LFS/Q1201
Production Manufacturing Chemist Theory Set 1 Final Assessment

1. **LFS/N0203 Supervise production process**

Supervise production activities

PC1. Execute day-wise/shift-wise allocated work as per defined plan to ensure adherence to production schedule

1. What can be ensured by executing day-wise/shift-wise allocated work?
   a. Adherence to shiftwork
   b. Adherence to production schedule
   c. Adherence to company work policy
   d. Adherence to management policy

PC2. Follow-up on Dispensing/ Mixing / Granulation/ Compression/ Coating/ Filling/ Encapsulation/ Visual Inspection/ any other production activity as per Good Manufacturing Practices (GMP)

2. What type of safety gear should be used while carrying out work on the production floor? (LFS/N0203-PC2)
   a. Use safety gear similar to construction site workers.
   b. Use only head and face protective gear.
   c. **Use appropriate safety gears as mentioned in the guidelines**
   d. Use only body suit masks and gloves

PC3. Fill up batch manufacturing records and log books (including online)

3. How and when should batch production records (BPR) and log books be filled? (LFS/N0203-PC3)
   a. Offline, whenever time permits
   b. Online, at the end of the shift.
   c. **Online, as soon as the activity is completed**.
   d. Offline, on a weekly basis

PC4. Follow-up of manufacturing activity as per Standard Operating Procedures and Batch Manufacturing Records

4. Which of the following is an important aspect in manufacturing activities such as mixing, granulation and coating?
   a. Visual Inspection.
   b. Instructions sheet.
   c. FDA guidelines.
   d. Factory manager's instructions

PC5. Monitor batch mixing and other production activity and conditions required as per SOP/ and maintain BMR/ BPR

5. Who has the sole responsibility of maintaining the respective log books, BPR and Batch Manufacturing Record (BMR)? (LFS/N0203-PC5)
   a. Production operator.
   b. Departmental Head.
   c. Shift in-charge.
   d. Security officer.

PC6. Co-ordinate with quality assurance, quality control & packing department

6. Based on what aspect should materials and chemicals be stored in the shop-floor? (LFS/N0203-PC6)
   a. Nature and compatibility with proper labeling.
   b. Chemical composition with name of chemical.
   c. Ascending alphabetical order.
   d. Packing size, volume and bulk.

PC7. Raise the incidents/deviations/change control to Quality Assurance

7. What document helps to one to initiate Quality Assurance about deviations in process? (LFS/N0203-PC7)
   a. Incident control standard operating procedure (SOP)
   b. Department manual for staff.
   c. Batch production record.
   d. Factory rules and regulations

PC8. Plan the equipment for idle condition to prepare for preventive maintenance and cleaning as per schedule

8. What is necessary to ensure least idle time for pressure gauges in the shop-floor? (LFS/N0203-PC8)
   a. Calibration and verification master schedule.
   b. Department guidelines
   c. Individual equipment log books.
   d. Operator's manual.

PC9. Ensure that the work area is clean, dry and in a sanitized condition

9. How should buildings used in the manufacture of APIs and intermediates be located, designed, and constructed? (LFS/N0203-PC9)
   a. To enable cleaning, maintenance, and operations.
   b. To enable men and material entry and departure .
   c. For cleaning as appropriate to the type and stage of manufacture.
   d. For operation as appropriate to the type and stage of manufacture.

PC10. Fill the CCF (Change Control Form) for changes as mandated and create planned deviation report

10. Which of the following drafts, reviews and approves proposals for Good Manufacturing Practice relevant changes? (LFS/N0203-PC10)
    a. World Health Organization (WHO).
    b. Change order department.
    c. Quality control department.
    d. Quality unit.

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

11. What is necessary to avoid break down of equipment in the shop-floor or production area? (LFS/N0203-PC11)
    a. Preventive maintenance and calibration master schedule
    b. Manufacturer's manual and calibration master schedule.
    c. Quality manual and preventive schedule.
    d. Standard calibration master schedule.

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)

12. What aspect deters the entry of pests and extraneous material from the outside into the building and from one area to another? (LFS/N0203-PC12)
    a. The design, construction and maintenance of the premises
    b. High compound walls around the area
    c. Proper screening and certification at the security gate
    d. Proper health and safety adherence by staff

PC13. Calibration and verification of the balances and equipment used in the process area

13. Which **two** aspects should usage logs for testing equipment include? (LFS/N0203-PC13)
    a. Identification of products, dates of operation
    b. Neat wrapper and labeling of product.
    c. Downtime due to frequent or serious malfunctions
    d. Signature and approval of the manager.

PC14. Coordinate for line clearance activities

14. What is required before an equipment or processing room is used for a process/activity? (LFS/N0203-PC14)
    a. Line clearance.
    b. Physical inspection .
    c. Approved label.
    d. Signature of the QA manager.

PC15. Carry out error free documentation of the production activities

15. Which of the following has the authority of issuance, revision, superseding and withdrawal of all documents? (LFS/N0203-PC15)
    a. Quality Assurance.
    b. Quality Control.
    c. Stores in-charge.
    d. Purchase department.

