

Model Curriculum

Production/ Machine Operator- Life Sciences

Production/ Machine Operator- Life Sciences

SECTOR: LIFE SCIENCES
SUB-SECTOR: PHARMACEUTICAL, BIOPHARMACEUTICAL
OCCUPATION: MANUFACTURING
REFERENCE ID: LFS/ Q 0207 Ver 1.0
NSQF LEVEL: LEVEL 4



Table of Content:

Curriculum..... **Error! Bookmark not defined.**

Annexure1: Assessment Criteria.....13

Annexure2: Trainer Prerequisites.....14



Production / Machine Operator- Life Sciences

CURRICULUM / SYLLABUS

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

Program Name	Production/ Machine Operator- Life Sciences		
Qualification Pack Name & Reference ID.	Production/ Machine Operator – Life Sciences LFS/ Q 0207 Ver1.0		
Version No.	1.1	Version Update Date	18 – 03 – 2015
Pre-requisites to Training	Minimum qualification – 10+2/ ITI		
Training Outcomes	<p>After completing this programme, participants will be able to:</p> <ul style="list-style-type: none"> • Gain knowledge about Life Sciences Industry Eco System, Regulations, GMP to enable him/herself for establishing the Industry Standards in his/her performance • Gain scientific knowledge about Pharmaceutical and Bio Pharmaceutical Manufacturing (Both API and Formulation), concept and procedure to operate and maintain various machines like (Reactor, Multimill, mixer, granulation machine, coating machine etc.) • Practice the professional Skills at workplace; like Decision Making, Planning & Organizing, Customer Centricity, Problem Solving, Objection Handling, Analytical Thinking, Critical Thinking; • Prepare machines and accessories for the manufacturing process • Perform manufacturing operations and carry out broad level quality checks before, in-process and post manufacturing • Ensure cleanliness in the work area/ shop floor • Carryout reporting and documentations as per SoP and GMP and GDP guidelines • Follow the EHS norms and Maintain a health, safe and secure working environment in the filed sciences facility 		

This course encompasses Six (6) out of Six (6) National Occupational Standards (NOS) of “Production/ Machine Operator – Life Sciences LFS/ Q 0207 Ver1.0” Qualification Pack issued by “Life Sciences Sector Skill Development Council”.

Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
1	Orientation Module	10:00	00:00	<ul style="list-style-type: none"> • Know about Life Sciences Industry, its sub-sectors • Know about Regulatory Authorities and Government 		Participant Manual, Power point presentation, Case Studies, Computer system, LCD Projector & Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				<p>Policies, rules and Regulations and their impact on manufacturing in Life Sciences Industry in India and Emerging Markets (Both Regulated and Semi Regulated)</p> <ul style="list-style-type: none"> • Know about Standards for Manufacturing in Life Sciences like cGMP, ISO, etc. • Understand Existing Organization in Life Sciences Industry (in context of Large/Medium/ Small Enterprises): Their Organization Structure and Benefits. Know the typical manufacturing function in a Life Sciences organization. • Understand the Role of a Machine/ Production Operator and required skills and knowledge (As per Qualification Pack) and its Career Path 		<p>Marker/ chalk, duster, flip charts</p>



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
2	Fundamentals of Pharmaceutical Production	24:00	06:00	<ul style="list-style-type: none"> Know about Basics of Human Anatomy and Physiology. Know and apply the fundamentals of Metrology i.e Systems of weights and measures; like – Percentage calculations, velocity measurements, pressure measurements, specific gravity and viscosity, flow, level, thermal and temperature etc. Know about Quality Management System for Production in Life Sciences Industry including its introduction and importance, QC and QA Systems, Productivity norms and concept of overall equipment efficiency (OEE) Know the Basic Concept of Techniques to improve productivity (Lean and 6 sigma), and to control the 	LFS/N0213, LFS/N0214, LFS/N0215	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



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				<p>rejects. Know and apply the techniques to control and predict the breakdown.</p> <ul style="list-style-type: none"> Know and follow Deviation ,incident and change control procedure and Required Documentation practices by GMP and GDP norms at shop floor Learn and apply the concepts of Data Integrity aligned to cGMP for activities at shop floor. Follow Shift Schedules and process of Shift handover 		
3	Production Process for API	25:00	17:00	<ul style="list-style-type: none"> Know and apply the 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 and 	LFS/N0213, LFS/N0214, LFS/N0215	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, 50 Ltr Reactor, Reciever, Condensor, centrifuge, drier flatbed lab model, volves, Chemicals (Mandatory Solvents 14), Packaging Material, Drums, Poly Bags, Seals, Silica Gel Bags, Labels , Half Face Mask, Full Face Mask, Safety



