



LFS/Q0302: Set 2
Quality Assurance Chemist Theory - Final Assessment

1. LFS/N0303 Perform Quality Checks

Pre-production checks/Documentary activities

PC1 formulate and implement regulatory policies and procedures

1. As per Indian patent act 1970, what is the basic requirement to be eligible for price exception?
 - a. A patented new drug developed using foreign R&D facility
 - b. A patented new drug developed through indigenous R&D**
 - c. A patented new drug developed in collaboration with a foreign investor
 - d. A patented new drug developed abroad and manufactured locally

2. What basic procedure should be implement for good quality pharma products?
 - a. Good inspection practices (GIP)
 - b. Good manufacturing practices (GMP)**
 - c. Good communication practices (GCP)
 - d. Good housekeeping practices (GHP)

PC2 keep oneself abreast with the current knowledge of relevant regulations

3. What basic methodology is required to be updated with relevant pharma regulations?
 - a. Maintain regular communication with the production department
 - b. Discuss with colleagues and subordinates for any new enforcement
 - c. Maintain regular communication with governing agencies**
 - d. Refer to research articles published in pharma journals

PC3 train staff in regulatory policies or procedures

4. What type of training is essential to know about legislative requirements on research in human subjects?
 - a. FDA guidelines
 - b. WHO guidelines
 - c. GCP guidelines**
 - d. GMP guidelines

PC4 to plan and participate self-inspections for various departments on the site as per predefined schedules and coordinate with cross functional teams

5. Which of the following process is covered under the scope of self-inspection in a pharma industry?
- Equipment calibration**
 - Equipment production capability
 - Equipment production capacity
 - Equipment repeatability

PC5 compiles statistical data and writes narrative reports summarizing quality assurance findings, along with review of documents

6. Which document is reviewed for consistency in product performance while summarizing quality assurance audit findings?
- Trend analysis for shift wise production
 - Trend analysis for time taken to restore the equipment after repair
 - Trend analysis of breakdown incidents
 - Trend analysis of various quality parameters**
7. Which document is reviewed to check the measures taken on the event of nonconformance while summarizing quality assurance audit findings?
- Equipment breakdown trend
 - Raw material inspection report
 - Trend analysis for quality parameters
 - Corrective and preventive action report**

PC6 assist in continuous improvement initiatives to enhance product quality, compliance, drive efficiencies and cost effectiveness of Quality Assurance team

8. Which of the following helps in continuous improvement initiatives to enhance cost effectiveness of the quality assurance team?
- Restrict material procurement
 - Reduce staff members
 - Demonstrate value engineering projects**
 - Recommend increase in product price

In-Process checks/activities

PC7 carry out sampling activities for quality assurance audit across stages

9. How are multiple stage sampling activities carried out?
- Prepare and circulate the dispatch plan
 - Prepare and circulate the maintenance plan
 - Prepare and circulate the audit plan**
 - Prepare and circulate the production plan

PC8 assess repetitive incidences of OOS and OOT. Prepare and evaluate the trend of OOS and OOT investigation periodically

10. How is the credibility of laboratory error hypothesis checked for out of specification (OOS) test results incidence?
- Cross examination of laboratory personnel for the errors made
 - Reexamination of actual solutions used in original measurements**
 - Prepare fresh solutions in an accredited laboratory and use for measurements

d. Check for past incidence of error made by the laboratory person

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

11. What should be done to comply with health and safety procedures in a pharma production plant?
- Face hazardous situations confidently
 - Carry out process optimization exercises
 - c. Wear appropriate personal protective equipment**
 - Reduce product rejection levels

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

12. Which personal protective equipment is used while working on a granulator in a pharma production plant?
- a. Nose mask**
 - Safety helmet
 - Oxygen respirator
 - Absorptive lenses

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

13. What is considered the **best first step** to be followed when reporting any identified breach in health and safety procedures?
- Report the incident immediately
 - Escalate the incident to the reporting supervisor
 - c. Record the incident before reporting to the appropriate person**
 - Take disciplinary action within the concerned department

