APPRENTICESHIP CURRICULUM

for

Production/ Machine Operator- Life Sciences

Under

Life Sciences

for

NSQF compliance

National Apprenticeship Promotion Scheme

1	**Program Title**	Production/ Machine Operator- Life Sciences
2	**Program Code, if any**	LFS/Q0207
3	**Any related NSQF approved QP/Course/NOS and code**	LFS/Q0207- Production/ Machine Operator- Life Sciences 1. LFS/N0213 Prepare machines and accessories for the manufacturing process 2. LFS/N0214 Perform manufacturing operations 3. LFS/N0103 Ensure cleanliness in the work area 4. LFS/N0102 carry out reporting and documentation 5. LFS/N0215 Carry out broad level quality checks before, in-process and post manufacturing 6. LFS/N0101 Maintain a healthy, safe and secure working environment in the life sciences facility
4	**Hours for Basic Training (Block I)**	376 Hours /1.9 Months
5	**Hours for On the Job Training (Block II)**	Total 4088 Hours / 22.1 Months Year 1: 1970 Hours / 10.1 Months Year 2: 2160 Hours / 12 Months **Note:** (48 hours per week for Year 1 & 45 hours per week for Year 2)
6	**Certifying body for Basic Training Program**	Life Sciences Sector Skill Development Council
7	**Certifying Body for On the Job training**	Industry under/ associated with Life Sciences Sector Skill Development Council
8	**Any Licensing requirements, wherever applicable**	NA
9	**Minimum eligibility criteria (Educational and/ or technical Qualification)** **Exemptions, if any**	10+2
10	**Trainer's Qualification and Experience**	12th/ D. Pharm. with 6 years relevant exp. or

		Graduate with 4 years relevant exp. Or Post Graduate with 2 years relevant exp.
11	**NCO code and occupation**	NCO-2004/ NIL, Manufacturing
12	**Proposed NSQF level**	4
13	**Indicative list of training tools required to deliver this qualification (may be attached)**	Attached in Annexure A
14	**Formal structure of the curriculum**	

	Modules	**Notional hours-Theory**	**Notional hours-Practical**	**Total duration**
Basic Training Program	1.Describe Life Sciences Industry and its regulations for manufacturing	10:00	00:00	10 Hours
	2. Explain Fundamentals of Manufacturing in Life Sciences Sector	24:00	10:00	34 Hours
	3. Perform Production Process for API/ Bulk Drug/ Intermediates	21:00	33:00	54 Hours
	4. Perform Production Process for Non-Formulations	21:00	33:00	54 Hours
	5. Perform Production Process for Sterile Formulations	21:00	33:00	54 Hours
	6. Ensure Cleanliness in the work area	08:00	16:00	24 Hours
	7. Perform Quality Checks in Pharma/ Bio Pharma Manufacturing Operations	16:00	24:00	40 Hour
	8. Complete Documentation and Reporting as per GMP and GDP	06:00	24:00	30 Hours

	9. Maintain a healthy, safe and secure working environment in the pharmaceutical manufacturing facility	16:00	24:00	40 Hours
	10. Use Information Technology Skills at work	12:00	24:00	36 Hours
On the Job Training Program	**Mandatory Common OJT Modules**			
	1.Maintain Safety and Hygiene	08:00	64:00	80 Hours
	2. Follow Good Manufacturing Practice	08:00	32:00	40 Hours
	3. Perform Waste disposal and Management as per GMP and EHS rules	08:00	32:00	40 Hours
	4. Use Utility System (HVAC/Water/Gases/Electrical) for manufacturing of life sciences products	08:00	64:00	80 Hours
	Mandatory Electives for OJT (One of following elective is MUST)			
	Elective-A (API)			
	A1. Follow SOPs for API manufacturing and documentation	16:00	64:00	80 Hours
	A2. Practice Clean room behavior in API manufacturing unit	08:00	32:00	40 Hours
	A3. Operate Machines for API production	120:00	1624:00	1744 Hours
	A4. Clean and Maintain Machines for API production	24:00	56:00	80 Hours

	A5. Perform Production Process for API	40:00	1560:00	1600 Hours
	A6. Complete documentation as per SOP and GMP	16:00	64:00	80 Hours
	A7. Perform Quality Checks in Pharma/ Bio Pharma Manufacturing Operations	24:00	200:00	224 Hours
	Elective-B (Non Sterile Formulation)			
	B1. Follow SOPs for Non-sterile formulation manufacturing and documentation	16:00	64:00	80 Hours
	B2. Practice Clean room behavior in Non-sterile formulation manufacturing unit	08:00	32:00	40 Hours
	B3. Operate Machines for Non-Sterile Formulation production	120:00	1624:00	1744 Hours
	B4. Clean and Maintain Machines and equipment for Non-Sterile Formulation production	24:00	56:00	80 Hours
	B5. Perform Production Process for Non-Sterile Formulations	40:00	1560:00	1600 Hours
	B6. Complete documentation as per SOP and GMP	16:00	64:00	80 Hours
	B7. Perform in process Quality Checks during non-sterile formulation Manufacturing	24:00	200:00	224 Hours
	Elective-C (Sterile Formulations)			
	C1. Follow SOPs for Sterile formulation manufacturing and documentation	16:00	64:00	80 Hours

	C2. Practice Clean room behavior in Sterile formulation manufacturing unit	08:00	32:00	40 Hours
	C3. Operate Machines for Sterile Formulation production	120:00	1624:00	1744 Hours
	C4. Clean and Maintain Machines and equipment for Sterile Formulation production	24:00	56:00	80 Hours
	C5. Perform Production Process for Sterile Formulations	40:00	1560:00	1600 Hours
	C6. Complete documentation as per SOP and GMP	16:00	64:00	80 Hours
	C7. Perform in process Quality Checks during sterile formulation Manufacturing	24:00	200:00	224 Hours

15 Total Pass marks

	Pass Marks-Theory	**Pass Marks- Practical**
Basic Training Program	**290**	**310**
On the Job Training Program	**0**	**100**

16	**Job description-brief**	Machine operator is responsible for monitoring the events of a manufacturing of drugs/medicines. They verify materials and products to ensure that a perfect mixture is used and may perform superficial quality checks to ensure total quality management.
17	**Progression from the qualification (Please show Professional and academic progression)**	**Upward progression:** Production/ Manufacturing Chemist – Life Sciences (Level 5) Production Supervisor/ In-charge- Life Sciences (Level 5) **Lateral/ Horizontal progression:** Clean Room Engineer (Level 4)

18	**Employment avenues/opportunities**	The candidates after their tenure as apprentice may do any of the following: a. Production/ Machine Operator (immediately) b. Clean Room Engineer (with 1-2 years exp.) c. Production Supervisor/ In-charge (4-5 years of exp.) d. Production/ Manufacturing Chemist (with 4-5 years exp)
19	**Assessment strategy (Basic training and On the Job)**	Attached in Annexure B
20	**Curriculum update version and date**	V1.0, 10/12/2018
21	**Curriculum revision date**	10/12/2022