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				<p>Determination of Particle size of powders by Sieve analysis and by optical microscope</p> <ul style="list-style-type: none"> Know in detail and follow Production Process of API with an in depth understanding and practical skills on following: <ol style="list-style-type: none"> Unit processes: Oxidation, Reduction, Hydrogenation, Sulfonation, Nitration, and Halogenation. Bulk organic chemicals as building blocks for manufacture of drugs and drug intermediates Catalysis and Bio catalysis in Industrial production. Downstream processes like Filtration, Centrifugation, Extraction, Evaporation, Crystallization, Drying and Size reduction Operations and cleaning of Pharmaceutical Manufacturing 		<p>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, Material Safety Data Sheet, Various Safety Signage</p>



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				Equipment for API like - Reactor, Reciever, Condensor, centrifuge, etc.		
4	Production Process for Formulations	38:00	30:00	<ul style="list-style-type: none"> Know in detail 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 and practice Standard weight procedure or standard quantity effect in formulation Learn and apply the conceptual and practical skills about Production process of Oral Solid Dosage including Definition of Tablets and Capsules and types of tablets and capsules, Different processes of formulating tablets and capsules like Process of 	LFS/N0213, LFS/N0214, LFS/N0215	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 for BMR & BPR, Formats of Log Books, Format of Shift Schedule, Format of Job Cards, GMP Guidelines, Sample Labels, safety signage, Sample SoP document, GMP Guidelines, GDP Guidelines, Compression Machine commercial- 10 Stn (Min), Coating Machine Prototype, Hardness Tester, DT Apparatus, Multimill, Airjet Cleaning Machine, Filter Press, Inline homogeniser Cum Mixer, Automatic Filling Machine , Planetary mixer(jackatted with electrical heating facility), Preparation vessel, reactor & Storage Tank, Agitator- Stirrer, Weighing balance (1.2kg, 6.0kg with printer), Rapid mixer granulator (table top 1/5 L capacity), Double cone blender (5L Capacity), Remi stirrers, Machine Hooper, Sifter, Tablet



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				<p>Granulation, Compression, Coating, Capsule Filling, Operation and maintenance of General equipment for different processes like Process of Granulation, Compression, Coating, Capsule Filling, Excipients used in OSD, General in process checks and methods for performing these tests, determination of bulk density and tapped density of powders and calculation of Hausner's ratio and compressibility index, performance of in-process checks for compressed tablets, filled capsules and visual inspection of coated tablets</p> <ul style="list-style-type: none"> Learn and apply the conceptual and practical skills of machine operations about Production process of Liquid Oral Dosage covering aspects like: 		<p>Deduster, Paste Kettle, Jet Claerner, Semi-Automatic Cap Sealing Machine, Online Inspection, Turn Table, Labelling machine, Semi-Automatic Ropp Cap Sealing Machine and screw capping machine, Tube Filling Machine Prototype, Laboratory Microscopes(40X and 100X), pH meter , Bulk density and Tapped density tester, Friabilator, Vernier calipers, Micrometer screw gauge, Scale, Hot plate with magnetic stirrer, UV Analyser (Make: Perkin elmer/shimadzu/Thermo), 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, analytical balance, Pipettes (1mL, 2mL, 5 ml/10 ml), water bath, Desiccator, Dissolution Apparatus, Lab equipped with Fume Hoods, Glassware for Lab, Burette stand with white tile, Various Cartridges, Sodium Metal in kerosine for testing</p>



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				<p>Types of Liquid oral dosage forms, Different processes of formulating liquid oral dosage forms, Machine operations and maintenance of General equipment for different processes like mixing, filtration, suspension preparation, emulsion, , Excipients used in liquid oral dosage forms, General in process checks and methods for performing these tests, determination of viscosity of liquid using oswald’s viscometer, determination of surface tension of liquid, preparation of syrup IP and evaluation of specific gravity of syrup, in process checks in liquid preparations, Determination of equilibrium solubility</p> <ul style="list-style-type: none"> To learn the conceptual and practical skills to operate 		



