

**LFS/Q2201 Production / Manufacturing Biologist  
API Practical Set 1**

**1. LFS/N0701(Supervise the bio pharmaceutical production process)**

**Supervise bio pharmaceutical production activities**

**PC1. Follow-up on bio pharmaceutical production activities as per Good Manufacturing Practices (GMP)**

**PC2. Fill up batch manufacturing records and log books**

1. Which of the following statement is **true as per term GMP for manufacturing of products?**
  - a. **GMP is implemented to minimize risk production process**
  - b. **GMP is implemented to** produce nonconformities products
  - c. **GMP is implemented to** increase risk process
  - d. All the above

**PC4. Monitoring of batch mixing and other production condition conditions for biopharmaceutical products required as per Standard Operating Procedures.**

2. Which of the following parameters are monitored during media preparation in vessels?
  - a. Agitation
  - b. Conductivity
  - c. Temperature
  - d. **All the above**

**PC5. Co-ordinate with quality assurance, quality control & packing department**

**PC6. Raise the appropriate incidents to Quality Assurance**

3. Which of the following can be considered as minor deviation ?
  - a. Changed material dispensed by ware house
  - b. Flask of stocks breakage during batch process
  - c. Filter leakage during sterile filtration.
  - d. **Skip of FEFO principle**

**PC7. Plan the equipment for idle condition to prepare for preventive maintenance and cleaning.**

**PC8. Ensure that the work area is cleaned and in a sanitized condition.**

4. Which of the following statement is **true?**
  - a. **Drains are sanitized with disinfectants solution**
  - b. Drains are sanitized with acid solution
  - c. Drains are sanitized with alkali solution
  - d. Drains are sanitized with IPA solution

**PC9. Fill the CCF (Change Control Form) and create planned deviation report**

5. Which of the following needs change control?
  - a. Shifting of portable equipment from one place to another
  - b. **Change in equipment usage during batch processing**
  - c. Change in General Control Record version.
  - d. All of the above

**PC12. Calibrate and verify of the balances used in the process area**

6. Which of the following factors affect the measuring of a material on the weighing balance?
  - a. Temperature
  - b. Vibrations
  - c. Human errors/user error
  - d. **All of the above**

**PC13. Manufacturing, labeling and packing of the products as per BMR**

7. Which of the following information should be contained on the label attached to the sample sent to Quality Control?
  - a. Protocol number/sampling plan
  - b. Stage of the sample of the batch
  - c. Name of the test should be performed
  - d. **All the above**

**PC18. Execute the work as per risk control procedure**

**PC19. Complete day wise allocated work and its documentation/ online documentation**

8. Which of the following is **false** with respect to the word “online documentation”?
  - a. Document should be completed along with the process
  - b. **Work should be done after completion of documentation**
  - c. Document should be completed as per SOP
  - d. Work should be planned for completion of documents.

**Manage staff and inventory**

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

9. Which of the following should be crosschecked before collecting the dispensed materials?
  - a. Batch number
  - b. A.R number
  - c. Approved label
  - d. **All the above**

**PC21. Train down the line staff**

**PC22. Manage manpower**

10. On what basis is the schedule planned and implemented in the manufacturing shop floor?
- To achieve maximum productivity**
  - Production schedule**
  - Availability of manpower
  - On client preference

**Participate as a team member during audits**

**PC23. Ensure that the production area is always audit ready**

**PC24. Provide necessary response to audit query via appropriate channel**

11. How can we ensure that the production area is audit ready ?
- Arranging documents as per SOP
  - Investigations
  - Internal audits
  - All of the above**

**LFS/N0101 (Maintain a healthy, safe and secure working environment in the life sciences facility)**

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

12. Which of the following statement is correct according to the health and safety policy?
- Organisations having five or more employees should have a written health and safety policy**
  - The policy should cover all incidents of the organization
  - The policy should not be revised and reviewed
  - All of the above

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

13. Which of the following PPE is used while handling flex hoses after CIP process of vessel?
- Heat resistant gloves**
  - Nose mask
  - Eye glasses
  - None of the above

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

14. If a leakage in pure steam valve gasket occurs and work still continues, then it is a \_\_\_\_\_.
- Breach of health and safety policy**
  - Deviation from the SOP
  - Being undisciplined on the shop floor
  - Root cause for batch failure

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

15. Why is it necessary to maintain discipline on the shop floor by employee?

- a. **To attain professionalism at the workplace**
- b. For punishing employees
- c. For monitoring employees
- d. None of the above

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

16. Which of the following safety precautions should be used while handling a deep freezer?

- a. **Wear cryogenic gloves**
- b. Wear safety goggles
- c. Wear rubber gloves
- d. Any of the above

**PC8. Complete any health, safety and security activities like safety drills and prepare records legibly and accurately**

17. Why are the health, safety and security records maintained?

- a. For legal compliance
- b. It ensures key information is easily retrievable
- c. It enables senior managers to monitor health and safety performance
- d. **All of the above**

**PC10. Follow your company's emergency procedures promptly, calmly, and efficiently**

18. Why is keeping calm an effective way of handling an emergency?

- a. Easier to implement safety measures
- b. Panic will lead to more chaos
- c. Can guide colleagues better
- d. **All the above**