PC16. Minimize wastage

16. What should be done with intermediates or APIs even after purification/re-working and which cannot meet the predetermined quality? (LFS/N0203-PC16)
    a. Blend with high quality intermediates or APIs.
    b. Disposed off as per the established procedure.
    c. Mixed with n-1 intermediates or APIs.
    d. Handed over to the local waste disposal unit.

PC17. Ensure optimal usage of resources by effective deployment of the same, including identification of process optimization opportunities and reducing breakdowns

17. Which of the following is one of the methods to ensure optimal usage of resources? (LFS/N0203-PC17)
    a. Process optimization.
    b. Increase number of batches.
    c. Increasing the batch size.
    d. Achieve monthly target.

PC18. Coordinate with maintenance teams for planning preventive maintenance activities in order to resolves machine-related issues

18. Who holds the responsibility of collecting the preventive maintenance schedule from the engineering department? (LFS/N0203-PC18)
    a. Production department.
    b. Quality control.
    c. Quality assurance.
    d. Purchase department.

PC19. Execute the work as per risk control procedure

19. Which of the following is protected by the evaluation of the risk to quality and its management? (LFS/N0203-PC19)
    a. Patient.
    b. Policies.
    c. Release of the products.
    d. Queries from regulatory authorities..

Manage staff and inventory

PC20. Check the availability of dispensed raw material, packaging material and finished goods for ideal conditions, batch number and quantities

20. Until when should raw materials, packing materials, in-process (intermediate) drugs, and bulk drugs be held in quarantine? (LFS/N0203-PC20)
    a. Released by the Quality Control Department.
    b. Permission from Quality Assurance Department.
    c. Permission from Central Excise Department.
    d. Permission from the Drugs Control Department.

PC21. Train down the line staff on processes and controls (including on best practices)

21. Which of the following is required by those involved in the fabrication of drugs which is highly technical in nature? (LFS/N0203-PC21)
    a. constant vigilance, attention to detail and a high degree of competence
    b. constant vigilance, hardworking and sincere
    c. attention to details and a high degree of competence
    d. High degree of competence by both employer and customer.

PC 22. Manage manpower

22. Who directly controls and supervises the shop-floor and each working shift during which activities under their control are being conducted? (LFS/N0203-PC22)
    a. Production in charge.
    b. Production manager.
    c. Human resource manager.
    d. inward-outward officer.

Participate as a team member during audits

PC23. Ensure that the production area is always audit ready

23. What aspects help during audits for production activities such as producing Intermediates and APIs including their documentation? (LFS/N0203-PC23)
    a. Always online records.
    b. Always offline records.
    c. Sometimes online records.
    d. Sometimes offline records.

PC24. Provide necessary response to audit query via appropriate channel

24. After an audit, how should implemented corrective actions be communicated to the respective authority? (LFS/N0203-PC24)
    a. Submitting the implemented records by affixing 'uncontrolled document' seal.
    b. Sending a confirmation mail with subject 'implemented'
    c. Submitting the implemented records in person.
    d. Showing the records of implementation during next audit

2. LFS/N0101 Maintain a healthy, safe and secure working environment in the life sciences facility

Ensuring healthy, safe and secure working environment

PC1. Observe and comply with the company's current health, safety and security policies and procedures

25. Who shall **not have** access to any area where a drug is exposed during its fabrication or packaging/labeling? (LFS/N0101-PC1)
    a. Those whose health is affected or compromised in any manner.
    b. Those whose health records are not approved by the manager
    c. those with no knowledge of manufacturing process
    d. those not related to the production manager.

PC2. While carrying out work, use appropriate safety gears like head gear, masks, gloves and other accessories as mentioned in the guidelines

26. Which of the following should have written procedures for precautions, personal safety instructions, and material safety instructions? (LFS/N0101-PC2)
    a. Every department/ sub-department involved in production/ fabrication
    b. All the meetings rooms in the factory
    c. At the place where all the functions are carried out.
    d. At the time of festivals celebration at the production unit

PC3. Report any identified breaches in health, safety, and security policies and procedures to the designated person

27. What should be checked before carrying out an activity using an instrument or equipment? (LFS/N0101-PC3)
    a. Cleaning, calibration and preventive maintenance status.
    b. Cleaning and preventive maintenance status.
    c. Calibration status of all instruments
    d. Preventive maintenance status of all equipment

PC4. Responsible for maintaining discipline at the shop-floor/ production area

28. What should be avoided by personnel carrying out any activity on the production floor? (LFS/N0101-PC4)
    a. Direct contact with the intermediates and APIs.
    b. Direct contact with Equipment.
    c. Direct contact with Utility lines.
    d. Direct contact with Packing materials.

PC5. Identify and correct any hazards that the individual can deal with safely, competently and within the limits of their authority

29. What should be done if a hazard that has been noticed and corrected? (LFS/N0101-PC5)
    a. Properly documented and implemented.
    b. Instruct the next shift in-charge during handing over
    c. Brought to the notice of local factory association
    d. Brought to the notice of the maintenance members.

PC6. Adhere and comply to storage and handling guidelines for hazardous material

30. What is the criterion to follow when using hazardous material on the basis of manufacturer's COA? (LFS/N0101-PC6)
    a. Should be from the company's approved vendor list.
    b. should be a known local manufacturer.
    c. should be a well-known international manufacturer.
    d. should be from an international supplier.