

# Model Curriculum

## Production / Manufacturing Chemist- Life Sciences

### Production/ Manufacturing Chemist- Life Sciences

SECTOR: LIFE SCIENCES  
SUB-SECTOR: PHARMACEUTICAL  
OCCUPATION: MANUFACTURING  
REFERENCE ID: LFS/Q 1201 Ver1.0  
NSQF LEVEL: LEVEL 5



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## Production/ Manufacturing Chemist- Life Sciences

### CURRICULUM / SYLLABUS

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

<b>Program Name</b>	<b>Production/ Manufacturing Chemist</b>		
<b>Qualification Pack Name &amp; Reference ID.</b>	Production/ Manufacturing Chemist – Life Sciences LFS/ Q 1201 Ver1.0		
<b>Version No.</b>	1.0	<b>Version Update Date</b>	24–12 – 2015
<b>Pre-requisites to Training</b>	B.Pharma preferable/ Graduate in Science (chemistry specialization preferable for Pharmaceuticals)/ B.Tech in chemistry		
<b>Training Outcomes</b>	<p><b>After completing this programme, participants will be able to:</b></p> <ul style="list-style-type: none"> <li>Gain Knowledge about Life Sciences Industry, and Regulations (cGMP, ISO) to enable him/herself for establishing the Industry Standards in his/her performance.</li> <li>Gain Scientific knowledge about Basic of Industrial Chemistry for API and Formulation Production, Production Process for API &amp; Formulations, Equipment and Machinery and how to use them, QMS for Production, EHS requirement and Industrial practices, detailed norms of cGMP, Quality Risk Management and required documentation to enable him/herself able to supervise the Production Process and to enable him/ her to deal with potential risks and challenges for quality and data integrity.</li> <li>Learn how to supervise production process activities and how to manage staff and inventory to achieve the Organizational Goals.</li> <li>Gain knowledge to maintain a healthy, safe and secure working environment at the pharmaceutical manufacturing shop floor and area around that. He/ she become capable of managing emergency procedures.</li> <li>Learn how to coordinate with Shift Supervisor, cross functional teams and within the team for effective supervision and development and grooming of team</li> <li>Learn how to ensure all-time audit readiness and participate in shop floor audits and/ or one-o-one discussion with auditors as a production team member and generate the responses for audit queries.</li> <li>Learn Professional Skills like Decision Making, Planning &amp; Organizing, Customer Centricity, Problem Solving, Objection Handling, Analytical Thinking and Critical Thinking.</li> </ul>		

This course encompasses Three (3) out of Three (3) National Occupational Standards (NOS) of “Production/ Manufacturing Chemist LFS/ Q 1201 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"> <li>Know about Life Sciences</li> </ul>	LFS/N0203 LFS/N0101	Participant Manual, Power point presentation, Case



Transforming the skill landscape

Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				<p>Industry, its sub-sectors</p> <ul style="list-style-type: none"> <li>Know about Regulatory Authorities and Government Policies, rules and Regulations and their impact on manufacturing in Life Sciences Industry in India and Emerging Markets (Both Regulated and Semi Regulated)</li> <li>Know about Standards for Manufacturing in Life Sciences like cGMP, ISO, etc. Orientation with Pharmacopeia and how to read them.</li> <li>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.</li> <li>Understand the Role of a</li> </ul>	<p>LFS/N0204 LFS/N0203, LFS/N0101, LFS/N0204</p> <p>LFS/N0203, LFS/N0101, LFS/N0204</p> <p>LFS/N0203, LFS/N0101, LFS/N0204</p>	<p>Studies, Computer system, LCD Projector &amp; Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board 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
				<p>apply the techniques to control and predict the breakdown, Handle the market complaints.</p> <ul style="list-style-type: none"> <li>• Know and follow Deviation ,incident and change control procedure and Required Documentation practices by QMS, and implement these at shop floor</li> <li>• Learn and apply the concepts and practical skills of Quality Risk Management and Data Integrity aligned to cGMP in the context of Indian Culture.</li> <li>• Learn and follow the documentation practices required by cGMP and implement these learnings at shop floor</li> </ul>		
3	Production Process for API	18:00	18:00	<ul style="list-style-type: none"> <li>• Know and apply the Fundamental Science in API Production including Size Separation, Mixing and homogenization</li> </ul>	LFS/N0203	50 Ltr Reactor, Reciever, Condensor, Rotary Chemicals (Mandatory Solvents 14), Metal Sodium, Sieving Machine, Multi Mill, Dryer, Packaging Material, Drums, Poly Bags, Seals,



