Table 16-6 Examples of Test Questions Related to Aseptic Manufacturing Practices

Objective Questions

1. Define basic terms: sterile, sterility assurance, aseptic, aseptic processing, terminal sterilization, endotoxin, pyrogen, bioburden, clean room grad and class, HEPA filter, laminar flow, media fill.
2. Identify the criteria required for facilities and type of equipment used in an aseptic environment.
3. Describe the value/limitations of laminar flow/sanitization in promoting sterility.
4. Define environmental monitoring and identify what it can and cannot do to assure sterility.
5. Identify the steps required for vial/stopper preparation.
6. Define and explain six sterilization methods.
7. Describe the materials used in container/closure systems and the pros/cons of each type.
8. Identify the factors that contribute to sterility assurance.
9. Describe the unit operation steps in aseptic processing.
10. Identify five major sterility issues that affect pharmaceutical companies today.
11. Identify the topics covered within FDA guidelines on aseptic processing and explain key points associated with each topic.
12. Evaluate case studies related to sterility assurance/aseptic process validation issues. Determine the appropriate course of action to take based on your understanding of FDA guidelines and GMPs.

True or False Questions

1. Air samples are quantitatively accurate.
2. Microbiology is an exact science.
3. Contamination detected by active air samplers means that the product made at the same time is contaminated.
4. Air sampling devices are generally equal in their ability to detect contamination.
5. Statistics plus sampling plan analysis is sufficient to enable you to create a formula for determining accept/reject of a product lot.
6. Microbes will survive forever in a clean room unless killed by a disinfectant.
7. Microbes develop resistance to chemical disinfectants over time; therefore, disinfectants must be rotated.
8. Once released into a clean room environment, microbes will proliferate.
9. Microbes are highly motile and can easily float and fall into a product.
10. RODAC plates give the best data when used at the END of a day because they can find all contamination that might have fallen out of the air.
11. Sampling of product contact surfaces after completion of an aseptic process can give excellent indication of the environmental conditions.
12. Microbiological data can be trended and evaluated using ordinary statistical methods.
13. Detection of a number of CFUs (colony forming units) higher than expected is cause for immediate concern.
14. Anaerobes, molds, and yeast are common contaminants in aseptic processing areas and monitoring for their presence is essential.
15. The aseptic environment is full of organisms that cannot be detected in our EM (environmental monitoring) programs. These organisms pose a serious health threat to consumers.
16. Formaldehyde and UV light are not effective antimicrobial agents.
17. Lack of sterility assurance has been the no. 1 reason for recalls for the past 4 years. The greatest number of these recalls occurred in 2001.
18. In certain situations, it can be acceptable to use a non-sterilized tool for an intervention during aseptic processing.
19. About half of the drug products recalled due to nonsterility over the past 10 years were produced by aseptic processing.
20. Data indicating loss of environmental control may not always need to be treated seriously.
21. According to the FDA, there may not be any level of microcontamination in aseptic processing rooms.
22. FDA becomes very concerned about EM data when they show an adverse trend. A single atypical result is not cause for alarm.
23. FDA is very concerned about temperature differences inside and outside a freeze dryer that result from air flowing into the chamber when the chamber door is open. This air must be HEPA-filtered.
24. The FDA has not identified any concerns related to barrier/isolator technology, which is why so many pharmaceutical companies are interested in using it.
25. Loss of GMP control in aseptic rooms is usually the result of poor equipment design.
26. Equipment design issues outweigh poor personnel practices in causing deviations in acceptable environmental monitoring data.
27. Invalidation of a media fill is acceptable if the deviation would also be cause for aborting a commercial run.
28. You can justify removing a unit of media if the unit legitimately would be removed as part of the aseptic process during an intervention.