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				<p>machines about Production process of Sterile Dosage covering aspects like: Types of injectable dosage forms, Different processes involved in manufacturing injectable dosage form, General equipment / machine operations and maintenance for different processes, Water for injection and other excipients used in injectable dosage forms, General in process checks and methods for performing these tests, visual inspection of ampoules and vials</p> <ul style="list-style-type: none"> Learn and apply the conceptual and practical skills to operate machines about Production process of Semi-solid Formulations covering aspects like: Types of in semi-solid dosage forms, 		



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				<p>Different processes involved in manufacturing semisolid dosage form, General equipment. Machine operations for different processes, Excipients used in excipients dosage form, General in process checks and methods for performing these tests, evaluation of different semi solid bases</p> <ul style="list-style-type: none"> • Learn and apply knowledge of Pharmaceutical packaging including types of packaging for different dosage forms, regulatory guidelines regarding labelling, in process checks in packaging, visual inspection of finished dosage forms • Learn and practice Related Core Skills and Professional Skills: Reading, writing, listening, speaking, Plan and organize, Critical thinking, 		



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				problem solving, decision making, customer centricity		
	Ensure Cleanliness in the work area	08:00	04:00	<ul style="list-style-type: none"> Gain and apply knowledge of different Material, chemicals, manufacturing equipment and filling lines, various equipment parts like filters etc and their cleaning procedure as per manufacturer's guide and follow the validation process of cleaning Gain and apply Knowledge about Electronic and Optical Sensors in laboratory equipment Follow the methodology for storage area inspection with methods and materials required for cleaning variety of surfaces and equipment, methods to check the treated surface and equipment on completion of cleaning, disposal methods for 	LFS/N0103, LFS/N0101	Various types of cleaning material, chemicals, cleaning equipment, Half Face Mask, Full Face Mask, 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, Material Safety Data Sheet, Various Safety Signage



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				waste, used/ unused solutions and relevant SOP, Procedures for reporting any unidentified soiling and Escalation procedures for soils or stains that could not be removed • Practice Related Core Skills and Professional Skills at work like; Reading, writing, listening and speaking, Critical thinking, problem solving, decision making, customer centricity, plan and organizing.		
	Quality Checks in Pharma/ Bio Pharma Manufacturing Operations	16:00	05:00	• Know about Pharmaceutical Science inclusive of Organic Nomenclature System and Basic Chemistry fundamentals. • Know about Basic Analytical Chemistry fundamentals including , Balancing chemical equations, Chemical equilibrium, Acid and base chemistry,	LFS/N0213, LFS/N0214, LFS/N0215	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 for BMR & BPR, Formats of Log Books, Format of Shift Schedule, Format of Job Cards, GMP Guidelines, Sample Labels, safety signage, Sample SoP document, GMP Guidelines, GDP Guidelines, Periodic Table



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				<p>Stoichiometric calculations, Reduction and oxidation chemistry</p> <ul style="list-style-type: none"> • Know and apply the concept of interaction of light with matter • Gain basic understanding of Quality control function and laboratory • Applying correct method of Sampling and identification of non-conforming products/ intermediates • Gain and apply the knowledge of sample preparation, preservation and storage, handling glassware in lab and calibration of glassware, follow the guidelines for weighing and measuring the sample as well safety precautions for sample handling. • Carryout in process sampling for- API, Oral solid dosage form, liquid oral dosage form sterile dosage 		<p>of Elements, Chemistry lab equipment and glassware 50 Ltr Reactor, Reciever, Condensor, centrifuge, drier flatbed lab model, voves, Chemicals (Mandatory Solvents 14), Packaging Material, Drums, Poly Bags, Seals, Silica Gel Bags, Labels, Compression Machine commercial- 10 Stn (Min), Coating Machine Prototype, Hardness Tester, DT Apparatus, Multimill, Airjet Cleaning Machine, Filter Press, Inline homogeniser Cum Mixer, Automatic Filling Machine , Planetary mixer(jackatted with electrical heating facility), Preparation vessel, reactor & Storage Tank, Agitator- Stirrer, Weighing balance (1.2kg, 6.0kg with printer), Rapid mixer granulator (table top 1/5 L capacity), Double cone blender (5L Capacity), Remi stirrers, Machine Hooper, Sifter, Tablet Deduster, Paste Kettle, Jet Claerner, Semi-Automatic Cap Sealing Machine, Online Inspection, Turn Table, Labelling machine, Semi-Automatic Ropp Cap Sealing Machine and screw capping machine, Tube Filling Machine Prototype, Laboratory Microscopes(40X and 100X), pH meter , Bulk density and Tapped</p>