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				<p>Process, Mass Transfer, Fluid Flow, Heat Transfer, Size Reduction, Role of API in typical Pharmaceutical Manufacturing and role of API particle size in formulations</p> <ul style="list-style-type: none"> <li>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"> <li>Unit processes: Oxidation, Reduction, Hydrogenation, Sulfonation, Nitration, and Halogenation.</li> <li>Bulk organic chemicals as building blocks for manufacture of drugs and drug intermediates</li> <li>Catalysis and Bio catalysis in Industrial production.</li> <li>Downstream processes like Filtration, Centrifugation, Extraction, Evaporation, Crystallization,</li> </ol> </li> </ul>	LFS/N0203, LFS/N0101	<p>Silica Gel Bags, Labels, 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</p>







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"> <li>Learn and apply the conceptual and practical skills about Production process of Liquid Oral Dosage covering aspects like: Types of oral liquids Types of Monophasic liquid dosage forms Theoretical aspects of vehicles and additives for Monophasic liquid oral dosage forms Mixing processes Filtration : Definition, theory, filter media, selection of the filter media and filter aid Operation, cleaning and maintenance of filter press Biphasic dosage forms : Suspensions: Preparation of suspensions Types of suspensions Adjuvants used in suspension, types, selection, quantity used in formulation Biphasic dosage forms : Emulsions: Preparation of Emulsions Formulation of different types of emulsions Selection of Emulsifying agents based on HLB values</li> </ul>		<p>Single Head Ropp Cap Sealing Machine, Washing Machine, Glove box isolators for potent drugs, Autoclave, Climatic chambers (300 L capacity), Monoblock Rotary Dry Powder Filling &amp; Sealing Machine, Single Dose Filling Machine, Automatic(Liquid) Filling Machine , Tube Filling Machines For Laminated / Plastic Tubes, Multicolumn , Rectangular , teriliser , D.M. storage Tank , Dry Heat Sterilizer , Filling / Pressure Vessel, Brookfiled Viscometer, Tube Filling Machine Prototype, Preparation vessel, reactor &amp; Storage Tank, Dispo Homogenizer, Inline Homogenizer, 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,</p>



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				<p>Machineries required for preparation of Emulsions</p> <p>In process control parameters for Emulsions</p> <p>Processing of Liquid Orals</p> <p>Operation, cleaning and maintenance of Filling Lines</p> <p>Cleaning of manufacturing tanks and validation of cleaning process.</p> <p>To learn the conceptual and practical skills about Production process of Sterile Dosage covering aspects like:</p> <p>Definition and scope of Aseptic and terminally sterilized processing</p> <p>Water for injection production, testing and maintenance</p> <p>Gowning procedures</p> <p>Good aseptic techniques</p> <p>Basic microbiology and environmental monitoring</p> <p>Sterilization techniques and sterilization qualification</p> <p>Operation and maintenance of autoclave</p>	LFS/N0203	<p>Dissolution Apparatus, Lab equipped with Fume Hoods, Glassware for Lab, Burette stand with white tile, Various Cartridges, 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</p>



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				Liquid Filtration and filter integrity testing Lyophilisation Manage SIP and CIP processes Components preparations Operation and maintenance of Laminar flow hood Operation and maintenance of Isolators Filling of ampoules, vials prefilled syringes, bags Facility Design and HEPA system Handle Change Parts- SMED concept Good documentation practices Environmental Data trending and excursion analysis Testing of ampoules and vials for particulate matter. Equipment handling skills used in the Sterile Dosage production <ul style="list-style-type: none"> <li>Learn and apply the conceptual and practical skills about Production process of Dermatological Formulations covering aspects like:</li> </ul>		



