Model Curriculum

Manufacturing Assistant- Life Sciences

SECTOR: LIFE SCIENCES
SUB-SECTOR: PHARMACEUTICAL, BIOPHARMACEUTICAL
OCCUPATION: MANUFACTURING
REF ID: LFS/Q0216, V1.0
NSQF LEVEL: 2

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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: '**Manufacturing Assistant- Life Sciences'**
QP No. '**LFS/Q0216 NSQF Level 2**'

Date of Issuance: **December 28th, 2018**

Valid up to: **December 31st, 2020**

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

Authorized Signatory
(Life Sciences Sector Skill Development Council)

TABLE OF CONTENTS

Manufacturing Assistant- Life Sciences

CURRICULUM / SYLLABUS

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

Program Name	**Manufacturing Assistant- Life Sciences**		
Qualification Pack Name & Reference ID.	Manufacturing Assistant- Life Sciences LFS/Q0216, V1.0		
Version No.	2.0	**Version Update Date**	28-12- 2018
Pre-requisites to Training	**Minimum qualification –** 10th to12th Class		
Training Outcomes	**After completing this programme, participants will be able to:** • Explain the salient aspects of the life sciences industry and its pertinent regulations in order to demonstrate performance that is in line with industry standards. • Demonstrate use of scientific knowledge of pharmaceutical and bio-pharmaceutical manufacturing • Support supervisor to operate and maintain various production machines used in life sciences product manufacturing as per good manufacturing practices (GMP) • Prepare machines and accessories for the manufacturing process • Assist in manufacturing operations as per standard operating procedures (SOP) • Demonstrate cleanliness in the work area/ shop floor • Demonstrate complete and accurate reporting and documentation as per standard operating procedure (SOP), good manufacturing practices (GMP) and good documentation practices (GDP) guidelines • Act as per the environment, health and safety (EHS) norms and maintain a healthy, safe, and secure working environment in the pharmaceutical manufacturing area and the surrounding area • Practice professional skills at workplace such as decision making, planning and organizing, customer centricity, problem solving, objection handling, analytical thinking, critical thinking.		

This course encompasses 4 out of 4 Compulsory NOS (National Occupational Standards) of "Manufacturing Assistant-Life Sciences" Qualification Pack issued by "Life Sciences Sector Skill Development Council".

Sr. No.	Module	Key Learning Outcomes	Equipment Required
1	**Life Sciences Industry and Manufacturing Related Regulations** **Theory Duration** (hh:mm) 02:00 **Practical Duration** (hh:mm) 00:00 **Corresponding NOS Code** Bridge Module	• Explain the Life Sciences industry and its sub-sectors • Summarize regulatory authorities rules and regulations for manufacturing • Recall detailed norms pertaining to good manufacturing practices (GMP), good documentation practices (GDP), and 5S guidelines • Explain the organizational structure and employment benefits in Life Sciences Industry • Outline the role of a Manufacturing Assistant and practice the required skills (as per Qualification Pack)	Participant Manual, Power point presentation, Computer system, LCD Projector and Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts
2	**Health and Safety** **Theory Duration** (hh:mm) 10:00 **Practical Duration** (hh:mm) 20:00 **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 • 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 core and professional skills such as planning and organizing, problem solving, objection handling, and critical thinking	Participant Manual, Power point presentation, Computer system, LCD Projector and Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts, Chemical Absorbent Roll, CO_2 type Fire Extinguisher, Full Face Mask, Gum Boots, Half Face Mask, PVC Apron, Safety Goggles, Safety Shoes, ABC Type Fire Extinguisher, Self-Contained Breathing Apparatus
3	**Support in Manufacturing Process** **Theory Duration** (hh:mm) 20:00 **Practical Duration** (hh:mm)	• Follow clean room operations guidelines • Follow the gowning procedures as per SOP • Perform simple calculations using standard measuring units and methods as laid in SOPs • Perform support activities in manufacturing process in line with GMP/ cGMP guidelines of	Participant Manual, Power point presentation, Computer system, LCD Projector and Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts,