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				<p>form, semisolid dosage form and packaging operations</p> <ul style="list-style-type: none"> • Gain the conceptual scientific knowledge and skill of analytical equipment and operate analytical equipment like Moisture analyser, In process testing equipment, pH meter etc • Follow SoPs and Perform pre-production quality checks like- equipment installation, qualification and readiness, material appropriateness and health and safety checks • Follow SoPs and perform in process checks and activities like- requisite acceptance criteria/ specification and met, cleanliness of equipment, material verification, check QMS elements like CAPA 		<p>density tester, Friabilator, Vernier calipers, Micrometer screw gauge, Scale, Hot plate with magnetic stirrer, UV Analyser (Make: Perkin elmer/shimadzu/Thermo), 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, analytical balance, Pipettes (1mL, 2mL, 5 ml/10 ml), water bath, Desiccator, Dissolution Apparatus, Lab equipped with Fume Hoods, Glassware for Lab, Burette stand with white tile, Various Cartridges, Sodium Metal in kerosine for testing, Half Face Mask, Full Face Mask, 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, Material Safety Data Sheet, Various Safety Signage</p>



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				<p>management, change control, incident management are followed at shop floor, check the facility upkeep, environmental condition and segregation of material is as per GMP norms.</p> <ul style="list-style-type: none"> • Perform Post manufacturing checks like-monitoring and review of batch manufacturing and packaging records, analytical records and logs before batch release, follow SoP and GMP guidelines for receipt, storage, testing, processing and dispatch of products • Learn and practice Related Core Skills and Professional Skills: Reading, writing, listening, speaking, Plan and organize, Critical thinking, problem solving, decision making, customer centrality 		
	Documentation and Reporting	06:00	5:00	<ul style="list-style-type: none"> • Gain Complete knowledge of 	LFS/N0102, LFS/N0213,	Participant Manual, Power point presentation, Case



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
	for Machine Operator			company's standard operating procedure and guidelines and Various coding system of the company <ul style="list-style-type: none"> • Apply Basic understanding of machines control panel, material labels & safety signage • Read and interpret the graphs/ images of product and instructions given in tool/ equipment manual, production plan and schedules, production work flow sequence and material safety sheet • Select the right format of documentation for Recording and communicating details of work done as per SOP and GMP and GDP guidelines • Follow daily report format and submission as per the SOPs 	LFS/N0214, LFS/N0215, LFS/N0103	Studies, Computer system, LCD Projector & Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts, Formats for BMR & BPR, Formats of Log Books, Format of Shift Schedule, Format of Job Cards, GMP Guidelines, Sample Labels, safety signage, Sample SoP document, GMP Guidelines, GDP Guidelines



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				<ul style="list-style-type: none"> • maintain record in appropriate manner • Follow the validation process of document • timely report about each and every incident management • Understand impact of wrong practices and inform supervisor as per SoPs and instructions • identify and report incidents where SOP are not followed • Identify reporting need to supervisor for finding solutions • Escalation matrix for decision making that is not defined in SOP • Read and write memos, job cards, reports like BPR/BMR, material receipt, logs etc. in pre decided format both Offline and online as per SOP • Record & communicate the work done in 		



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				local language and English • take inputs from team and make proper report of that input • Follow and practice efficient and clear communication methods for reporting the incidents and communication with team • Follow the documentation required for taking over and handing over in the shift • Reviewing and Verifying the handover documents while taking over from previous shift		
5	Maintain a healthy, safe and secure working environment in the pharmaceutical manufacturing facility	16:00	10:00	• Learn the Basic Concepts of Safety including Hazards, Accidents, Safety Signs and Signals and Henrich Pyramid and follow and practice same at shop floor • Know about Water Systems at Plant, Engineering related tools and techniques to	LFS/N0101, LFS/N0103	Half Face Mask, Full Face Mask, Safety Goggles, Safety Shoes, Gum Boots, Chemical Absorbent, Self-Contained Breathing Apparatus, PVC Apron, Gloves(Nitrile, {Heat, acid, chemical} resistant, washing etc..), Lab Coat, Surgical Gloves (in Microbiology), Eye washer with sprinkler/ Manual bottle eye washer, Co2 type Fire Extinguisher, ABC Type Fire Extinguisher



