required		
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. • 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. • Apply scientific knowledge about biological product and process in manufacturing of biologics products. • Plan and supervise production process for biologics active ingredient/ formulations • Coordinate with cross functional teams and supervise the team. • Apply good documentation practice (GDP) and data integrity while reporting and documentation as per standard operating procedures (SOP) and good manufacturing practices (GMP). • Respond to audit queries by citing evidence of work done. • 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.		

This course encompasses 3 out of 3 Compulsory NOS (National Occupational Standards) of "Production/Manufacturing Biologist" Qualification Pack issued by "Life Sciences Sector Skill Development Council".

Sr. No.	Module	Key Learning Outcomes	Equipment Required
1	**Life Sciences Industry and manufacturing related regulations** **Theory Duration** (hh:mm) 04:00 **Practical Duration** (hh:mm) 00:00 **Corresponding NOS Code** Bridge Module	• Describe the Life Sciences industry and its sub sectors • Summarize various regulatory authorities and their rules and regulations for manufacturing • Recall detailed norms pertaining to good manufacturing practices (GMP), 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 Production/manufacturing Biologist	
2	**Fundamentals of Pharmaceutical Sciences for Biologics Manufacturing** **Theory Duration** (hh:mm) 08:00 **Practical Duration** (hh:mm) 16:00 **Corresponding NOS Code** LFS/N0701	• Describe biologics and their application • Recall the basics of biology, microbiology and drug pharmacology for biologics manufacturing • Summarize biologics and biosimilar active ingredient production and formulation process • Discuss the role of assay in biologics formulation • Demonstrate how to perform assay calculation procedure • Explain standard quantity effect in formulation	GMP Guidelines
3	**GMP guidelines and production overview** **Theory Duration** (hh:mm) 08:00 **Practical Duration** (hh:mm) 08:00 **Corresponding NOS Code** LFS/N0701	• Explain quality management system for production of biologics and good manufacturing practices (GMP) • Interpret basics of formulation like route of drug administration, dosage forms and their relevant benefits • Practice productivity norms and concept of overall equipment efficiency (OEE) • Describe the techniques to improve productivity and control rejects • Describe standard manufacturing process using quality by design (QbD) methodology • Discuss ways to implement the techniques to control and predict the breakdown	

		• Explain the process of change recommendation using change control procedure • Discuss quality risk management system and checks for conforming data Integrity aligned to cGMP	
4	**Health and safety** **Theory Duration** (hh:mm) 12:00 **Practical Duration** (hh:mm) 40:00 **Corresponding NOS Code** LFS/N0101	• Explain the concepts of safety including hazards, accidents, safety signs and signals • Explain the clean room classifications and requirements • List appropriate personal protection equipment (PPEs) for entry and exit in manufacturing area • 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 and chemicals • Explain EHS rules and Heinrich pyramid at shop floor • Explain the fire safety procedure to be followed in case of fire emergency in manufacturing area • Discuss ways to conduct health, safety and security activities like safety drills and maintain its record • Describe the process of reporting critical information to concerned team members and supervisor • Practice core and professional skills such as planning and organizing, problem solving, objection handling, and critical thinking	Half Face Mask, Full Face Mask, Various Cartridges, Safety Goggles, Safety Shoes, Gum Boots, Chemical Absorbent, Self Contained Breathing Apparatus, Gloves (Nitrile, {Heat, acid, chemical} resistant, washing etc,) CO_2 type Fire Extinguisher, ABC Type Fire Extinguisher
5	**Production activities for active ingredient (bulk) biologics manufacturing** **Theory Duration** (hh:mm) 24:00 **Practical Duration** (hh:mm) 88:00 **Corresponding NOS Code** LFS/N0203	• Discuss pre and post-production checks for active ingredient (bulk) biologics manufacturing as per GMP • Explain preparation of culture media and solutions for manufacturing • Demonstrate various sterilization techniques of media and solutions • Explain the fermentation process using bioreactors • Discuss harvesting procedure and the purification procedure of harvested material • Discuss sampling and storage of bulk material • Demonstrate the cleaning operations and cleaning validation as per GMP • Explain the process of chemical and industrial bio pharmaceutical waste disposal as per SOP, GMP and EHS guidelines	Autoclave, Laboratory Microscopes (40X and 100X), pH meter, Hot plate with magnetic stirrer, analytical balance with printer, water bath, Vortex Mixer, Micropipette (20 to 200 microlitre),Micropipette (100 to 1000 microlitre),Micropipette (0.5 ml to 5 ml), Biosafety Cabinet, Laminar air flow, Dry Heat Air Oven, Depyrogenation oven, Refrigerator, Deep freezer, incubator for different temperature range, Shaker incubator, Phase contrast microscope ,CO_2 Incubator, Refrigerated Centrifuge ,Water Bath Incubator, Liquid Nitrogen Container , Rotational Vacuum concentrator ,Electronic balance , Fermenter, Homogenizer ,Ultra Sonicator,

