

Quality Control Chemist - Microbiology (API) Practical Set 1 Final Assessment

LFS/N0321: Perform inspection of incoming materials

PC1. observe, monitor and identify microorganisms and their growth/colonies in the sample and conduct tests like LAL tests for detecting endotoxins, etc.

PC2. monitor and assess samples from a range of sources like raw material sampling (microbiology), microbiological analysis of water for purified water and raw water for MCT/ BET/ Sterility

PC3. use a variety of identification methods, like molecular testing to test samples

1. Growth is observed as a pellicle at the liquid-air interface in a test tube during microbiological testing of a water sample. Identify the class under which this microbe falls as per its oxygen requirement.
 - a. **Obligate aerobes**
 - b. Obligate anaerobes
 - c. Microaerophiles
 - d. Aerotolerant bacteria

PC4. identify the reason for unwanted growth of microorganisms and check for OOT and OOS samples

PC5. manage and oversee the laboratory work with respect to maintaining sterile conditions and work in isolation (wherever needed)

PC6. work with specialised computer software to undertake studies and research and train production line staff for sterile conditions, good micro trial operations

2. Identify the class of microbes that can be handled safely at Biosafety level 1?
 - a. Microbes that cause moderate hazards to personnel and environment
 - b. Microbes that can cause serious potential hazards to personnel and environment
 - c. **Microbes which normally do not cause any disease in healthy humans**
 - d. Microbes which can cause non-treatable serious or lethal hazards to personnel

PC7. identify and classify microorganisms found in specimens collected from humans, plants, animals, or the environment

PC8. validate test methods and undertake calibration exercises

PC9. serve as the primary contact for all QC Microbiology related filings and inspections of Regulatory Agencies

3. Which of the following is an example for comma shaped bacteria?
 - a. *Staphylococcus aureus*
 - b. ***Vibrio cholerae***
 - c. *Shigella*
 - d. *Salmoella typhi*

PC10. undertake culture/media preparation to conduct quality analysis on the samples and maintain standard cultures

PC11. maintain restricted access to the microbiological laboratory as per cGMP and GLP guidelines

4. Match the following microbes with the media used specifically for their culture.

I. <i>Shigella</i>	A. MacConkey agar
II. <i>Staphylococcus aureus</i>	B. Cetrimide agar
III. <i>Pseudomonas aeruginosa</i>	C. Gram negative (GN) broth
IV. <i>Escherichia coli</i>	D. Mannitol salt agar

- I-D, II-A, III-B, IV-C
- I-C, II-D, III-B, IV-A**
- I-C, II-B, III-D, IV-A
- I-D, II-B, III-A, IV-C

PC12. minimize the risks of cross-contamination, false-positive and false-negative results

PC13. define alert and action limits and maintain positive and negative controls during testing as considered appropriate

PC14. fulfil requirements of sterility testing like aseptic conditions

5. How can cross-contamination be prevented?
- Carrying out operations on different products in different areas
 - Providing adequate air control to prevent generation and spreading of dust
 - Ensuring that there is no residue on the equipment/operator
 - All of the above**

PC15. ensure that all reagents (including stock solutions), media, diluents and other suspending fluids are adequately labelled to indicate the identity, concentration, storage conditions, preparation date, validated expiry date and/or recommended storage period

6. What is the maximum temperature used for cryopreservation?
- 196°C
 - 186°C
 - 135°C**
 - 155°C

LFS/N0322: Perform research work to support the development of new products

PC1. grow strains of bacteria in various conditions to understand their reaction

7. Match the following types of bacteria with their respective growth temperatures.

A. Mesophiles	1. 4°C -25°C
B. Psychrophiles	2. 20°C -45°C
C. Thermophiles	3. <0°C
D. Hyperthermophiles	4. 80°C -110°C
E. Psychrotrophs	5. 50°C -80°C

- A-III, B-II, C-IV, D-I, E-V
- A-II, B-I, C-IV, D-V, E-III
- A-II, B-III, C-V, D-IV, E-I**
- A-III, B-IV, C-II, D-V, E-I

PC2. work with technicians, chemists and scientists of other fields to contain the growth of microorganisms

8. Identify the statement, which correctly defines decimal reduction time or D-value.
- Time taken to reduce the microbial population by 90%**
 - Time taken to reduce the microbial population by 80%
 - Time taken to reduce the microbial population by 70%
 - Time taken to completely eliminate a microbial population

PC3. present research findings to scientists, non-scientist executives, engineers, other colleagues, and the public

PC4. keep up with new research

9. Which of these search engines has articles that are primarily present in the MEDLINE database?
- Google scholar
 - CiteSeer
 - Pubmed**
 - Scirus