	50:00 **Corresponding NOS Code** LFS/N0239	pharmaceutical quality / manufacturing standards • Assist in machine operations and transportation of materials and tools as per SOPs • Perform loading and unloading of machines as per operator or supervisor instructions • Set the machines and equipments in ready state for production as per requirement and SOP • Perform safety checks, troubleshooting to ensure accuracy of equipments as per SOP • Perform dismantling and cleaning of production machines after batch manufacturing operations • Remove waste and scrap from shop floor • Perform waste disposal as per SOPs and GMP guidelines • Follow the layout design and basic signals used in factories or organizations in production line	Cables, CO2 type ,Fire Extinguisher, Full Face Mask, Glassware for Production (beaker, glass rod, flask etc.), Gloves({Heat, acid, chemical} resistant),Gloves(Nitrile) ,Gloves(washing),Gum Boots, Half Face ,Mask, Full body Gown used in Production area, Pipettes, PVC Apron, Safety Goggles, Safety Shoes, sterile Surgical Gloves, Analytical Weighing Balance, Scale, Vernier callipers, Weighing Balance, Agitator- Stirrer, Double cone blender (5L Capacity),Hot plate with magnetic stirrer, Preparation vessel, reactor and Storage Tank, Remi stirrers, Trolley, Turn Table ,Valves (reactor),water bath, Paste Kettle
4	**Workplace Cleanliness** **Theory Duration** (hh:mm) 10:00 **Practical Duration** (hh:mm) 25:00 **Corresponding NOS Code** LFS/N0103	• Maintain level of hygiene in manufacturing area • Use basic instructions and tools for housekeeping • Recall methodology for shop floor area inspection with methods and materials required for cleaning variety of surfaces and equipments • Recall methodology for lab area inspection with methods and materials required for cleaning variety of surfaces and equipments • Recall all types of stains and cleaning material required to remove the specific stain • Distinguish the area under maintenance with the help of signage or labelling • Check all types of working environment conditions (ventilation, temperature) and required personal protective equipment at the time of cleaning method and material usage. • Use correct methods as per GMP for various types of soiling and surface. • Describe all types of accidental damage at the time of work	Participant Manual, Power point presentation, Computer system, LCD Projector and Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts, Cleaning Agent (Alconox), Cleaning Agent (Soap), Gloves(washing), Gloves({Heat, acid, chemical} resistant), Lab Coat, Glassware for Production (beaker, glass rod, flask etc.), Gloves(Nitrile)

		• Assess any out of control situation and report to supervisor • Examine the shop floor for cleanliness after every batch manufacturing operation and update the cleaning status • Examine the area after cleaning activity for residue of oily substance and scrap material • Evaluate accidental damage and reinforce the GMP protocol and workplace SOPs • Assess the need of cleaning kit and supplies • Inform supervisor to initiate the procurement request for replenishing the stock of cleaning kit and supplies • Maintain stock of cleaning kit and supplies as per GMP and GDP protocols • Use personal protective equipment and after use put them at neat and clean place • Dispose waste and scrap as per SOP • Clean all equipments as per SOP and manufacturer instructions	
5	**Reporting and Documentation** **Theory Duration** (hh:mm) 10:00 **Practical Duration** (hh:mm) 25:00 **Corresponding NOS Code** LFS/N0102	• Follow the instructions given by supervisor and operator • Comprehend the written and verbal instruction and specifications of the manufacturing process that needs to be followed • Report and record the observation, details of activities performed as required by the SOPs, cGMP and WHO guidelines • Use the basic computer skills at work for record keeping as per SOPs and cGMP/WHO guidelines • Demonstrate adherence to the data integrity and information security guidelines	Participant Manual, Power point presentation, Computer system, LCD Projector and Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts, Format of Job Card, Format of Shift Schedule, Formats for BMR and BPR, Formats of Log Books, GMP Guidelines, Computer Lab
6	**Professional and Communication Skills** **Theory Duration** (hh:mm) 08:00 **Practical Duration** (hh:mm) 20:00 **Corresponding NOS Code** LFS/N0239	• Communicate with peers and supervisors • Assist in planning and execution of manufacturing activities • Use escalation matrix for reporting and problem or getting any instruction • Interpret all details while understanding the job requirement and performing the work/task assigned	Participant Manual, Power point presentation, Computer system, LCD Projector and Screen/ LCD Monitor, Mike, Sound System, Laser Pointer, White/ Black Board, White Board Marker/ chalk, duster, flip charts