Curriculum

Module Name with duration	Key Learning outcomes
Theory/Basic Training Program- Block I	
Describe Life Sciences Industry and its regulations for manufacturing **Theory Duration** (hh:mm) 10:00 **Practical Duration (hh:mm)** 00:00 **Corresponding NOS Code** Bridge Module	• Explain the Life Sciences industry, its sub-sectors • Summarize regulatory authorities and government rules and regulations for manufacturing in Life Sciences industry in India and emerging markets (both regulated and semi regulated) • Practice standards for manufacturing (GMP) at work • Explain the organizational structure and employment benefits in Life Sciences Industry • Explain the role of a Machine/ Production Operator and required skills and knowledge (as per Qualification Pack) and its career path
Explain Fundamentals of Manufacturing in Life Sciences Sector **Theory Duration** (hh:mm) 24:00 **Practical Duration**	• Recall the basic biology and pharmacology required to interpret the manufacturing specifications • Use the fundamentals of metrology i.e. systems of weights and measures • Follow quality management system for production in Life Sciences industry • Practice productivity norms and concept of overall equipment efficiency (OEE) • Explain techniques to control the rejects and techniques to control and predict the breakdown. • Follow deviation/ incident reporting procedure

(hh:mm) 10:00 **Corresponding NOS Code** LFS/N0213 LFS/N0214 LFS/N0215	• Follow change control procedure and implement required documentation practices as per GMP and GDP norms at shop floor • Practise data integrity aligned to cGMP for activities at shop floor. • Follow shift schedules and process of shift handover/ shift takeover
Perform Production Process for API/ Bulk Drug/ Intermediates **Theory Duration** (hh:mm) 21:00 **Practical Duration** (hh:mm) 33:00 **Corresponding NOS Code** LFS/N0213 LFS/N0214 LFS/N0215	• Apply the fundamental science in API production including size separation, mixing and homogenization process, mass transfer, fluid flow, heat transfer and size reduction • Explain role of API in typical pharmaceutical manufacturing and role of API particle size in formulations • Determine the particle size of powders by sieve analysis and by optical microscope • Perform Unit process of oxidation, reduction, hydrogenation, sulfonation, nitration, and halogenation • Produce bulk organic chemicals as building blocks for manufacture of drugs and drug intermediates • Perform catalysis and bio-catalysis in industrial production. • Perform downstream process of filtration, centrifugation, extraction, evaporation, crystallization, drying and size reduction • Perform cleaning of reactor, receiver, condenser, centrifuge and other API manufacturing plant components • Operate reactor, receiver, condenser, centrifuge and other API manufacturing plant components for API/ bulk drug/ intermediates manufacturing • Explain the use of utilities
Perform Production Process for Non-Formulations **Theory Duration** (hh:mm) 21:00 **Practical Duration** (hh:mm) 33:00 **Corresponding NOS Code** LFS/N0213	• Recall the basic biology and pharmacology required to interpret the manufacturing specifications • Follow clean room operation rules • Perform gowning process • Manufacture Oral Solid Dosage (OSD) by performing process of granulation, mixing, compression, coating, and capsule filling • Operate OSD manufacturing machines • Clean and maintain OSD manufacturing machines • Recall the excipients used in OSD • Perform in-process checks and tests as per SOP and GMP for OSD manufacturing • Manufacture Liquid Oral Dosage (LOD) and Ointment by performing process of mixing, filtration, suspension preparation, emulsion and bottle filling • Operate LOD and ointment manufacturing machines • Clean and maintain LOD and ointment manufacturing machines

LFS/N0214 LFS/N0215	• Recall the excipients used in LOD and ointment formulations • Perform in-process checks and tests as per SOP and GMP for LOD and ointment manufacturing • Follow the regulatory (cGMP) guidelines regarding labelling, in process checks in packaging, visual inspection of finished dosage forms • Explain the use of utilities • Practice core skills and professional skills
Perform Production Process for Sterile Formulations **Theory Duration** (hh:mm) 21:00 **Practical Duration** (hh:mm) 33:00 **Corresponding NOS Code** LFS/N0213 LFS/N0214 LFS/N0215	• Manufacture sterile formulations • Perform the environment monitoring at the shop floor • Follow clean room operation rules • Perform gowning and sterilization process • Operate automated machines for sterile formulations as per SOP • Clean and maintain sterile formulation manufacturing machines as per SOP • Perform in-process checks and tests as per SOP and GMP for sterile formulation manufacturing • Follow the regulatory (cGMP, WHO) guidelines regarding labelling, in process checks in packaging, visual inspection of visual inspection of ampoules and vials • Explain the use of utilities • Maintain water for injection and other excipients used in injectable dosage forms • Practice core skills and professional skills
Ensure Cleanliness in the work area **Theory Duration** (hh:mm) 08:00 **Practical Duration** (hh:mm) 16:00 **Corresponding NOS Code** LFS/N0103 LFS/N0101	• Use the knowledge of different material, chemicals, manufacturing equipment and filling lines, various equipment parts and their cleaning procedure as per manufacturer's guide • Follow the guidelines for cleaning and maintaining electronic and optical sensors in manufacturing machines • Perform cleaning validation as per SOP and GMP • Follow the methodology for storage area inspection with methods and materials required for cleaning variety of surfaces and equipment • Follow methods to check the treated surface and equipment on completion of cleaning, • Perform disposal of waste, used/ unused solutions as per SOP, GMP and EHS guidelines • Perform procedures for reporting any unidentified soiling and follow escalation procedures for soils or stains that could not be removed • Practice related core skills and professional skills at work

Perform Quality Checks in Pharma/ Bio Pharma Manufacturing Operations **Theory Duration** (hh:mm) 16:00 **Practical Duration** (hh:mm) 24:00 **Corresponding NOS Code** LFS/N0213 LFS/N0214 LFS/N0215	• Follow SOPs and perform pre-production quality checks for equipment installation, qualification and readiness, cleanliness of equipment, material verification, CAPA management, change control, deviation reports, environmental condition and segregation of material as per GMP • Conduct a safety check before start of the machine • Use basic analytical chemistry fundamentals of balancing chemical equations, chemical equilibrium, acid and base chemistry, stoichiometric calculations, reduction and oxidation chemistry • Use the concept of interaction of light with matter • Explain the need of quality control during manufacturing • Select correct method of sampling • Perform the in-process quality check for requisite acceptance criteria/ specification as per SOP and GMP rules • Identify non-conforming products/ intermediates • report the deviation and any unwanted incidents as per SOP and GMP • Follow the guidelines for weighing and measuring the sample as well safety precautions for sample handling. • Coordinate with QC team for sampling • Operate moisture analyser, in-process testing equipment and pH meter • Perform post-manufacturing checks 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 • Practice related core skills and professional skills
Complete Documentation and Reporting as per GMP and GDP **Theory Duration** (hh:mm) 06:00 **Practical Duration** (hh:mm) 24:00 **Corresponding NOS Code** LFS/N0102	• Follow company's standard operating procedure and guidelines and various coding system of the company • Interpret the machines control panel signs, 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 • Maintain record as per SOP and GMP rules • Perform the document validation process • Report and record each and every incident / deviation in time and as per SOP

