LFS/Q1301 Set 1
Quality Control Chemist (Assessment 2) V3 Final Assessment

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

Commented [SV[1]]: NOS 1 to 4 have been approved for QCC-Version 1

Only NOS 5 & 6 requires validation

Ensuring healthy, safe and secure working environment

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

1. What is the reason for designating separate areas for smoking, eating, drinking, chewing and storage of food items?
   a. **Company's health, safety and security policies and procedures**
   b. To encourage individuals to follow policies and procedures
   c. Required by certain religions to do so
   d. Human resource requirement of the company

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

2. Which of the following should be used to protect self from accidents or injury while carrying out work in quality control?
   a. Use whatever the other workers are using
   b. Head gear and face mask
   c. **Safety gear as mentioned in the guidelines**
   d. Gloves and apron as mentioned in the guidelines

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

3. What should be done in case of an instrument or equipment breakdown/ malfunction?
   a. Notify the production manager
   b. Ensure the security officer is alerted
   c. Repair it and continue with work
   d. **Notify the supervisor and maintenance team**

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

4. What is an important criterion to be followed to carry out any type of analysis in a quality control laboratory?
   a. Good behavioral practices (GBP) and good manufacturing practices (GMP)
   b. Good factory practices (GFP) and good manufacturing practices (GMP)
   c. Good individual practices (GIP) and current good manufacturing practices (cGMP)

d. **Good laboratory practices (GLP) and current good manufacturing practices (cGMP)**

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

5. What should be done when hazards are identified during analysis and needs to be corrected?
   a. **Deal safely, competently and within the limits of the individual's authority**
   b. Inform the housekeep department
   c. Deal with the issue on the basis of previous experience
   d. Ask friend and colleagues to handle the emergency

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

6. How should hazardous materials handled in the quality control laboratory be stored?
   a. **Separately**
   b. With other material
   c. Wherever space is available
   d. In a closed environment

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

7. A heavy duty laboratory equipment has an exposed wire. Under which of the following categories can it be considered?
   a. Electrical
   b. Emergency
   c. **Health, safety and security**
   d. Security, electrical and electronic

PC8 complete any health, safety and security activities like safety drills and prepare records legibly and accurately

8. What can be ensured by training personnel on onsite emergency plan?
   a. Knowing how to avoid danger
   b. Knowledge of material safety procedures
   c. **Role specific handling of emergencies**
   d. Contacting the right department

Managing emergency procedures

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

9. What should be done if a colleague is involved in malpractice or malfunction in the production of quality product?
   a. **Escalate to immediate supervisor**
   b. Try to rectify the error unknown to the other person
   c. Confide it to family members
   d. Expose it on social media

PC10 follow the company's emergency procedures promptly, calmly, and efficiently

10. Why should every employee be trained on the Onsite Emergency Plan?
    a. **To ensure appropriate behaviour in times of emergency**
    b. To safeguard against damage to premises
    c. To evacuate people and material safely
    d. To safeguard the security personnel

2. LFS/N0103 To ensure cleanliness in the work area

Pre housekeeping activities

PC1 inspect the area while taking into account various surfaces

PC2 identify the material requirements for cleaning the areas inspected, by considering risk, time, efficiency and type of stain

11. What should be included in the sanitation program for those dealing with chemicals?
    a. Cleaning procedures for personnel
    b. Cleaning procedures for the premises
    c. **Cleaning procedures for the premises, personnel and the equipment**
    d. Cleaning procedures for the equipment where the drug is fabricated or packed/labelled

PC3 ensure that the cleaning equipment is in proper working condition

PC4 select the suitable alternatives for cleaning the areas in case the appropriate equipment and materials are not available and inform the appropriate person

12. What is the criterion for equipment that is used to clean the laboratory?
    a. Should be of a good brand
    b. Should be from a reputed company
    c. **Should be in a proper working condition**
    d. Should be used by quality control manager

PC5 plan the sequence for cleaning the area to avoid re-soiling clean areas and surfaces

PC6 inform the affected people about the cleaning activity

13. What should every equipment/ instrument in the laboratory have?
    a. **Proper label with used status and cleaning status with the signature of the designate**
    b. Label with instrument code, employee ID and signature
    c. No label but the last used date is required
    d. Cover and brand name

PC7 display the appropriate signage for the work being conducted
PC8 ensure that there is adequate ventilation for the work being carried out
PC9 wear the personal protective equipment required for the cleaning method and materials being used

14. What should be used for one's safety while carrying out cleaning work in the laboratory?
    a. Safety gears as mentioned in the company guideline
    b. Head and eye gear
    c. **Appropriate Personal Protective Equipment (PPE)**
    d. Gloves and overalls

Operations

PC10 use the correct cleaning method for the work area, type of soiling and surface
PC11 deal with accidental damage, if any, caused while carrying out the work

15. What should a company's written cleaning procedure explain?
    a. Use of general detergent for all
    b. **Type of cleaning agent for every type of floor, equipment and glass ware**
    c. Use common cleaning agent invariable of floors, equipment and glass ware
    d. Use of only water