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

14. How can discipline be maintained at shop floor/ production area?
- Recommend wage revisions
 - Provide guidance to superiors
 - c. Design bottlenecks**
 - Increase man power
15. What measures should be undertake to maintain discipline at shop floor/ production area?
- Ensure overtime from employees
 - Presence of self at all times in the shop floor
 - c. Ensure adherence to standard operating procedures**
 - Ensure timely payment to employees

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

16. What helps to correct a hazard safely, competently and within the limits of one's authority?
- Order PPEs in preparedness for such situations
 - Compare with the current controls established
 - Access the likelihood of severity/ risk before taking action**
 - Discuss with colleagues on the best way forward
17. What is the first step followed in identifying a hazard?
- List out product manufactured
 - List equipment being used
 - List activities performed**
 - List out raw materials used

PC6 adhere and comply with storage and handling guidelines for hazardous material

18. What should be accomplished to comply and adhere to storage guidelines for hazardous chemicals in a laboratory?
- Maintain limited inventory level
 - Maintain excessive inventory level
 - Maintain accurate inventory level**
 - Maintain nil inventory level
19. What is the basic procedure followed to comply storage guidelines for hazardous chemicals?
- Storing all chemicals together
 - Training on how to use the chemical
 - Proper labelling of chemicals**
 - Provision of sealed cabinets

PC7 identify and recommend opportunities for improving health, safety, and security to the designated person

20. What is the best method to identify opportunities for improving health and safety?
- Consultation and involvement with subordinates
 - Consultation and involvement with customers
 - Consultation and involvement with worker**
 - Consultation and involvement with senior management

3. LFS/N0104 Coordinate with Supervisor and team members

Coordinate with supervisor

PC1 understand the work output requirements

21. How is work output requirements understood in a quality assurance laboratory?
- a. Organizing manpower with the recruiter
 - b. Referring to SOP with the supervisor**
 - c. Discussing with workers on targets
 - d. Allocating unimportant work to subordinates
22. Which of the following methods are followed to understand work output requirements?
- a. Escalating the requirements to seniors
 - b. Referring to GMP standards**
 - c. Estimating the manpower required
 - d. Computing the number of days required to work

PC2 comply with company policy and rule

23. What guarantees an employee's compliance of the company rules and policies to the reporting supervisor?
- a. Recommend strict disciplinary actions
 - b. Providing results on time**
 - c. Increase educational credentials
 - d. Reducing department expenses
24. How can one comply with organizational rules and policies in a quality assurance department?
- a. By meeting the requirements of the work force
 - b. By meeting the terms of the code of conduct**
 - c. By meeting personal requirements of superiors
 - d. By meeting the demands of subordinates

PC3 proactively inform supervisor on issues requiring intervention

25. For which of the following information is the supervisor's intervention required?
- a. Over target productivity
 - b. Quality deviations**
 - c. When mean time to repair is more
 - d. When mean time between failures is less
26. When should the supervisor take note and action information received?
- a. Leave sanctioning activity
 - b. Equipment malfunction**
 - c. Low customer orders
 - d. Low productivity

PC4 deliver quality work on time and report any anticipated reasons for delays

27. What helps delivery of quality work in a timely manner?
- a. Understanding operational problems

b. Clear interpretation of requirements

- c. Increasing technical qualification
- d. Understanding manufacturing feasibility of a product

28. What step should be followed to deliver quality work on-time?

- a. Reduce unnecessary manpower
- b. Use statistical analysis techniques**
- c. Decrease process cycle time
- d. Ensure staff availability at all times

Coordinate with team members

PC5 Put team over individual goals

29. What helps to put the team over individual goals?

- a. Convincing
- b. Common understanding
- c. Dictating
- d. Motivation**

30. What sort of support towards team members helps to put the team over their individual goals?

- a. Political
- b. Personal finance
- c. Personal expenses
- d. Moral**