	• Explain impact of wrong practices and inform supervisor as per SOPs and instructions • Follow escalation matrix for decision making that is not defined in SOP • Read and write memos, job cards, reports in pre-decided format both Offline and online as per SOP • Use local language or English for recording and reporting as defined in SOP • Record team inputs for suitable action • Perform the documentation required for taking over and handing over in the shift • Review and verify the handover documents while taking over from previous shift
Maintain a healthy, safe and secure working environment in the pharmaceutical manufacturing facility **Theory Duration** (hh:mm) 16:00 **Practical Duration** (hh:mm) 24:00 **Corresponding NOS Code** LFS/N0101 LFS/N0103	• Explain the concepts of safety including hazards, accidents, safety signs and signals • Follow EHS rules and Heinrich pyramid at shop floor • Recall the use of the water systems at plant and engineering related tools • Use techniques to operate the machine safely. • Follow the clean room classifications and requirements • Perform environmental monitoring and follow clean room behaviour practices • Use material safety data sheet (MSDS) and follow the process of safety analysis. • Follow the fire safety concepts and prepare oneself to act in case of fire emergency at shop floor. • Use personal protection equipment (PPEs) in different production operations • Follow the emergency procedures and perform first aid as and when needed • Practice related core skills and professional skills
Use Information Technology Skills at work **Theory Duration** (hh:mm) 12:00 **Practical Duration** (hh:mm) 24:00	• Use basic computer skills (Ms Office, internet) at work. • Use lab management information system in a production plant as needed • Follow the operating procedures in automated machines and perform online data entries as per SOP

Corresponding NOS Code LFS/N0102	
On the Job Training Program- Block II (Part 1 and Part 2)	
Part 1: Mandatory Common OJT Modules	
Maintain Safety and Hygiene **Theory Duration** (hh:mm) 08:00 **OJT Duration** (hh:mm) 64:00 **Corresponding NOS Code** LFS/N0101	• Practice safety while operating machines in manufacturing area by following gowning procedures as per SOP • Follow Man-material movement as per SOP • Follow Material Handling SOPs • Use personal protective equipment while operation machines • Use the fire safety concepts and prepare oneself to act in case of fire emergency in manufacturing area • Perform Fire Extinguisher operations in case of any accident • Use material data safety sheets to conduct safety analysis for every process • Follow organization guidelines for spillage and waste management • Follow the permit systems
Follow Good Manufacturing Practice **Theory Duration** (hh:mm) 08:00 **OJT Duration** (hh:mm) 32:00 **Corresponding NOS Code** LFS/N0101 LFS/N0103 LFS/N0213 LFS/N0214	• Perform the role of a Production/Machine operator following the good manufacturing practices • Explain the importance of GMP in life sciences manufacturing • Practice deviation management • Follow CAPA and change control procedure • Follow the principals of total productivity maintenance, 6-Sigma and lean sigma • Use the knowledge of process validation and equipment qualification during the pre-production checks • Follow Ten Principles of GMP • Follow steps of quality risk management • Practice data Integrity
Perform Waste disposal and Management as	• Explain categories for pharmaceutical and bio-pharmaceutical industrial waste • Follow the material segregation rules as per SOP • Follow 5S principles for material handling

per GMP and EHS rules **Theory Duration** (hh:mm) 08:00 **OJT Duration** (hh:mm) 32:00 **Corresponding NOS Code** LFS/N0301	• Perform decontamination of toxic waste before disposal • Perform disposal of waste, discarded or rejected intermediates/API/finished goods as per SOP, GMP and EHS guidelines • Summarize and implement waste management technologies used in life sciences manufacturing facilities
Use Utility System (HVAC/ Water/Gases/ Electrical) for manufacturing of life sciences products **Theory Duration** (hh:mm) 08:00 **OJT Duration** (hh:mm) 64:00 **Corresponding NOS Code** LFS/ N0213 LFS/ N0215 LFS/ N0102	• Control the clean room operations using HVAC and electrical systems • Explain pharmaceutical water system and utilize different types of water in manufacturing of drugs • Use gases for machine operation wherever applicable • Use electricity for machine operation and identify the backup system available • Practice lean sigma, six sigma and GMP for smooth operations
Part 2: Mandatory Electives for OJT (Choose any one elective)	
Elective-A (API)	
A1. Follow SOPs for API manufacturing and documentation **Theory Duration** (hh:mm)	• Follow legislation, GxP standards, policies, regulations and SOPs in organisation • Explain role of API in typical pharmaceutical manufacturing and role of API particle size in formulations • Follow quality management system for production • Practice productivity norms and concept of overall equipment efficiency (OEE)

16:00 **OJT Duration** (hh:mm) 64:00 **Corresponding NOS Code** LFS/ N0102 LFS/ N0213 LFS/ N0214 LFS/ N0215	• Explain techniques to control the rejects and techniques to control and predict the breakdown. • Follow deviation/ incident reporting procedure • Adapt reporting and escalation matrix of the organization • Follow change control procedure and implement required documentation practices as per GMP and GDP norms at shop floor • Practise data integrity aligned to cGMP for activities at shop floor. • Follow shift schedules and process of shift handover/ shift takeover
A2. Practice Clean room behaviour in API manufacturing unit **Theory Duration** (hh:mm) 08:00 **OJT Duration** (hh:mm) 32:00 **Corresponding NOS Code** LFS/ N0101 LFS/ N0103	• Follow the clean room classifications and requirements • Perform gowning process • Perform environmental monitoring of manufacturing area before and during the production process • Follow clean room behaviour practices in case of sterile API/ bulk drug production • Perform cleaning validation under supervision
A3. Operate Machines for API production **Theory Duration** (hh:mm) 120:00 **OJT Duration** (hh:mm) 1624:00 **Corresponding NOS Code**	• Practise fundamentals of metrology – Weights & measure, temperature, pressure, vacuum, flow, weight and level measurement • Explain design and operation of chemical Reactor and function of each component • Explain design and operation of centrifuge and function of its component • Explain design and operation of agitated nutsche filter cum dryer (AFND) and function of its component • Explain design and operation of particle side reduction equipment and function of its component • Explain design and operation of particle side distribution equipment and function of its component