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				<p>operate the machine safely. Understand the clean room classifications and requirements, Know and follow Clean room behaviour practices</p> <ul style="list-style-type: none"> • Use Material Data Safety Sheet, and follow the Process of Safety Analysis. Know and follow the Fire Safety concepts and prepare oneself 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 and provide these critical information to concerned team members. • Learn and follow the Basic Concepts and practical skills for managing Emergency 		



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				<p>Procedures and how to do first aid</p> <ul style="list-style-type: none"> Learn and practice Related Core Skills and Professional Skills: Reading, writing, listening, speaking, Plan and organize, Critical thinking, problem solving, decision making, customer centricity 		
8	Information Technology Skills	12:00	24:00	<ul style="list-style-type: none"> Apply Basic Computer Skills (Ms Office, Internet) at Work. Use Lab Management Information System in a Production plant 	LFS/N0102	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
9	Internship	00:00	120:00	<ul style="list-style-type: none"> Prepare machines and accessories for the manufacturing process Perform manufacturing operations Ensure cleanliness in the work area Carry out reporting and documentation Carry out broad level quality checks before, in- 	LFS/N0213, LFS/N0214, LFS/N0215, LFS/N0101, LFS/N0102, LFS/N0103	Internship Monitoring Report



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				process and post manufacturing <ul style="list-style-type: none"> Maintain a healthy, safe and secure working environment in the life sciences facility 		
	Total Duration	155:00	221:00	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, Computer Lab, Formats for BMR & BPR, Formats of Log Books, Format of Shift Schedule, Format of Job Cards, GMP Guidelines, Sample Labels, safety signage, Sample SoP document, GMP Guidelines, GDP Guidelines, Periodic Table of Elements, Chemistry lab equipment and glassware, 50 Ltr Reactor, Reciever, Condensor, centrifuge, drier flatbed lab model, volves, Chemicals (Mandatory Solvents 14), Packaging Material, Drums, Poly Bags, Seals, Silica Gel Bags, Labels, Compression Machine commercial- 10 Stn (Min), Coating Machine Prototype, Hardness Tester, DT Apparatus, Multimill, Airjet Cleaning Machine, Filter Press, Inline homogeniser Cum Mixer, Automatic Filling Machine , Planetary mixer(jackatted with electrical heating facility), Preparation vessel, reactor & Storage Tank, Agitator- Stirrer, Weighing balance (1.2kg, 6.0kg with printer), Rapid mixer granulator (table top 1/5 L capacity), Double cone blender (5L Capacity), Remi stirrers, Machine Hooper, Sifter, Tablet Deduster, Paste Kettle, Jet Claerner, Semi-Automatic Cap Sealing Machine, Online Inspection, Turn Table, Labelling machine, Semi-Automatic Ropp Cap Sealing Machine and screw capping machine, Tube Filling Machine Prototype, Laboratory Microscopes(40X and 100X), pH meter , Bulk density and Tapped density tester, Friabilator, Vernier calipers, Micrometer screw gauge, Scale, Hot plate with magnetic stirrer, UV Analyser (Make: Perkin elmer/shimadzu/Thermo), 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, analytical balance, Pipettes (1mL, 2mL, 5 ml/10 ml), water bath, Desicattor, Dissolution Apparatus, Lab equipped with Fume Hoods, Glassware for Lab, Burette stand with white tile, Various Cartridges, Sodium Metal in kerosine for testing, Various types of cleaning material, chemicals, cleaning equipment, Half Face Mask, Full Face Mask, Safety Goggles, Safety Shoes, Gum Boots, Chemical Absorbent, Self-Contained Breathing Apparatus,		



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				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, Material Safety Data Sheet, Various Safety Signage		