	LFS/N0103 LFS/N0102 LFS/N0101		
7	**On the job Training** **Theory Duration** (hh:mm) 00:00 **Practical Duration** (hh:mm) 00:00 **OJT Duration** (hh:mm) 48:00 **Corresponding NOS Code** LFS/N0101 LFS/N0102 LFS/N0103 LFS/N0239	• Assist supervisors and operators in manufacturing process • Ensure cleanliness in the work area • Carry out reporting and documentation • Maintain a healthy, safe and secure working environment in the premises	OJT Monitoring Report
	Total Duration **Theory Duration** **60:00** **Practical Duration** **140:00** **OJT Duration** **48:00**	**Unique Equipment Required:** Participant manual, Cables, Chemical Absorbent Roll, Cleaning Agent (Alconox) (Ltr),Cleaning Agent (Soap) (Ltr),CO_2 type ,Fire Extinguisher, Full Face Mask, Glassware for Production (beaker, glass rod, flask etc.), Gloves({Heat, acid, chemical, sterile } resistant),Gloves(Nitrile),Gloves(washing),Gum Boots, Half Face ,Mask, Full body Gown used in Production area, Pipettes, PVC Apron, Safety Goggles, Safety Shoes, Weighing Balance, Scale, Vernier callipers, Weighing Balance, Agitator- Stirrer, Double cone blender, Hot plate with magnetic stirrer, Preparation vessel, reactor and Storage Tank, Remi stirrers, Trolley, Turn Table ,Valves (reactor),water bath, Paste Kettle, ABC Type Fire Extinguisher, Manual bottle eye washer, Self Contained Breathing Apparatus, Format of Job Card, Format of Shift Schedule, Formats for BMR and BPR, Formats of Log Books, GMP Guidelines Book, Material Safety Data Sheet, White Board, White Board Duster, White Board Marker, Flip Charts, LCD Projector, Ropes, Laptop/ Computer ,for trainer ,Computer, Computer Work desk, OJT monitoring report	

Grand Total Course Duration: **248 Hours (200 hours class room and skill lab training + 48 hours mandatory OJT)**

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

Trainer Prerequisites for Job role: "Manufacturing Assistant-Life Sciences" mapped to Qualification Pack: "LFS/Q0216, V1.0"

Sr. No.	Area	Details
1	**Job Description**	To deliver accredited training service, mapping to the curriculum detailed above, in accordance with the Qualification Pack "LFS/Q0216, V1.0".
2	**Personal Attributes**	Aptitude for conducting training, and pre/ post work to ensure competent, employable candidates at the end of the training. Strong communication skills, interpersonal skills, ability to work as part of a team; a passion for quality and for developing others; well-organised and focused, eager to learn and keep oneself updated with the latest in the mentioned field.
3	**Minimum Educational Qualifications**	12th Class, Graduate, Preferably B. Sc. / B. Pharma.
4a	**Domain Certification**	Certified for Job Role: "Manufacturing Assistant – Life Sciences" mapped to QP: "LFS/Q0216, V1.0". Minimum accepted score is 80% as per LSSSDC guidelines.
4b	**Platform Certification**	Recommended that the Trainer is certified for the Job Role: "Trainer", mapped to the Qualification Pack: "MEP/Q0102". Minimum accepted score is 80% as per LSSSDC guidelines.
5	**Experience**	Preferably Minimum 6 years' experience in life sciences (Nutraceutical/ Pharmaceutical/ Biopharmaceutical) Manufacturing occupation for non-trained and non-qualified talent with 12th Class / ITI educational qualification Or Preferably Minimum 4 years' experience in life sciences (Nutraceutical/ Pharmaceutical/ Biopharmaceutical) Manufacturing occupation for non-trained and non-qualified talent with B.Sc. (Chemistry) / B. Tech (Chemical Engg) educational qualification Or Preferably Minimum 2 years' experience in life sciences (Nutraceutical/ Pharmaceutical/ Biopharmaceutical) Manufacturing occupation for non-trained and non-qualified talent with M.Sc. (Chemistry) / M. Pharm. / M. Tech Chemical Engg.) educational qualification Or Minimum 3 years' experience in life sciences (Nutraceutical/ Pharmaceutical/ Biopharmaceutical) Manufacturing occupation as Manufacturing Assistant post Manufacturing Assistant-Life Sciences Level-2 (LFS/Q0216) qualification

Annexure: Assessment Criteria

Assessment Criteria	
Job Role	Manufacturing Assistant- Life Sciences
Qualification Pack	LFS/Q0216, 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 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 this criterion
5	To pass the Qualification Pack, every trainee should score a minimum of 50% in every NOS
6	In case of successfully passing only certain number of NOS's, the trainee is eligible to take subsequent assessment on the balance NOS's to pass the Qualification Pack

				Marks Allocation	
Assessment Outcome	**Assessment Criteria of outcome**	**Total Marks (400)**	**Out of**	**Theory**	**Skills Practical**
1. LFS/N0239 Support supervisors in the manufacturing process	PC1. start machines or equipment to begin production processes and work as per the production schedule	100	3	1	2
	PC2. load, stack, and transport stock, tools, dies, and work in process by hand or forklift (if requisite license is available)		4	2	2
	PC3. feed or place items into equipment for processing		3	1	2
	PC4. pull damaged or ineffective equipment off the line		3	1	2
	PC5. remove product and machine attachments		2	1	1
	PC6. scrape waste material from the machine		2	1	1
	PC7. load and unload processing equipment		3	1	2
	PC8. pour materials into the machine hopper		3	1	2
	PC9. wrap and unwrap parts, tools, and equipment		3	1	2
	PC10. signal co-workers to facilitate moving the product during processing		4	2	2