LFS/N0213 LFS/N0214 LFS/N0215	• Operate reactor, receiver, AFND, condenser, centrifuge and other API manufacturing plant components for API/ bulk drug/ intermediates manufacturing • Explain operation of Condensers for Distillation and Reflux • Operate of various types of centrifuge • Perform downstream process of filtration, centrifugation, extraction, evaporation, crystallization, drying and size reduction • Explain the use of utilities
A4. Clean and Maintain Machines for API production **Theory Duration** (hh:mm) 24:00 **OJT Duration** (hh:mm) 56:00 **Corresponding NOS Code** LFS/ N0103	• Perform cleaning of reactor, receiver, condenser, centrifuge and other API manufacturing plant components • Perform cleaning validation under supervision • Carry out routine maintenance of machines as per SOP and guidelines • Perform calibration of machines under supervision
A5. Perform Production Process for API **Theory Duration** (hh:mm) 40:00 **OJT Duration** (hh:mm) 1560:00 **Corresponding NOS Code** LFS/ N0213 LFS/ N0214 LFS/ N0215	• Follow shift schedules and process of shift handover/ shift takeover • Apply the fundamental science in API production including size separation, mixing and homogenization process, mass transfer, fluid flow, heat transfer and size reduction • Determine the particle size of powders by sieve analysis and by optical microscope • Perform unit process of oxidation, reduction, hydrogenation, sulfonation, nitration, and halogenation • Perform extraction, work-up, leaching, washing and quenching • Produce bulk organic chemicals as building blocks for manufacture of drugs and drug intermediates • Perform catalysis and bio-catalysis in industrial production • Perform downstream process of filtration, layer separation, centrifugation, extraction, evaporation, crystallization, drying and size reduction

A6. Complete documentation as per SOP and GMP **Theory Duration** (hh:mm) 16:00 **OJT Duration** (hh:mm) 64:00 **Corresponding NOS Code** LFS/ N0102	• Follow standard operating procedure, guidelines and various coding system of the company • Interpret the machines control panel signs, material labels & safety signage • Follow SOP and GMP guidelines for receipt, storage, testing, processing and dispatch of API • 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 • Use the right format of documentation for recording and communicating details of work done as per SOP, GMP and GDP guidelines • Follow daily report format and submission as per the SOPs • Maintain API manufacturing record as per SOP and GMP rules • Report and record every incident / deviation in time and as per SOP • Explain impact of wrong practices and inform supervisor as per SOPs and instructions • Follow escalation matrix for decision making that is not defined in SOP • Read and write memos, job cards, reports in pre-decided format both Offline and online as per SOP • Use local language or English for recording and reporting as defined in SOP • Perform the documentation required for taking over and handing over in the shift • Review and verify the handover documents while taking over from previous shift
A7. Perform in process Quality Checks during API/bulk drug Manufacturing **Theory Duration** (hh:mm) 24:00 **OJT Duration** (hh:mm) 200:00 **Corresponding NOS Code** LFS/ N0215	• Follow SOPs and perform pre-production quality checks for equipment installation, qualification and readiness, cleanliness of equipment, material verification, CAPA management, change control, deviation reports, environmental condition and segregation of material as per GMP • Conduct a safety check before start of the machine as per checklist • Use the concept of interaction of light with matter • Select correct method of sampling for in process check • Perform the in-process quality check for API and intermediates according to requisite acceptance criteria/ specification as per SOP and GMP rules with the help of QC/QA team • Identify non-conforming of API products/ intermediates • Report the deviation and any unwanted incidents as per SOP and GMP • Follow the guidelines for weighing and measuring the sample as well safety precautions for sample handling

	• Coordinate with QC team for sampling of API and intermediates • Operate moisture analyser, in-process testing equipment and pH meter • Perform post-manufacturing checks of API batch manufacturing and packaging records, analytical records and logs before batch release • Practice related core skills and professional skills
Elective-B (Non-Sterile Formulation)	
B1. Follow SOPs for Non-sterile formulation manufacturing and documentation **Theory Duration** (hh:mm) 16:00 **OJT Duration** (hh:mm) 64:00 **Corresponding NOS Code** LFS/ N0102 LFS/ N0213 LFS/ N0214 LFS/ N0215	• Follow legislation, GxP standards, policies, regulations and procedures in organisation • Carry out machine operations for Non-sterile manufacturing as per SOP and guidelines • Follow quality management system for production • Practice productivity norms and concept of overall equipment efficiency (OEE) • Explain techniques to control the rejects and techniques to control and predict the breakdown during formulation • Follow deviation/ incident reporting procedure • Follow change control procedure and implement required documentation practices as per GMP and GDP norms at shop floor • Practise data integrity aligned to cGMP for activities at shop floor. • Follow shift schedules and process of shift handover/ shift takeover
B2. Practice Clean room behaviour in Non-sterile formulation manufacturing unit **Theory Duration** (hh:mm) 08:00 **OJT Duration** (hh:mm) 32:00	• Follow the clean room classifications and requirements as per SOP and GMP • Perform gowning process as per SOP • Follow rules of personal hygiene as per SOP and GMP • Perform cleaning validation of work area under supervision

Corresponding NOS Code LFS/ N0101 LFS/N0103	
B3. Operate Machines for Non-Sterile Formulation production **Theory Duration** (hh:mm) 120:00 **OJT Duration** (hh:mm) 1624:00 **Corresponding NOS Code** LFS/ N0213 LFS/ N0214 LFS/ N0215	• Practise fundamentals of metrology – Weights & measure, temperature, pressure, vacuum, flow, weight and level measurement • Operate Oral Solid Dosage manufacturing machines for mixing, granulation, compression, encapsulation, coating and capsule/ tablet printing • Operate Liquid Oral Dosage and Semi solid dosage (dermatological formulation) manufacturing machines for mixing, filtering, emulsification, suspension preparation and filling operations • Explain the use of utilities during the manufacturing operations
B4. Clean and Maintain Machines and equipment for Non-Sterile Formulation production **Theory Duration** (hh:mm) 24:00 **OJT Duration** (hh:mm) 56:00 **Corresponding NOS Code** LFS/ N0103	• Clean and maintain Oral Solid Dosage (OSD) manufacturing machines • Clean and maintain Liquid Oral Dosage (LOD) and Semi solid dosage (dermatological formulation) manufacturing machines • Perform changeover of products as per SOP • Perform cleaning validation under supervision • Calibrate the machines under supervision

B5. Perform Production Process for Non-Sterile Formulations **Theory Duration** (hh:mm) 40:00 **OJT Duration** (hh:mm) 1560:00 **Corresponding NOS Code** LFS/ N0213 LFS/ N0214 LFS/ N0215	• Recall the basic chemistry and pharmacology required to interpret the manufacturing specifications • Manufacture Oral Solid Dosage (OSD) by performing process of granulation, mixing, compression, coating, and capsule filling • Recall the excipients used in OSD • Recall correct method of sampling • Manufacture Liquid Oral Dosage (LOD) and Ointment by performing process of mixing, filtration, suspension preparation, emulsion and filling • Recall the excipients used in LOD and Semi solid dosage (dermatological) formulations • Follow the regulatory (cGMP) guidelines regarding labelling, in process checks in packaging, visual inspection of finished dosage forms • Explain the use of utilities • Practice core skills and professional skills
B6. Complete documentation as per SOP and GMP **Theory Duration** (hh:mm) 16:00 **OJT Duration** (hh:mm) 64:00 **Corresponding NOS Code** LFS/ N0102	• Follow standard operating procedure, guidelines and various coding system of the company • Interpret the machines control panel signs, material labels & safety signage • Follow SOP and GMP guidelines for receipt, storage, testing, processing and dispatch of finished products • 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 • Use the correct format of documentation for recording and communicating details of work done as per SOP, GMP and GDP guidelines • Follow daily report format and submission as per the SOPs • Maintain formulation records as per SOP and GMP rules • Report and record every incident / deviation in time and as per SOP • Follow escalation matrix for decision making that is not defined in SOP • Read and write memos, job cards, reports in pre-decided format both Offline and online as per SOP • Use local language or English for recording and reporting as defined in SOP • Perform the documentation required for taking over and handing over in the shift • Review and verify the handover documents while taking over from previous shift

