

Examination Content

National Registry of Certified Microbiologists
SM: Pharmaceutical and Medical Device

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A list of the topics tested on the exam is provided below. Questions are classified first by area and then by specific topic. The examination will have at least one question from each topic.

LABORATORY INSTRUMENTS AND EQUIPMENT (24 questions)

1. Use and monitor sterilization equipment (e.g., autoclaves, ovens, ethylene oxide, radiation)
2. Use and monitor filters for sterilization of solutions
3. Use and monitor incubation devices such as ambient air, carbon dioxide, anaerobic and constant water temperature devices
4. Use and interpret data from a pH meter or conductivity meter
5. Use locally controlled environmental systems (e.g., biosafety cabinets, unidirectional [laminar] flow cabinets, isolators)
6. Use various types of microscopes
7. Use colorimetric and spectrophotometric equipment
8. Use electronic data processing equipment (chart recorders, multi-point data recorders) and understand electronic data trending (storage, retrieval, auditing, electronic signature; Code of Federal Regulations, title 21, section 11 [21 CFR 11])
9. Calibrate and maintain lab equipment

LABORATORY PREPARATIONS (10 questions)

10. Evaluate media (general, selective and differential) for growth, isolation, and identification of bacteria and fungi
11. Perform medium growth promotion tests
12. Use stains, both general and for specific structures (spores, flagella, capsules)

SAMPLE COLLECTION AND HANDLING (11 questions)

13. Select appropriate means of disposal for analyzed or unanalyzed samples
14. Use appropriate documentation procedures for controlled substances or samples involved in legal action (e.g., chain-of-custody documentation)
15. Select appropriate methods for sample storage and transport

16. Prepare samples for microbiological analyses (e.g., proper mixing, dilutions, dispersing, neutralization of microbial inhibitors)
17. Select appropriate sample plans, sample collection materials, and sample collection equipment

LABORATORY PROCEDURES (41 questions)

18. Identify and apply biochemical tests for bacterial identification (e.g., carbohydrate fermentations, redox reactions, catalase, coagulase, oxidase)
19. Isolate and identify coliforms
20. Isolate and identify common water-borne bacteria (e.g., *Pseudomonas* species, *Bulkholderia* species)
21. Isolate and identify common manufacturing environment fungi (e.g., *Aspergillus* species, *Penicillium* species, *Cladosporium* species, yeast)
22. Perform microbiological procedures for the evaluation of water and potable water
23. Perform measurements for the growth of microorganisms (e.g., substrate utilization, plate counts, turbidity)
24. Understand when to use "most probable number" (MPN) technique
25. Perform microbial tests on disinfectants (e.g., MIC, AOAC Use Dilution)
26. Perform identification of bacteria using biochemical, genetic, or chromatographic procedures (e.g., DNA probes, polymerase chain reaction [PCR], sequencing, fatty acid methyl esters, carbohydrate utilization)
27. Identify types of techniques used to detect viruses and/or mycoplasma
28. Evaluate new test procedures or procedures that are alternative to compendial procedures
29. Apply rapid microbiological techniques (e.g., bioluminescence, impedance, cytometry)
30. Isolate and identify gram-positive organisms
31. Isolate and identify gram-negative organisms
32. Perform and validate tests for sterility

33. Perform and evaluate tests for bioburden
34. Perform tests for bacterial endotoxins (*Limulus* amoebocyte lysate [LAL])
35. Perform and validate tests for the effectiveness of preservatives (e.g., USP[51], CTFA Preservative Adequacy Test)
36. Identify biocompatibility tests for medical devices (e.g., cytotoxicity, mutagenicity [Ames])
37. Perform immunoassays (e.g., ELISA, precipitation, agglutination, immunofluorescence)
38. Apply techniques for evaluating container/closure systems

**LABORATORY OPERATIONS
(27 questions)**

39. Monitor proper handling of hazardous chemicals, radioactive materials, and biological agents
40. Establish and maintain Standard Operating Procedures (SOP's) (e.g., methods, procedures, equipment maintenance, calibration, repair, replacement)
41. Develop and maintain effective laboratory quality systems (e.g., documentation, controls, trend analysis of laboratory data, proficiency testing)
42. Maintain stock cultures and preserve biological specimens
43. Develop and maintain laboratory safety practices
44. Apply appropriate statistical and analytical techniques to test results
45. Make recommendations for action based on analytical results, including failure investigation
46. Document and maintain an on-going training program
47. Perform risk analysis for determining objectionable microorganisms and actions to take)

**MANUFACTURING EQUIPMENT, FACILITIES, AND PROCESSES
(29 questions)**

48. Establish and maintain environmental monitoring procedures (e.g., of personnel; in laboratory, production areas, warehouses)
49. Evaluate clean-in-place and sterilize-in-place systems (e.g., validation procedures, monitoring procedures, trouble-shooting)
50. Define terminology and techniques used to determine lethal rates of microorganisms (e.g., sterility assurance level, *D* value, *F₀* value)

51. Perform and/or evaluate audits of contract manufacturers and laboratories
52. Understand and apply good laboratory practices according to existing regulations (e.g., U.S. Food and Drug Administration [FDA], Good Laboratory Practices [21CFR Part 58], AOAC International ISO 17025 [Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals])
53. Use centrifuges and/or ultracentrifuges
54. Apply concepts of the validation of filters for product sterilization
55. Evaluate and validate manufacturing processes, fill lines, and packaging
56. Monitor gowning for sterile manufacturing processes
57. Validate and monitor cleanrooms and controlled environments
58. Monitor and evaluate compressed gases used in manufacturing processes (e.g., air, oxygen, nitrogen)
59. Validate and monitor water purification systems (e.g., deionized water, purified water, water for injection, biofilm control)
60. Validate sterilization and depyrogenation processes (e.g., steam, dry heat, gas, radiation)

**REGULATIONS
(8 questions)**

61. Demonstrate knowledge of Good Manufacturing Practices (Code of Federal Regulations, Part 210, 211, 600)
62. Demonstrate knowledge of compendial and standard methods for microbiological analysis (e.g., AOAC International, United States Pharmacopeia and National Formula [USP-NF], and FDA Bacteriological Analytical Manual [FDA-BAM])