Grand Total Course Duration: **376 Hours 00 Minutes**

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

Annexure1: Assessment Criteria

Assessment Criteria for Production/ Machine Operator- Life Sciences	
Job Role	Production/ Machine Operator- Life Sciences
Qualification Pack	LFS/ Q 0207 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 (600)	Out Of	Theory	Skills Practical
LFS/N0213 (Prepare machines and accessories for the manufacturing process)	PC1. ensure that the machine, surrounding areas and classified areas are clean, dry, sterilised (wherever required) and fit for use as per the SOP to avoid contamination and highlight the risk if any	100	4	2	2
	PC2. set up machines at the beginning of the batch processing to ensure proper working order and refer to the machine history received from the supervisor/colleague		4	2	2
	PC3. perform testing procedures to ensure that machines work optimally to carry out production activities		4	2	2
	PC4. ensure that the approach path from the input storage area to storage area for output is free of obstructions to transportation		4	2	2
	PC5. select the correct material to be loaded		4	2	2
	PC6. ensure that the material is from a respective batch and is checked by the concerned supervisor and approved by the QA team		4	2	2
	PC7. assemble the machinery properly		4	2	2
	PC8. set critical parameters for the machinery (cycle time, temperature, pressure, ampere load, spray rate, etc.) as per the company's SOP		4	2	2
	PC9. keep all the accessories like cleaning brush, levers, release agent, etc. ready		4	2	2



PC10. monitor machines during every procedure to ensure optimum performance	4	2	2
PC11. perform random tests to ensure accuracy and maintain online documentation for the same along with justifications for any wrong entries, if any	4	2	2
PC12. coordinate with maintenance teams for preventive maintenance	4	2	2
PC13. ensure stocks of required materials are ready and available at all times	4	2	2
PC14. ensure that the compound/material to be fed is approved by the laboratory as per SOP and record the receipt details like product name, batch name and operator name	4	2	2
PC15. match the batch code/item code , AR.No of each compound/material with the batch code on the job schedule given by the planning department, ensuring FIFO and further record the name, shelf life and quantities during documentation	4	2	2
PC16. measure/weigh the raw material/compound as per the desired specifications (shape, size and weight) and return the unused material to warehouse with the appropriate label	4	2	2
PC17. ensure, by visual inspection, that the compound is of desired quality (free of contamination/bloom), and reach out to the supervisor for rejection control if disparities exist	4	3	3
PC18. ensure housekeeping/safety in the manufacturing area as per the SOP	4	2	2
PC19. maintain and clean the machines before and after batch processing	4	2	2
PC20. use lifting equipment such as forklift/trolleys while lifting heavy materials to avoid physical injury	4	2	2
PC21. ensure that the lift/ejection/slide/pneumatic valve mechanism of the machinery is properly functioning	4	2	2



	PC22. ensure that signs indicating hot surfaces are put up wherever necessary		4	2	2
	PC23. adhere to all safety norms (like wearing protective gloves, shoes)		4	2	2
	PC24. comply with health, safety, environment guidelines, regulations in accordance with international/national standards or organizational SOP		4	3	3
	Total		100	50	50
LFS/N0214 (Perform manufacturing operations)	PC1. handle the chemicals, materials and compounds appropriately to avoid contamination	100	8	4	4
	PC2. conduct pre-start checks		12	6	6
	PC3. start the equipment safely and perform 'dry runs' to warm hydraulics and components to operating temperature before production, as required		10	5	5
	PC4. load the identified material in the correct pattern as per the SOP to minimize material overflow/wastage/excess flash		8	4	4
	PC5. ensure smooth running of machines and the pressure and temperature is maintained in the machines as per the specifications		8	4	4
	PC6. adhere to the SOPs and guidelines for maintaining quality		6	3	3
	PC7. maintain both online and offline records in the log books and other documentation required as per GMP and GDP like – breakdown time, daily manufacturing record, yield report, etc		6	3	3
	PC8. take appropriate safety steps while carrying out manufacturing operations		5	2	3
	PC9. carry out status labelling		4	2	2
	PC10. provide support for line clearance before the next batch is produced		4	2	2
	PC 11. perform broad level in- process checks and report results to supervisor		4	2	2
	PC 12. ensure and confirm correctness of online process parameters		6	3	3
	PC 13. minimize waste during entire production operations		4	2	2
	PC14. coordinate and work with supervisor, team members in own department and		6	2	4



	cross functions to achieve the production targets and to ensure efficient workflow				
	PC15. take necessary steps as per SOP and escalation matrix in case of any disagreement with colleagues or in other conflict		5	2	3
	PC16. discuss with supervisor on own performance and receive support and feedback from supervisor or any other appropriate authority		4	2	2
	Total		100	48	52
LFS/N0103 (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
	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
LFS/N0102 (Carry out reporting and documentation)	PC1.report data/problems/incidents as applicable in a timely manner	100	10	5	5
	PC2.report to the appropriate authority as laid down by the company		10	5	5
	PC3.follow reporting procedures as prescribed by the company		10	5	5
	PC4.identify documentation to be completed relating to one's role		10	5	5
	PC5.record details accurately in an appropriate format		10	5	5
	PC6.complete all documentation within stipulated time according to company procedure		10	5	5
	PC7.ensure that the final document meets regulatory and compliance requirements		10	5	5
	PC8.make sure documents are available to all appropriate authorities to inspect		10	5	5