B7. Perform in process Quality Checks during non-sterile formulation Manufacturing **Theory Duration** (hh:mm) 24:00 **OJT Duration** (hh:mm) 200:00 **Corresponding NOS Code** LFS/ N0215	• Follow SOPs and perform pre-production quality checks for equipment installation, qualification and readiness, cleanliness of equipment, material verification, CAPA management, change control, deviation reports, environmental condition and segregation of material as per GMP • Conduct a safety check before start of the machine as per checklist • Perform in-process checks and tests as per SOP and GMP for OSD manufacturing • Perform in-process checks and tests as per SOP and GMP for LOD and Semi solid dosage (dermatological formulation) manufacturing with the help of QC/QA • Coordinate with QC team for sampling • Select correct method of sampling • Perform the in-process quality check for requisite acceptance criteria/ specification as per SOP and GMP rules • Identify non-conforming products/ intermediates • Report the deviation and any unwanted incidents as per SOP and GMP • Follow the guidelines for weighing and measuring the sample as well safety precautions for sample handling • Operate moisture analyser, in-process testing equipment and pH meter • Perform post-manufacturing checks of batch manufacturing and packaging records, analytical records and logs before batch release
Elective-C (Sterile Formulations)	
C1. Follow SOPs for Sterile formulation manufacturing and documentation **Theory Duration** (hh:mm) 16:00 **OJT Duration** (hh:mm) 64:00 **Corresponding NOS Code** LFS/ N0102	• Follow legislation, GxP standards, policies, regulations and procedures in organisation • Carry out machine operations for Sterile manufacturing as per SOP and guidelines • Follow quality management system for sterile production • Practice productivity norms and concept of overall equipment efficiency (OEE) • Explain techniques to control the rejects and techniques to control and predict the breakdown during formulation • Follow deviation/ incident reporting procedure • Follow change control procedure and implement required documentation practices as per GMP and GDP norms at shop floor • Practise data integrity aligned to cGMP for activities at shop floor. • Follow shift schedules and process of shift handover/ shift takeover

LFS/ N0213 LFS/ N0214 LFS/ N0215	
C2. Practice Clean room behaviour in Sterile formulation manufacturing unit **Theory Duration** (hh:mm) 08:00 **OJT Duration** (hh:mm) 32:00 **Corresponding NOS Code** LFS/ N0101 LFS/N0103	• Follow clean room operation according to the classification of manufacturing areas • Perform gowning process • Perform the sterilization process • Perform environmental monitoring and follow clean room behaviour practices • Monitor the room temperature and humidity as per SOP • Coordinate with QC/QA team for microbial monitoring in environment
C3. Operate Machines for Sterile Formulation production **Theory Duration** (hh:mm) 120:00 **OJT Duration** (hh:mm) 1624:00 **Corresponding NOS Code** LFS/ N0213 LFS/ N0214 LFS/ N0215	• Practise fundamentals of metrology – Weights & measure, temperature, pressure, vacuum, flow, weight and level measurement • Summarize methods of sterilization a) Steam b) Dry heat, c) Ionizing radiation d) Ethylene oxide e) passage through a bacteria retaining filter • Perform sterilization process using Autoclave, DHS, ETO • Recall principles and degree of sterility assurance by employing the terminal sterilization method • Operate automated machines (Vial washing, filing and sealing, lyophilisation, visual inspection and labelling) for sterile formulations as per SOP
C4. Clean and Maintain Machines and	• Clean and disinfect processing areas, equipment, and instruments per SOP

equipment for Sterile Formulation production **Theory Duration** (hh:mm) 24:00 **OJT Duration** (hh:mm) 56:00 **Corresponding NOS Code** LFS/ N0103	• Perform the sterilization process of each and every equipment as per SOP • Perform cleaning validation with the help of QC/ QA • Coordinate with maintenance team and vendor for scheduled maintenance of equipment • Calibrate the equipment under supervision
C5. Perform Production Process for Sterile Formulations **Theory Duration** (hh:mm) 40:00 **OJT Duration** (hh:mm) 1560:00 **Corresponding NOS Code** LFS/ N0213 LFS/ N0214 LFS/ N0215	• Manufacture Sterile formulations • Recall the excipients used in sterile formulation • Follow clean room operation according to the classification of manufacturing areas • Perform gowning and sterilization process • Operate automated machines (Vial washing, filing and sealing, lyophilisation, visual inspection and labelling) for sterile formulations as per SOP • Perform in-process checks and tests as per SOP and GMP for sterile formulation manufacturing • Perform various methods of sterilization • Follow principles and degree of sterility assurance • Maintain and use utilities and water systems for the manufacturing of sterile formulations as per SOP
C6. Complete documentation as per SOP and GMP **Theory Duration** (hh:mm) 16:00 **OJT Duration** (hh:mm)	• Follow standard operating procedure, guidelines and various coding system of the company • Interpret the machines control panel signs, material labels & safety signage • Follow SOP and GMP guidelines for receipt, storage, testing, processing and dispatch of products • 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

64:00 **Corresponding NOS Code** LFS/ N0102	• Select the right format of documentation for recording and communicating details of work done as per SOP, GMP and GDP guidelines • Follow daily report format and submission as per the SOPs • Maintain record as per SOP and GMP rules • Report and record every incident / deviation in time and as per SOP • Explain impact of wrong practices and inform supervisor as per SOPs and instructions • Follow escalation matrix for decision making that is not defined in SOP • Read and write memos, job cards, reports in pre-decided format both Offline and online as per SOP • Use local language or English for recording and reporting as defined in SOP • Perform the documentation required for taking over and handing over in the shift • Review and verify the handover documents while taking over from previous shift
C7. Perform in process Quality Checks during Sterile formulation Manufacturing **Theory Duration** (hh:mm) 24:00 **OJT Duration** (hh:mm) 200:00 **Corresponding NOS Code** LFS/ N0215	• Follow SOPs and perform pre-production quality checks for equipment installation, qualification and readiness, cleanliness of equipment, material verification, CAPA management, change control, deviation reports, environmental condition and segregation of material as per GMP • Conduct safety check and environmental monitoring before start of the machine as per checklist • Coordinate with QC team for sampling • Select correct method of sampling • Perform the in-process quality check for requisite acceptance criteria/ specification as per SOP and GMP rules • Identify non-conforming products/ intermediates • Report the deviation and any unwanted incidents as per SOP and GMP • Follow the guidelines for weighing and measuring the sample as well safety precautions for sample handling • Operate moisture analyser, in-process testing equipment and pH meter • Perform post-manufacturing checks of batch manufacturing and packaging records, analytical records and logs before batch release