PC11. load and unload items from machines , conveyors and conveyances		4	2	2
PC12. hold tape and rods and mark reference points to assist in layout		4	2	2
PC13. select the correct material to be loaded		3	1	2
PC14. assist the supervisor in status labelling and inline weighing of product containers		2	1	1
PC15. clean and lubricate the equipment to make it fit for use as per the SOP		3	1	2
PC16. clean the approach path of obstructions for transportation from the storage area for input to the storage area for output		3	1	2
PC17. support the supervisor in assembling the machine properly		2	1	1
PC18. keep all the accessories like the cleaning brush, levers, release agent ready		2	1	1
PC19. use hands and arms in handling, installing, positioning, and moving of materials		2	1	1
PC20. perform physical activities that require considerable use of arms and legs such as climbing, lifting, balancing, walking, stooping, and handling of materials		3	1	2
PC21. transfer finished products, raw materials, tools, or equipment between storage and work areas of plants and warehouses, by hand or using hand trucks or powered lift trucks		3	1	2
PC22. observe equipment operations so that malfunctions can be detected, and notify operators of any malfunctions		3	1	2
PC23. attach slings, ropes, or cables to objects such as pipes, hoses, or bundles		2	1	1
PC24. carry out disposal of waste and leftover tested material safely as per the SOP		3	1	2
PC25. dispose all materials used in the experiment safely as per the health and safety management system of the company		3	1	2
PC26. ensure the proper handling, storage, transportation and removal of all hazardous materials		3	1	2
PC27. check for damaged labels, outdated chemicals, and damaged containers		4	1	3
PC28. ensure that there are no leakages		4	1	3

	PC29. ensure compliance with all regulations and company policies		3	1	2
	PC30. report and take corrective action in response to typical faults and inconsistencies		3	1	2
	PC31. support in calibrating the testing equipment periodically as per the SOP		4	2	2
	PC32. verify the equipment accuracy by performing trial runs		4	2	2
	PC33. respond to emergency calls for system and equipment failure		3	1	2
	Total		**100**	**39**	**61**
2. LFS/N0103 Ensure cleanliness in the work area	PC1. inspect the area while taking into account various surfaces	100	4	2	2
	PC2. identify the material requirements for cleaning the areas inspected, by considering risk, time, efficiency and type of stain		5	2	3
	PC3. ensure that the cleaning equipment is in proper working condition		5	2	3
	PC4. select the suitable alternatives for cleaning the areas in case the appropriate equipment and materials are not available and inform the appropriate person		4	2	2
	PC5. plan the sequence for cleaning the area to avoid re-soiling clean areas and surfaces		4	2	2
	PC6. inform the affected people about the cleaning activity		4	2	2
	PC7. display the appropriate signage for the work being conducted		4	2	2
	PC8. ensure that there is adequate ventilation for the work being carried out		5	2	3
	PC9. wear the personal protective equipment required for the cleaning method and materials being used		4	2	2
	PC10. use the correct cleaning method for the work area, type of soiling and surface		4	2	2
	PC11. deal with accidental damage, if any, caused while carrying out the work		4	2	2
	PC12. report to the appropriate person any difficulties in carrying out work		4	2	2
	PC13. identify and report to the appropriate person any additional cleaning required that is outside one's responsibility or skill		4	2	2

	PC14. ensure that there is no oily substance on the floor to avoid slippage		4	2	2
	PC15. ensure that no scrap material is lying around		4	2	2
	PC16. maintain and store housekeeping equipment and supplies		4	2	2
	PC17. follow workplace procedures to deal with any accidental damage caused during the cleaning process		4	2	2
	PC18. ensure that, on completion of the work, the area is left clean and dry and meets requirements		4	2	2
	PC19. return the equipment, materials and personal protective equipment that were used to the right places making sure they are clean, safe and securely stored		5	2	3
	PC20. dispose the waste garnered from the activity in an appropriate manner		5	2	3
	PC21. dispose of used and un-used solutions according to manufacturer's instructions, and clean the equipment thoroughly		5	2	3
	PC22. maintain schedules and records for housekeeping duty		5	2	3
	PC23. replenish any necessary supplies or consumables		5	2	3
	Total		**100**	**46**	**54**
3. 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,		10	5	5

	safety, and security to the designated person				
	PC8. complete any health, safety and security activities like safety drills and prepare records legibly and accurately		10	4	6
	PC9. report any hazards that the individual is not competent to deal with to the relevant person in line with organizational procedures and warn other people who may be affected		10	4	6
	PC10. follow the company's emergency procedures promptly, calmly, and efficiently		10	5	5
	Total		**100**	**48**	**52**
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**