	PC9.respond to requests for information in an appropriate manner whilst following organizational procedures		10	5	5
	PC10.inform the appropriate authority of requests for information received		10	4	6
	Total		100	49	51
LFS/N0215 (Carry out broad level quality checks before, in-process and post manufacturing)	PC1.ensure that total range of checks are regularly and consistently performed	100	10	5	5
	PC2.check that the products, materials and equipment meet the requirements for production		10	5	5
	PC3.use appropriate measuring instruments, equipment, tools, accessories etc. as required		10	5	5
	PC4.identify non-conformities to quality assurance standards		10	5	5
	PC5.identify potential causes of non-conformities to quality assurance standards		10	5	5
	PC6.identify impact on final product due to non-conformance to company standards		15	7	8
	PC7.evaluate the need for action to ensure that problems do not recur		10	5	5
	PC8.suggest corrective action to address problems		12	6	6
	PC9.review effectiveness of corrective action		13	6	7
	Total		100	49	51
LFS/N0101 (Maintain a healthy, safe and secure working environment in the life sciences facility)	PC1.observe and comply with the company's current health, safety and security policies and procedures	100	10	5	5
	PC2.while carrying out work, use appropriate safety gears like head gear, masks, gloves and other accessories as mentioned in the guidelines		10	5	5
	PC3.report any identified breaches in health, safety, and security policies and procedures to the designated person		10	5	5
	PC4. responsible for maintaining discipline at the shop-floor/ production area		10	5	5
	PC5. identify and correct any hazards that the individual can deal with safely, competently and within the limits of their authority		10	5	5
	PC6.adhere and comply to storage and handling guidelines for hazardous material		10	5	5



	PC7.identify and recommend opportunities for improving health, safety, and security to the designated person		10	5	5
	PC8. complete any health, safety and security activities like safety drills and prepare records legibly and accurately		10	4	6
	PC9. report any hazards that the individual is not competent to deal with to the relevant 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
	Grand Total	600	600	290	310
	Percentage Weightage			48%	52%
	Minimum Pass Percentage to Qualify			70%	



Annexure2: Trainer Prerequisites for Job role: “Production/ Machine Operator- Life Sciences” mapped to Qualification Pack: “LFS/ Q 0207 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 <u>“LFS/Q0207 Ver1.0”</u> .
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	10+2/ ITI
4a	Domain Certification	Certified for Job Role: “Production/ Machine Operator” mapped to QP: <u>“LFS/Q 0207 Ver1.0”</u> . Minimum accepted score is 80% as per LSSSDC guidelines.
4b	Platform Certification	Recommended that the Trainer is certified for the Job Role: “Trainer”, mapped to the Qualification Pack: “SSC/1402”. Minimum accepted score is 80% as per LSSSDC guidelines.
5	Experience	Preferably Minimum Four (4) years’ experience in life sciences (Pharmaceutical/ Biopharmaceutical) manufacturing occupation for non-trained and non-qualified talent Or Minimum Two (2) years’ experience with Production/ Machine Operator- Life Sciences Level-4 qualified



Certificate

CURRICULUM COMPLIANCE TO QUALIFICATION PACK – NATIONAL OCCUPATIONAL STANDARDS

is hereby issued by the

LIFE SCIENCES SECTOR SKILL DEVELOPMENT COUNCIL

for the

MODEL CURRICULUM

Complying to National Occupational Standards of
Job Role/ Qualification Pack: 'Production/ Machine Operator- Life Sciences'
QP No. 'LFS/ Q 0207 NSQF Level 4'

Date of Issuance: December 28th, 2015

Valid up to: January 5th, 2017

Authorized Signatory
(Life Sciences Sector Skill Development Council)

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



Life Sciences Sector Skill Development Council
13, Palam Marg, 3rd Floor, Vasant Vihar, New Delhi, PIN 110057
Phone No. 011-41042408/ 407; E mail: info@lssdc.in;
www.lssdc.in