List of Assessable outcomes/assessment criteria

Assessment Criteria	
Job Role	**Production/ Machine Operator- Life Sciences**
Qualification Pack	**LFS/Q0207, V1.0**
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 center (as per assessment criteria below)
4	Individual assessment agencies will create unique evaluations for skill practical for every student at each examination/training center based on this criteria
5	To pass the Qualification Pack, every trainee should score a minimum of 70% 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	
Assessment Outcome	**Assessment Criteria of outcome**	**Total Marks (600)**	**Out of**	**Theory**	**Skills Practical**
1. LFS/N0213 Prepare machines and	PC1. Take handover from the colleague in previous shift and ensure that the machine, surrounding areas and classified areas are	100	4	2	2

accessories for the manufacturing process		clean, dry, sterilised (wherever required) and fit for use as per the SOP to avoid contamination and highlight the risk if any				
	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		4	2	2

	along with justifications for any wrong entries, if any				
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, authorized return (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**
2. 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
	PC11. perform broad level in-process checks and report results to supervisor		4	2	2
	PC12. ensure and confirm correctness of online process parameters		6	3	3
	PC13. minimize waste during entire production operations		4	2	2
	PC14. coordinate and work with supervisor, team members in own department and cross functions to achieve the production targets and to ensure efficient workflow		6	2	4
	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**
3. LFS/N0103 Ensure cleanliness	PC1. inspect the area while taking into account various surfaces	100	4	2	2

in the work area	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**
4. 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**
5. 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		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**
6. 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		10	4	6

	person in line with organizational procedures and warn other people who may be affected				
	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%**	

Annexure A: List of Tools and Equipment for Production/Machine Operator

Table 1: For Basic Training

S. No.	Equipment Name	Minimum number of Equipment required (per batch of 30 trainees)	Unit Type	Is this a mandatory Equipment to be available at the Training Center (Yes/No)	Dimension/Specification /Description of the Equipment/ ANY OTHER REMARK
1	CO_2 Type & Abc Type Fire Extinguisher	2	Nos.	Yes	1 each type for Demonstration
2	Face Mask (Half & Full Face)	1	Nos.	Yes	1 each type
3	Flip Charts	5	Nos.	Yes	for each classroom
4	Formats For BMR & BPR	1	Nos.	Yes	Unit= Pc
5	Gloves	1	Nos.	Yes	Unit= Box; 1 box of each type (Nitrile, Heat/Chemical/Acid Resistant, Washing, Sterile)
6	GMP Guideline Book	2	Nos.	Yes	Unit= Pc
7	Gum Boots	1	Nos.	Yes	
8	Laser Pointer	1	Nos.	No	For Each class room
9	Material Safety Data Sheet	1	Nos.	Yes	For all materials & solvents in Lab
10	Micrometer Screw Gauge	1	Nos.	Yes	
11	Ph Meter	1	Nos.	Yes	
12	Pvc Apron	1	Nos.	Yes	One for Demonstration
13	Safety Goggles	1	Nos.	Yes	One for Demonstration
14	Safety Shoes	1	Nos.	Yes	One for Demonstration
15	Sample Job Card	1	Nos.	Yes	Unit= Pc

16	Sample Log Books	1	Nos.	Yes	Unit= Pc
17	Sample Production Planning Schedule	1	Nos.	Yes	Unit= Pc
18	Sample Shift Schedule	1	Nos.	Yes	Unit= Pc
19	Scale	1	Nos.	Yes	
20	Various Mask Cartridges	1	Nos.	Yes	one each type
21	Vernier Calipers	1	Nos.	Yes	
22	Commercial Weighing Balance	1	Nos.	Yes	(1.2Kg- 6.0Kg)
23	White Board	1	Nos.	Yes	
24	White Board Duster	1	Nos.	Yes	one for each class room
25	White Board Marker	2	Nos.	Yes	for each classroom
26	White Screen	3	Nos.	No	For Class Room and VR Lab
27	High End Computer	2	No.	Yes	Configuration of highend CPU: CPU INTEL (I-7 7700K) 7 TH ; MOTHERBOARD GIGABYTE Z 270X-GAMING7 ; HARDDISK (250 SSD GB) ; HARDDISK (2 TB) ; RAM 16GB *2 ; DVD RW ; KEYBOARD KIT WL ; CABINET ; SMPS ; GRAPHICS CARD Nvidia GTX 1070; Windows 10 Pro ; Internet Connection; Wireless Mouse; MS Office

28	Computer/ Laptop	30	No.	Yes	For Hybrid Class room Cum Lab, CPU (Celeron or higher version Processor with Graphics Card); HARDDISK (500GB) ; RAM 4GB ; DVD RW ; KEYBOARD KIT ; CABINET ; SMPS 550W; Windows 8 and above; Monitor 15”; Optical Mouse; Head Phones with Mike; Internet Connection; Ms Office
29	Projector	3	No.	Yes	Maximum Brightness: 3000 lm; Horizontal Resolution: 1280 Pixels; Max Vertcial Resolution: 800 Pixels; Aspect Ratio: 4:03; Minimum Projection Distance: 15.7 inch; Projection Ratio: 0.626; Wattage: 240 W; Video and Audio Ports: HDMI IN, VGA IN, VGA OUT, AUDIO IN, AUDIO OUT, USB, Ethernet Port; Graphic Mode: XGA; Other Connections: Bluetooth, WI-FI
30	HDMI Cable for Projector	3	No.	Yes	10 Mtr.
31	VGA Cable for Projector	3	No.	Yes	
32	Access Control System	2	No.	Yes	For Virtual Reality lab
33	LED TV 40 inch	2	No.	Yes	Any make for VR lab

34	Virtual Reality Lab Kit	2	No.	Yes	For Virtual Reality lab- Make: HTC Vive Kit; Package Contents: [2 Base Stations (Trackers), 1 Set Hand Controllers (2 Nos.), 1 HMD Unit, 1 Junction Box (Wires - PC, Wires - VR), Charging Cables, Wall Mounts, Sync Cables (for manual sync), Earphones]; Platform: Steam VR; Display technology: Pen Tile OLED; Resolution: 2160 × 1200 (1080 × 1200 per eye); Refresh Rate: 90 HZ; Field Of View: About 110 Degrees; Tracking System: Lighthouse; Connection: HDMI 1.4, Display Port 1.2, USB 3.0; Controller Input: Steam VR Wireless Motion Tracked Controllers; Maintenance Kit
35	LAN Cable	35	No.	Yes	For Connecting Computers with LAN in Hybrid Class Room/ IT Lab
36	Trainer Laptop	1	No.	Yes	For Class room Instructor : INTEL CORE I3 and above ; RAM 4 GB; HARDDISK (500GB) ; GRAPHICS CARD 2GB; SCREEN 15"; MOUSE Wireless; MS Office