			Cold room, Purification and Filtration system for filtration of fluids, Garment cubicle, Needle burner, Hygrometer ,Half Face Mask, Full Face Mask, Various Cartridges, Safety Goggles, Safety Shoes, Gum Boots, Chemical Absorbent Roll, Self Contained Breathing Apparatus, , Gloves (Nitrile), Gloves ({Heat, acid, chemical} resistant), Gloves(washing), Lab Coat, Non sterile Surgical Gloves, Formats for BMR, Formats of Log Books, Format of Shift Schedule, Format of Job Cards,Sample Labels, Sample SOP document, Microwave oven, Magnetic stirrer and Stirring bars, Scalpel handle, Spatula, Scoop, Forceps, Graduated cylinders (10ml),Graduated cylinders (100ml), Graduated cylinders (1000 ml),Culture Tubes, Culture Dishes, Culture vessel
6	**Production activities for biologics formulation manufacturing** **Theory Duration** (hh:mm) 24:00 **Practical Duration** (hh:mm) 88:00 **Corresponding NOS Code** LFS/N0203	• Discuss sterilization and sanitation process as per SOP and GMP rules • Explain on-line environmental and microbial monitoring as per clean room classification, SOP and GMP rules • Discuss how to manage material segregation at shop floor as per SOP and GMP rules • Demonstrate pre- and post-production checks as per GMP • Demonstrate the preparation of excipients • Describe the blending procedure for biologics • Demonstrate simulated blending for biologics formulation manufacturing • Discuss how to monitor the filling and containerization of biologics • Describe machine operations for biologics formulation manufacturing as per GMP • Explain the cleaning and sterilization operations for biologics formulation as per GMP • Discuss the decontamination process before waste disposal for biologics formulation as per SOP, GMP and EHS guidelines	Autoclave, pH meter, analytical balance with printer, water bath, Micropipette (20 to 200 microlitre),Micropipette (100 to 1000 microlitre),Micropipette (0.5 ml to 5 ml), Biosafety Cabinet, Laminar air flow, Dry Heat Air Oven, Depyrogenation oven, Refrigerator, Deep freezer, Garment cubicle, Needle burner, Hygrometer ,Half Face Mask, Full Face Mask, Various Cartridges, Safety Goggles, Safety Shoes, Gum Boots, Chemical Absorbent Roll, Self Contained Breathing Apparatus, , Gloves (Nitrile), Gloves ({Heat, acid, chemical} resistant), Gloves (washing), Lab Coat, Non sterile Surgical Gloves, Sample formats for BMR, Sample formats of Log Books, Sample format of Shift Schedule, sample format of Job Cards,Sample Labels, Sample SOP document , Microwave oven, Magnetic stirrer and Stirring bars, Scalpel handle, Spatula, Scoop, Forceps, Graduated

			cylinders (10ml),Graduated cylinders (100ml), Graduated cylinders (1000 ml),Culture Tubes, Culture Dishes, Culture vessel
7	**Reporting and Documentation** **Theory Duration** (hh:mm) 08:00 **Practical Duration** (hh:mm) 16:00 **Corresponding NOS Code** LFS/N0701	• Summarise reports and manufacturing related documents as per SOP • Describe how to select the correct method of documentation as per SOPs and GMP protocols • Prepare reports in pre-decided format as per SOPs • Explain the importance of timely reporting of incident • Discuss document validation process as per GMP protocols • Discuss the importance and ways to maintain confidentiality of the data and internal processes	Sample formats for BMR, Sample formats of Log Books, Sample format of Shift Schedule, sample format of Job Cards,Sample Labels, Sample SOP document
8	**Information Technology Skills at work** **Theory Duration** (hh:mm) 08:00 **Practical Duration** (hh:mm) 31:00 **Corresponding NOS Code** Bridge Module	• Explain the procedure for maintaining online records • Demonstrate the use of equipment/machine specific software used to operate them in production area • Discuss the requirements of 21 CFR Part 11 and data integrity rules • Demonstrate proficiency in IT tools for communication and coordination	
9	**Coordinate with Shift Supervisor, cross functional teams and within team** **Theory Duration** (hh:mm) 04:00 **Practical Duration** (hh:mm) 08:00 **Corresponding NOS Code** LFS/N0204	• Explain general reporting process, protocol and escalation matrix for any internal communication • Exhibit the core and professional skills like communication, problem-solving, planning and organizing, critical thinking during the coordination related activities • Coordinate with the team members during the manufacturing for the cases, and inform intervention-requiring issues to supervisor • Participate in the departmental audits	