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				Definition of Dermatological products Classification and types of dermatological products Dermatological product formulations Excipients used in formulation and their characteristics Process flow chart Manufacturing equipment's and process for different types of Dermatological products Filling line equipment's and processes Cleaning and disinfection of the manufacturing and filling equipment's In process testing for Dermatological Common manufacturing and filling defects and trouble shooting Critical process parameters and critical quality attributes		
5	Supervising a Production Team	16:00	10:00	<ul style="list-style-type: none"> <li>Learn and apply the concept and practical skills for Production Planning, monitor shift-wise production and practice</li> </ul>	LFS/N0203, LFS/N0204	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>required documentation like scheduled reports, weekly and monthly review and analysis reports, DPRs etc.</p> <ul style="list-style-type: none"> <li>Learn and apply the key concept and practical skills for Training, Supervising and delegating &amp; monitoring in a manufacturing shop floor of Life Sciences Industry including the practical use of psychological concepts</li> <li>Learn and apply the concepts and practical skills for the required documentation in various production process. Check documents like log book, BMR /BPR, On line documentation entries. Learn and apply the Concepts of GDP and respond to an audit query from QA.</li> <li>Know and follow generic Organizational Policy &amp; various internal Process</li> </ul>	<p>LFS/N0203, LFS/N0204</p> <p>LFS/N0203, LFS/N0204</p> <p>LFS/N0203, LFS/N0101, LFS/N0204</p> <p>LFS/N0203</p>	<p>Marker/ chalk, duster, flip charts, Formats of BMR, BPR, Log Books, Production Planning Schedule, Shift Schedule</p>



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				<p>relevant for Production Chemist</p> <ul style="list-style-type: none"> <li>Learn and practice related Core Skills and Professional Skills: Reading, writing, listening and speaking, Observation &amp; Critical thinking, problem solving, decision making, customer centricity, plan and organizing, Analytical thinking, Execution and Escalation</li> </ul>		
6	Maintain a healthy, safe and secure working environment in the pharmaceutical manufacturing facility	16:00	10:00	<ul style="list-style-type: none"> <li>Learn the Basic Concepts of Safety including Hazards, Accidents, Safety Signs and Signals and Henrich Pyramid and follow and practice same at shop floor</li> <li>Know about Water Systems at Plant, Engineering related tools and techniques to operate the machine safely. Understand the clean room</li> </ul>	<p>LFS/N0101</p> <p>LFS/N0203, LFS/N0101</p> <p>LFS/N0101</p>	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>classifications and requirements, Know and follow Clean room behaviour practices</p> <ul style="list-style-type: none"> <li>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.</li> <li>Learn and follow the Basic Concepts and practical skills for managing Emergency Procedures and how to do first aid</li> </ul>	<p>LFS/N0101</p> <p>LFS/N0101</p>	



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"> <li>Learn and practice Related Core Skills and Professional Skills: Reading, writing, listening, speaking, Plan and organize, Critical thinking, problem solving, decision making, customer centricity</li> </ul>		
7	Coordinate with Shift Supervisor, cross functional teams and within the team	16:00	10:00	<ul style="list-style-type: none"> <li>Manage Supervisor-Reportee Relationship and identify Partnering Opportunities at work; know and follow General reporting process, protocol and escalation policy. Understand Importance of reports and communication with Supervisor including DPR handover</li> <li>Learn and Use techniques for Collaborating with Other Groups and Divisions in order to achieve organizational goals</li> <li>Learn and follow the conceptual and practical</li> </ul>	LFS/N0203, LFS/N0204  LFS/N0204  LFS/N0203, LFS/N0204  LFS/N0204	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, Sample Audit Report and Sample Responses





Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				<p>skills required by Production Chemist in Audits:</p> <p>Importance of cGMP/QMS/ SOP related documentation</p> <p>Method to Respond to Audit Queries</p> <p>How to Face Internal Audit Interactions</p> <p>Use of IT in communication and coordination</p> <ul style="list-style-type: none"> <li>Learn and practice Related Core Skills and Professional Skills: Reading, writing, listening, speaking, Analytical thinking, problem solving, decision making, customer centricity</li> </ul>		
8	Information Technology Skills	12:00	24:00	<ul style="list-style-type: none"> <li>Apply Basic Computer Skills (Ms Office, Internet) at Work. Use Lab Management Information System in a Production plant</li> </ul>	LFS/N0203, LFS/N0101, LFS/N0204	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	200:00	<ul style="list-style-type: none"> <li>To learn the practical skills for instrument handling, documentation and supervision required for API Production</li> </ul>	LFS/N0203  LFS/N0203	Internship Monitoring Report