37	Tablet	1	No.	Yes	Configuration: Screen Size: 9"; Operating System: Android 5.0; Processor: 1.8GHz; CPU Type: Quad Core ; Resolution: 2048 x 1536 (QXGA); Technology(Main Display): Super AMOLED; RAM: 2GB; Standard Battery Capacity(mAh): 5000; Video Resolution: FHD (1920 x 1080); ROM: 16 GB; AR Application by Simulanis
38	Mini HDMI Cable	1	No.	Yes	For Connecting Tablet to Projector
39	Augmented Reality Instructor Manual developed by Simulanis	1	No.	Yes	For Class room Instructor
40	Air Conditioner 2 Ton	2	No.	Yes	for VR lab
41	Air Conditioner 1.5 Ton	2	No.	Yes	for Class Room
42	License for VR Software by Simulanis	2	No.	Yes	For Virtual Reality lab
43	License for PC Gaming Modules Developed by Simulanis	30	No.	Yes	For Hybrid lab
44	Class Room Chairs with writing pad/ flap	28	No.	Yes	For VR Lab, Server room and instructor
45	Student Chair	34	No.	Yes	For Hybrid lab, VR Lab, and server room
46	Office Table	1	No.	Yes	For Hybrid lab
47	Computer Table/ desk	30	No.	Yes	For Hybrid lab
48	UPS	32	No.	Yes	For PC lab and VR Lab

49	Internet Connection	1	No.	Yes	8 MBPS Minimum
50	Genset Back-up	1	No.	Yes	4 KVA
51	Sound System 5.1 Channel Surround	2	No.	Yes	Power Output: 40 W; One Subwoofer; Five Speakers; Maximum Output RMS Per Satellite 15 W; Maximum Output RMS Subwoofer 45 W; Remote; Chassis Material -Wood Chassis
52	Sound System 2.1 Channel Surround	1	No.	Yes	2.1 Dolby Sound System; Frequency 35-200Hz; Power Output: 42W; One Subwoofer; Two Satellite Speakers

Table 2: For OJT Training

S. No.	Equipment Name	Minimum number of Equipment required (per batch of 30 trainees)	Unit Type	Is this a mandatory Equipment to be available at the Training Center (Yes/No)	Dimension/Specification /Description of the Equipment/ ANY OTHER REMARK
1	CO_2 Type & Abc Type Fire Extinguisher	2	Nos.	Yes	1 each type for Demonstration
2	Face Mask (Half & Full Face)	1	Nos.	Yes	1 each type
3	Flip Charts	5	Nos.	Yes	for each classroom
4	Formats For BMR & BPR	1	Nos.	Yes	Unit= Pc
5	Gloves	1	Nos.	Yes	Unit= Box; 1 box of each type (Nitrile, Heat/Chemical/Acid Resistant, Washing, Sterile)
6	GMP Guideline Book	2	Nos.	Yes	Unit= Pc
7	Gum Boots	1	Nos.	Yes	
9	Material Safety Data Sheet	1	Nos.	Yes	For all materials & solvents in Lab
10	Micrometer Screw Gauge	1	Nos.	Yes	
11	Ph Meter	1	Nos.	Yes	
12	PVC Apron	1	Nos.	Yes	One for Demonstration
13	Safety Goggles	1	Nos.	Yes	One for Demonstration
14	Safety Shoes	1	Nos.	Yes	One for Demonstration
15	Organization Job Card	1	Nos.	Yes	Unit= Pc
16	Organization Log Books	1	Nos.	Yes	Unit= Pc

17	Organization Production Planning Schedule	1	Nos.	Yes	Unit= Pc
18	Organization Shift Schedule	1	Nos.	Yes	Unit= Pc
19	Scale	1	Nos.	Yes	
20	Various Mask Cartridges	1	Nos.	Yes	one each type
21	Vernier Calipers	1	Nos.	Yes	
22	Commercial Weighing Balance	1	Nos.	Yes	(1.2Kg- 6.0Kg)
23	White Board	1	Nos.	Yes	
24	White Board Duster	1	Nos.	Yes	one for each class room
25	White Board Marker	2	Nos.	Yes	for each classroom
26	White Screen	3	Nos.	No	For Class Room and VR Lab
27	Utilities(Water System, HVAC ,Gases)	1	Nos.	Yes	1 each type
28	Vial Filling and sealing machine	1	Nos.	Yes	1 each type
29	Lyophilizer	1	Nos.	Yes	1 each type
30	Autoclave	1	Nos.	Yes	1 each type
31	DHS	1	Nos.	Yes	1 each type
32	ETO	1	Nos.	Yes	1 each type
33	Visual Inspection machine	1	Nos.	Yes	1 each type
34	Automatic labelling machine	1	Nos.	Yes	1 each type
35	Packing machine	1	Nos.	Yes	1 each type
36	Rapid Mixer Granulator	1	Nos	Yes	1 each type

36	Fluid Bed Dryer	1	Nos	Yes	1 each Type
37	Compression Machine	1	Nos	Yes	1 each type
38	Tablet coating machine	1	Nos	Yes	1 each type
39	Capsule filling machine	1	Nos	Yes	1 each type
40	Blender	1	Nos	Yes	1 each type
41	Filter Press	1	Nos	Yes	1 each type
42	Sieve Shaker with meshes	1	Nos	Yes	1 each type
43	Bottle Filling Machine	1	Nos	Yes	1 each type
44	Tube filling machine	1	Nos	Yes	1 each type
45	Cap sealing machine	1	Nos	Yes	1 each type
46	Tablet Deduster	1	Nos	Yes	1 each type
47	Multimill	1	Nos	Yes	1 each type
48	Induction machine	1	Nos	Yes	1 each type
49	Purifier	1	Nos	Yes	1 each type
50	API reactor	1	Nos	Yes	1 each type
51	Condenser	1	Nos	Yes	1 each type
52	Machine Hooper	1	Nos	Yes	1 each type
53	Sifter	1	Nos	Yes	1 each type

Annexure B:

Assessment Strategy for Production/ Machine Operator

The assessment for the Basic Training and On the Job Training will be conducted toward the end of the OJT duration.

Assessment Process:

The assessment will be in two parts as below:

Part 1: OJT Assessment

For OJT assessment the Industry nominated assessor will be assessing the candidates based on the OJT monitoring report submitted by Industry supervisor and Viva by the Industry nominated assessor

1.1 Industry nominated assessor:

The Assessors are engaged to conduct the assessments by Industry. The selection takes place as follows

- Industry defines the criteria for profile of an assessor.
- Assessor is a person who is currently working in the same industry on same or higher job role and has minimum 5-7 years of experience.
- Once selected, the assessor is oriented by Industry using LSSSDC guidelines on various aspects of the assessment and management of assessment, such as
- QP and its background.
- Training on Assessment methodology and how to use Assessment tools. Scoring system. (as per the attached assessment guide)
- Maintain integrity at the assessment site.
- Crisis handling and support system available for the same.
- Scope of his authorities
- Administrative responsibilities.
- Required documentation of Trainee credentials, mark sheet management.
- Confidentiality management.