10	**On the Job Training** **Theory Duration** (hh:mm) 00:00 **Practical Duration** (hh:mm) 00:00 **OJT Duration** (hh:mm) 100:00 **Corresponding NOS Code** LFS/N0701	• Practice clean room behaviour at shop floor as per SOP and GMP rules • Manage the machine operations and troubleshooting for biologics manufacturing • Perform documentation as per cGMP and GDP • Manage production shop floor at life sciences facility • Maintain a healthy, safe and secure working environment • Coordinate with cross functional teams and operators • Carry out reporting and documentation to meet quality standards	On the job training monitoring report
	Total Duration **Theory Duration** 100:00 **Practical Duration** 295:00 **OJT Duration** 100:00	**Unique Equipment Required:** Autoclave, Laboratory Microscopes (40X and 100X), pH meter, Hot plate with magnetic stirrer, analytical balance with printer, water bath, Vortex Mixer, Micropipette (20 to 200 microlitre),Micropipette (100 to 1000 microlitre),Micropipette (0.5 ml to 5 ml), Biosafety Cabinet, Laminar air flow, Dry Heat Air Oven, Depyrogenation oven, incubator for different temperature range, Shaker incubator, Phase contrast microscope,CO_2 Incubator, Refrigerated Centrifuge ,Water Bath Incubator, Liquid Nitrogen Container, Rotational Vacuum concentrator , Refrigerator, Deep Freezer -20^oC ,Electronic balance , Fermenter, Homogenizer ,Ultra Sonicator, Cold room, Purification and Filtration system for filtration of fluids, blending vessel /tank, Filling and containerization machine, sealing machine, labelling machine, Garment cubicle, Needle burner, Hygrometer ,Half Face Mask, Full Face Mask, Various Cartridges, Safety Goggles, Safety Shoes, Gum Boots, Chemical Absorbent Roll, Self Contained Breathing Apparatus, Gloves (Nitrile), Gloves ({Heat, acid, chemical} resistant), Gloves (washing), Lab Coat, Non sterile Surgical Gloves, Eye washer with sprinkler, CO_2 type Fire Extinguisher, ABC Type Fire Extinguisher, sample formats for BMR and BPR, Sample Formats of Log Books, Sample Format of Shift Schedule,Sample Format of Job Cards, Sample Labels, safety signage, Sample SOP document, GMP Guidelines, GDP Guidelines, Microwave oven, Magnetic stirrer and Stirring bars, Scalpel handle, Spatula, Scoop, Forceps, Graduated cylinders (10ml),Graduated cylinders (100ml), Graduated cylinders (1000 ml),Culture Tubes, Culture Dishes, Culture vessel **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: 395 **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: "Production/ Manufacturing Biologist" mapped to Qualification Pack: "LFS/Q2201, 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/Q2201, 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. Pharma preferable/ B. Sc / M. Sc with Chemistry/ Biology/ Biochemistry as major subject/ Graduation in Biotechnology
4a	**Domain Certification**	Certified for Job Role: "Production/ Manufacturing Biologist" mapped to QP: "LFS/Q2201, 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 (Biopharmaceutical) Manufacturing occupation for non-trained and non-qualified talent with B. Pharma / Graduation in Biotechnology/ B. Sc with Chemistry/ Biology/Biochemistry/ Biotechnology Or Preferably Minimum Two (2) years' experience in life sciences (Biopharmaceutical) Quality control occupation for non-trained and non-qualified talent with M. Pharma/ M.Tech Chemical/Biotechnology Or Minimum Two (2) years' experience in life sciences (Biopharmaceutical) Manufacturing occupation with Production/ Manufacturing Biologist (LFS/Q2201, V1.0) Level-5 qualified

Annexure: Assessment Criteria

Please refer to the QP PDF for the Assessment Criteria.