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"> <li>To learn the practical skills for instrument handling, documentation and supervision required for Formulations Production</li> <li>Learn how to Maintain a healthy, safe and secure working environment in the pharmaceutical facility of manufacturing /testing/ analysis / research laboratory</li> <li>Coordinate with Shift Supervisor, cross functional teams especially QA, QC, Maintenance and SCM and within the team</li> </ul>	<p>LFS/N0101</p> <p>LFS/N0204</p>	
	<b>Total Duration</b>	<b>128:00</b>	<b>306:00</b>	<b>Unique Equipment Required:</b> 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, Periodic Table of Elements, Chemistry lab glassware, Formats of BMR, BPR, Log Books, Production Planning Schedule, Shift Schedule, Sample Audit Report and Sample Responses, Computer Lab, Internship Monitoring Report, 50 Ltr Reactor, Reciever, Condensor, Rotary, Chemicals (Mandatory Solvents 14), Metal Sodium, Sieving Machine, Multi Mill, Dryer, Packaging Material, Drums, Poly Bags, Seals, Silica Gel Bags, Labels, 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		



Sr. No.	Module	Theory Duration (hh:mm)	Practical Duration (hh:mm)	Key Learning Outcomes	Corresponding NOS Code	Equipment Required
				Extinguisher, ABC Type Fire Extinguisher, Material Safety Data Sheet, Compression Machine prototype, Coating Machine Prototype, FBE Prototype, Hardness Tester, DT Apparatus, Multimill, SA9 Capsule Filling Prototype, 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, Colloid Mill , Vacuum Homogenizer Mixer, Skid CIP-WIP System, Weighing balance (1.2kg, 6.0kg with printer), Rapid mixer granulator (table top 1/5 L capacity), Double cone blender (5L Capacity), Remi stirrers, Semi-Automatic Cap Sealing Machine, Turn Table, Labelling machine, Induction machine, Dose mono filling machine Prototype, Induction Sealing Machine Prototype, Cap Sealing Machine Prototype, Labeling Machine, Automatic Self Adhesive Vertical Labelling Machine, Automatic Single Head Ropp Cap Sealing Machine, Washing Machine, Glove box isolators for potent drugs, Autoclave, Climatic chambers (300 L capacity), Monoblock Rotary Dry Powder Filling & Sealing Machine, Single Dose Filling Machine, Automatic(Liquid) Filling Machine , Tube Filling Machines For Laminated / Plastic Tubes, Multicolumn , Rectangular , teriliser , D.M. storage Tank , Dry Heat Sterilizer , Filling / Pressure Vessel, Brookfiled Viscometer, Tube Filling Machine Prototype, Preparation vessel, reactor & Storage Tank, Dispo Homogenizer, Inline Homogenizer, 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		

Grand Total Course Duration: **434 Hours 00 Minutes**

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



### Annexure1: Assessment Criteria

<b>Assessment Criteria for Production/ Manufacturing Chemist- Life Sciences</b>	
<b>Job Role</b>	<b>Production/ Manufacturing Chemist- Life Sciences</b>
<b>Qualification Pack</b>	<b>LFS/Q 1201 Ver1.0</b>
<b>Sector Skill Council</b>	<b>Life Sciences Sector Skill Development Council</b>

<b>Sr. No.</b>	<b>Guidelines for Assessment</b>
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

		<b>Marks Allocation</b>			
		<b>Total Marks (300)</b>	<b>Out Of</b>	<b>Theory</b>	<b>Skills Practical</b>
LFS/N0203 (Supervise production process)	PC1. execute day-wise/shift-wise allocated work as per defined plan to ensure adherence to production schedule	100	4	2	2
	PC2. follow-up on Dispensing/ Mixing / Granulation/ Compression/ Coating/ Filling/ Encapsulation/ Visual Inspection/ any other production activity as per Good Manufacturing Practices (GMP)		4	2	2
	PC3. fill up batch manufacturing records and log books (including online)		5	2	3
	PC4. follow-up of manufacturing activity as per Standard Operating Procedures and Batch Manufacturing Records		4	2	2