1.2 Assessment Tool for OJT:

1.2.1 OJT Monitoring Report:

- As in Life Sciences Sector reproducing the evidence for assessment is not feasible due to constraints like cost, confidentiality and controlled environment, every apprentice is required to record the evidences performed during the OJT and the same gets authorized by his/her supervisor.
- The evidence recording is done in a structured monitoring report, termed as OJT monitoring report.
- During the OJT, every trainee is required to fill the OJT monitoring report which is required to be signed by his/her supervisor.
- Towards the end of OJT period these reports are submitted with the HR department of company
- These duly submitted reports are then verified by an Industry nominated assessor for verification of evidence.

1.2.2 Viva:

Scope – Is used to test the knowledge and understanding and skills acquired during the OJT as well as to conform the OJT monitoring report.
Some personality traits and generic skills (such as – promptness, sharpness, communication skills, depth of knowledge, comprehension, presentation, patience etc) can also be tested required for the QP.

Tools – Direct dialogue between assessor and Trainee.

Method – Direct questions open and close ended questions, situation-based questions, analytical questions, and decision making based questions. Different questions are included to test relevant PCs from the QP

Analysis – Assessor draws a spectrum of ready answers to be expected from trainee. This reduces effect of subjectivity of the assessor. Comparative quality of trainees with in a batch or different institutes can be gauged.

1.3 Execution of OJT Assessment:

- HR department then hands over the individual OJT monitoring report with Industry nominated assessor and schedules an assessment meeting for each trainee
- Industry nominated assessor assesses each trainee based on OJT monitoring report, viva on each PC and attendance with each trainee towards the end of the OJT period.

- The OJT marks are compiled for each NOS by the Industry nominated assessor and submitted with HR department of company.
- The OJT assessment results are then sent to LSSSDC by HR department of company in a sealed envelope for compiling the assessment results.

Part 2: Basic Training Assessment

For Execution of the assessment for basic training, LSSSDC will be engaging more than one assessment agencies/ body.

2.1 Criteria of selection of assessment body/agency:

The assessment body/agency is selected on the basis of

- Prior experience and understanding of Life Sciences or similar sector.
- Experience in conducting assessments for similar job roles.
- Manpower and Technical capabilities.
- Geographical reach
- Existing Network in the Life Sciences Sector
- Agencies internal policies to maintain standards, quality & professional Integrity
- Agencies policy in assessor management

2.2 Assessment tool for Basic Training:

For the Basic training assessment, the assessment instrument development is done by the selected assessment body with close monitoring and support of LSSSDC at every stage.

2.2.1 Digital Written test for knowledge assessment:

Scope – Is used to test the knowledge component of the QP.

Tools –computer or tab based online or offline.

Method – objective type questions, match the columns, fill in the blanks, tick the odd man out, choose the correct option, choose the best answer, True or false, Identify the object, tool or machinery, arrange in proper sequence, case study, scenario-based responses.

Analysis – Question paper is divided in sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.

2.2.2 Digital Written test for skill assessment:

Scope – Is used to test primarily the Skill component of the QP. Trainee's expertise in handling and managing the situation is tested.

Tools – computer or tab based online or offline questions

Method – A situation is narrated or created in the question posed to the trainee and he is asked objective type questions to select the correct reaction to the situation. The selected situations are based on real situations.

Analysis – Question paper is divided in sections. Each Section intends to assess a particular skill field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.

2.3 Steps for assessment development:

- Selection of assessment tool(s) is done as per the assessment criteria prescribed in Qualification Pack.
- For Production/Machine operator assessment a blue print of the question paper, is part of assessment tool for basic training.
- Development of lay-out of Question paper is such that the entire PCs (Performance Criteria) of that QP are covered.
- Score per question maps with the weightage given to that PC, in the assessment criteria and the level of difficulty of the question.
- An expert from industry is selected who is called "Subject Matter Expert" (SME). This SME must have over 13-15 years of experience in the industry in Manufacturing occupation.
- SME is screened and approved by LSSSDC. He is the oriented by both LSSSDC and Assessment agency on – creating question Bank, level of questions, end desired outcome of the assessment.

2.4 Execution of Basic Training Assessment:

- Once LSSSDC receives the OJT assessment results, the assessment date for basic training is decided with common agreement of Industry and LSSSDC and turn is directed to an assessment body/agency.
- Assessment agency ensures the availability of required infrastructure, tools for the assessment.
- The assessment is executed in two possible ways depending on the choice of industry:

2.4.1 Tab based assessment using physical proctoring
2.4.2 Smart phone-based assessment using e-proctoring

2.4.1 Tab-based assessment using physical proctoring

- A representative from Assessment agency are present on the day of assessment to execute the assessment at venue in case of physical proctoring.
- Assessment agency representative carries an identity card and letter from the council authorising to conduct the assessment.
- Assessment agency representative ensures authenticity of Trainee's identity by verifying the documents (any document issued by GOI, such as Ration card, Aadhaar Card, Driving Licence, Passport, election card etc)
- Assessment agency representative maintains the records of attendance, verified documents and tablet instruments used in assessment.
- Assessment agency representative collects evidences of the assessment in best possible way (videos, pictures, voice recordings etc)
- Assessment agency representative transfer the assessment scores from tab to assessment agency server, using a secure, encrypted web-based program.
- The assessment agency after processing the results and putting them in standard format hands over to LSSSDC within 7 days of assessment.

2.4.2 Smart phone-based assessment using e-proctoring

- All trainees due for assessments are registered on a assessment tool application using their unique mobile number and e-mail ID along with a Govt. ID issued proof.
- An assessment link is sent to the mail ID of each trainee with a defined expiry date of the link.
- Trainee at any location can click on the link using his/her smart phone or a web camera enabled computer system
- Using the unique credentials and govt ID number, trainee logs in for start of assessment and completes the assessment.
- Authenticity of Trainee's identity is done by assessment application by verifying the documents (any document issued by GOI, such as Ration card, Aadhaar Card, Driving Licence, Passport, election card etc.) and a live photo capture
- A live video of candidate during the assessment is captured to collect the evidences of the assessment
- Once the assessment is complete, the assessment application automatically assessment scores to assessment agency server, using a secure, encrypted web-based program.
- The assessment agency after processing the results and putting them in standard format hands over to LSSSDC within 7 days of assessment.

Assessment Result compilation:

- LSSSDC compiles the score submitted by assessment agency and OJT score submitted by Industry HR department.
- LSSSDC cross checks and validates the data and declares the result to Industry and trainee.
- Passed trainees are provided with certificate