PC12 report to the appropriate person any difficulties in carrying out work
PC13 identify and report to the appropriate person any additional cleaning required that is outside one's responsibility or skill

16. Why should issues such as cracking of surfaces, peeling of paint, a hole in the door, window, ceiling or floor be notified immediately?
    a. **To ensure work flow is not hampered**
    b. It is a security policy compliance
    c. For proper upkeep of fixtures
    d. It is an ISO standard

Post housekeeping activities

PC14 ensure that there is no oily substance on the floor to avoid slippage
PC15 ensure that no scrap material is lying around

17. What is one of the **chief** causes for slips and trips in a laboratory?
    a. **Oily substances or spills on the floor**
    b. During transfer of material from stores
    c. Used equipment kept for cleaning
    d. Blocked staircase

PC16 maintain and store housekeeping equipment and supplies
PC17 follow workplace procedures to deal with any accidental damage caused during the cleaning process

18. What should be ensured to have an effective housekeeping activity?
    a. Heavy duty power points
    b. **Proper housekeeping SOP**
    c. Equipment and cleaning agents
    d. Efficient procurement team

PC18 ensure that, on completion of the work, the area is left clean and dry and meets requirements
PC19 return the equipment, materials and personal protective equipment that were used to the right places making sure they are clean, safe and securely

19. What is the basic principle for storing equipment, materials and protective gear?
    a. First-in-first-out basis
    b. At a convenient and reachable place
    c. Where ever space is available
    d. **Everything should be stored in its designated place**

PC20 dispose the waste garnered from the activity in an appropriate manner
PC21 dispose of used and un-used solutions according to manufacturer's instructions, and clean the equipment thoroughly

20. How should used and un-used solutions be disposed?
    a. **As per SOP and regulatory guidelines**
    b. As per instructions of the senior technician
    c. As per instructions of quality control manager
    d. As per instructions of town municipal/city corporation

3. LFS/N0314 To carry out reporting and documentation to meet quality standards
Reporting
PC1 report defects/problem/incidents/quality issues/test results as applicable in a timely manner

21. What should be done if an 'impurity' which is essential for carrying out Thin Layer Chromatography analysis is exhausted?
    a. Use another category of impurity and document the same
    b. Use a supplement to complete the job and report the incident
    c. **Reported and documented immediately as per process**
    d. Ensure the test results are not visible to others

PC2 report to the appropriate authority as laid down by the company
PC3 follow reporting procedures as prescribed by the company

22. Whom should we intimate when a colleague is observed to be carrying out titration without wearing safety goggles?
    a. **The reporting supervisor**
    b. Manager of safety equipment
    c. Chief security officer
    d. All department heads

PC4 work with production management and quality assurance to provide feedback regarding quality standards and issues

PC5 help other R&D lab staff with any other testing required during the developmental work

23. To fulfill pharmacopoeal requirements, with which other department/s should QC coordinate to decrease the level of an impurity found in a finished product?
    a. Production
    b. Research and development
    c. Technology transfer
    d. **All the above**

Recording and documentation

PC6 identify documentation to be completed relating to one's role

PC7 record details accurately in appropriate format

24. Where should activities related to equipment usage, in a quality control laboratory, be recorded?
    a. **Respective log books**
    b. Departmental manual
    c. Instruction register
    d. Personal dairy

PC8 accurately document the results of the inspections and testing

25. Apart from regular QC activities such as testing, releasing of intermediates, raw materials, etc. what is a criterion that should be in line with standard operating procedure?
    a. Safety of the material
    b. Detailed log books
    c. Personal safety
    d. **Online documentation**

PC9 maintain all controlled document files and test records in a timely and accurate manner

26. How should test reports of a finished product, which was analysed a year ago, be submitted when requested by an auditor?
    a. Submit as and when a report is asked for
    b. All reports submitted in the manager's cabin
    c. **In an orderly and accurate manner**
    d. Along with batch production records

PC10 ensure that the final document meets regulatory and compliance requirements

PC11 make sure documents are available to all appropriate authorities to inspect

27. What aspects should a final document meet which is being sent to the US market?

a. Drug control norms
b. **USFDA regulatory requirements**
c. Customer requirements
d. Local corporation norms

PC12 evaluate problems and make initial recommendations for possible corrective action to supervise

28. Why is evaluation needed for changing the column used if there is continuous deterioration in the resolution criteria between two impurities under related substances by Gas chromatography technique?
    a. To ensure there is sufficient documentation to validate
    b. To motivate the personnel to do better in the next round of tests
    c. To ensure better control over the personnel
    d. **To make initial recommendations for possible corrective action**

PC13 perform review of records and other documentation for compliance to established procedures and good documentation practices

29. For which of the following is good documentation practice (GDP) most important?
    a. Regulatory requirements
    b. Product development
    c. Product market share
    d. Process requirement

PC14 write and update the inspection procedures, protocols and checklists
PC15 prepare inspection reports as per the inspection activity performed

30. What is the basis for preparing inspection reports?
    a. Per the quality manual
    b. **Per the activity performed**
    c. Per the batch production record
    d. Per the previous quality data