PC5. monitor batch mixing and other production activity and conditions required as per SoP/ and maintain BMR/ BPR	4	2	2
PC6. co-ordinate with quality assurance ,quality control & packing department	5	2	3
PC7. raise the incidents/deviations/change control to Quality Assurance	4	2	2
PC8. plan the equipment for idle condition to prepare for preventive maintenance and cleaning as per schedule	3	1	2
PC9. ensure that the work area is clean, dry and in a sanitized condition	4	2	2
PC10. fill the CCF (Change Control Form) for changes as mandated and create planned deviation report	5	2	3
PC11. communicate any equipment breakdown to the maintenance team as per defined organization procedure without time delay, get maintenance date and shutdown dates from maintenance team, ensure that the issues are resolves as per desired level and plan batches accordingly in order to meet the production schedules	4	2	2
PC12. online monitoring of environment conditions in the process area, quarantine area and other as defined by SoP (including necessary escalations in case of observed abnormalities)	4	2	2
PC13. calibration and verification of the balances and equipment used in the process area	4	2	2
PC14. coordinate for line clearance activities	4	2	2
PC15. carry out error free documentation of the production activities	4	2	2
PC16. minimize wastage	4	2	2
PC17. ensure optimal usage of resources by effective deployment of the same, including identification of process optimization opportunities and reducing breakdowns	4	2	2
PC18. coordinate with maintenance teams for planning preventive maintenance activities in order to resolves machine-related issues	4	2	2
PC19. execute the work as per risk control procedure	4	1	3
PC20. check the availability of dispensed raw material, packaging material and	2	1	1



	finished goods for ideal conditions, batch number and quantities				
	PC21. train down the line staff on processes and controls (including on best practices)		4	2	2
	PC22. manage manpower		6	3	3
	PC23. ensure that the production area is always audit ready		5	2	3
	PC24. provide necessary response to audit query via appropriate channel		5	3	2
	<b>Total</b>		<b>100</b>	<b>47</b>	<b>53</b>
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
	<b>Total</b>		<b>100</b>	<b>48</b>	<b>52</b>
LFS/N0204 (Coordinate with Shift Supervisor,	PC1. understand the work output requirements	100	12	6	6
	PC2. understand the quality standards to be maintained		12	6	6



cross functional teams and within the team)	PC3. proactively inform supervisor on issues requiring intervention		12	6	6
	PC4. comply with company policy and rule		13	6	7
	PC5. deliver quality work on time and report any anticipated reasons for delay		13	6	7
	PC6. be able to resolve conflicts		12	6	6
	PC7. multi-task relevant activities to align with team goals		12	6	6
	PC8. put team over individual goals		14	6	8
	<b>Total</b>		<b>100</b>	<b>48</b>	<b>52</b>
<b>Grand Total</b>			<b>300</b>	<b>143</b>	<b>157</b>
<b>Percentage Weightage</b>				<b>48%</b>	<b>52%</b>
<b>Minimum Pass Percentage to Qualify</b>				<b>70%</b>	



**Annexure2: Trainer Prerequisites for Job role: “Production/ Manufacturing Chemist- Life Sciences”  
mapped to Qualification Pack: “LFS/Q 1201 Ver1.0”**

Sr. No.	Area	Details
1	<b>Job Description</b>	To deliver accredited training service, mapping to the curriculum detailed above, in accordance with the Qualification Pack “ <u>LFS/Q 1201 Ver1.0</u> ”.
2	<b>Personal Attributes</b>	Aptitude for conducting training, and pre/ post work to ensure competent, employable candidates at the end of the training. Strong communication skills, interpersonal skills, ability to work as part of a team; a passion for quality and for developing others; well-organised and focused, eager to learn and keep oneself updated with the latest in the mentioned field.
3	<b>Minimum Educational Qualifications</b>	B.Pharma preferable/ Graduate in Science (chemistry specialization preferable for Pharmaceuticals)/ B.Tech in chemistry
4a	<b>Domain Certification</b>	Certified for Job Role: “Production/ Manufacturing Chemist-Life Sciences” mapped to QP: “ <u>LFS/Q 1201 Ver1.0</u> ” Minimum accepted score is 80% as per LSSSDC guidelines.
4b	<b>Platform Certification</b>	Recommended that the Trainer is certified for the Job Role: “Trainer”, mapped to the Qualification Pack: “SSC/1402”. Minimum accepted score is 80% as per LSSSDC guidelines.
5	<b>Experience</b>	Preferably Minimum Four (4) years’ experience in life sciences (Pharmaceutical/ Biopharmaceutical) Manufacturing occupation as Production/ Manufacturing Chemist for non-trained and non-qualified talent Or Minimum Two (2) years’ experience with Production / Manufacturing Chemist-Life Sciences Level-5 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/ Manufacturing Chemist- Life Sciences'  
QP No. 'LFS/Q 1201 NSQF Level 5'

Date of Issuance: December 24<sup>th</sup>, 2015

Valid up to: June 01<sup>st</sup>, 2016

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

Authorized Signatory  
(Life Sciences Sector Skill Development Council)



Life Sciences Sector Skill Development Council  
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