PC5. attend national and international conferences and other events

10. How can one ensure that research is made available to scientists across the world?
- By presenting the research data in national and international conferences
 - By presenting the research data in lab meets
 - By publishing your research in relevant journals
 - Both a and c**

PC6. work with specialised computer software to undertake studies and research

11. Which of these is a program used for visualization of articles and management of references?
- Scientific journal finder (SJ finder)
 - Mendeley**
 - ContentMine
 - Scopus

LFS/N0314: Carry out reporting and documentation to meet quality standards

PC1. report defects/problem/incidents/quality issues/test results as applicable in a timely manner

PC2. report to the appropriate authority as laid down by the company

PC3. follow reporting procedures as prescribed by the company

12. What should be done when a microbial spill is detected?
- Inform the reporting Supervisor and act as per web-based protocol
 - Inform the reporting Supervisor and act as per company protocol**
 - Carry on your work without informing anybody
 - Evacuate the place without informing anybody

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

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

PC7. record details accurately in appropriate format

13. What are the documents to be maintained for each microbial seed lot?
- Origin and subculture history records
 - Storage and proliferation conditions
 - Batch manufacturing records
 - Both a and b**

PC8. accurately document the results of the inspections and testing

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

PC10. ensure that the final document meets regulatory and compliance requirements

14. How could one ideally prevent potential damage to technical/scientific records?
- Storing them in easily accessible locations
 - Training staff on the creation/modification of records
 - Implementing restricted access to storage areas
 - Both b and c**

PC11. make sure documents are available to all appropriate authorities to inspect
PC12. evaluate problems and make initial recommendations for possible corrective action to supervise

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

15. Which of the following are allowed in a document compliant with good documentation practices (GDP)?
- Ditto marks
 - Data recorded in pencil
 - Handmade changes not dated
 - Data recorded in indelible ink**

PC14. write and update the inspection procedures, protocols and checklists

PC15. prepare inspection reports as per the inspection activity performed

PC16. respond to requests for information in an appropriate manner whilst following organizational procedures

PC17. inform the appropriate authority of requests for information received

16. The term "CIA" in information security refers to _____.
- Confidentiality, Independence, and Accountability
 - Control, Interdependence, and Accountability
 - Control, Integrity, and Availability
 - Confidentiality, Integrity, and Availability**

LFS/N0104: Coordinate with Supervisor and team members

PC1. understand the work output requirements

PC2. comply with company policy and rule

17. _____ is a guideline used for establishing environmental management systems in organizations.
- ISO 9001
 - ISO14001**
 - OHSAS 18001
 - OHSAS 18002

PC3. proactively inform supervisor on issues requiring intervention

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

18. What should be the action taken when there is a biological spill detected?
- Inform supervisor and act as per company procedure**
 - Ignore the issue
 - Evacuate the place without informing anybody
 - Create panic amongst all employees regarding the spill

PC5. put team over individual goals

PC6. be able to resolve conflicts

19. Which of the following can be the most effective step in resolving conflicts that are personal in nature?
- Understand destructive conflicts
 - Meet up for a resolution
 - Discuss the impact on work
 - Discuss and respect perspective for both sides**

PC7. learn how to multi-task relevant activities

PC8. impart training to team members/cross-function team members

20. If an employee has to perform endotoxin tests on a sample, he/she should refer USP chapter _____.
- 85**
 - 31
 - 71
 - 62

LFS/N0320: Carry out quality checks in the quality control process.

PC1. ensure that total range of checks are regularly and consistently performed

PC2. use appropriate measuring instruments, equipment, tools, accessories etc. ,as required

21. A QCC Microbiologist is checking whether the photo fluorometer and its required accessories are supplied as per the purchase order placed. What kind of qualification does this fall under?

- a. Design qualification
- b. **Installation qualification**
- c. Operational qualification
- d. Performance qualification

PC3. ensure the status and accuracy of instruments used for measurement

PC4. identify non-conformities to quality assurance standards

22. When microbial growth is detected during a product test for sterility, what should the QCC Microbiologist be concerned about?

- a. Adherence to the test protocol
- b. Equipment used for analysis
- c. Mode of working of the analyst
- d. **All of the above**

PC5. identify potential causes of non-conformities to quality assurance standards

PC6. identify impact on final product due to non-conformance to company standards

23. Which of these techniques is best suited for the determination of root cause when a process is being evaluated stepwise?

- a. 5 Whys
- b. **Process mapping**
- c. Kepner Tregoe (KT) matrix
- d. Qualitative tools

PC7. evaluating the need for action to ensure that problems do not recur

PC8. suggest corrective action to address problem

PC9. review effectiveness of corrective action

24. Which of the following requirements should CAPA fulfil?

- a. It should address the root cause of the non-conformity
- b. Action suggested should be implementable
- c. Monitoring phase should be included to ensure its effectiveness
- d. **All of the above**