

## SCENARIO 29

Your company renovates your aseptic fill facility. Your fill group must sample the environment, people, and process used to aseptically fill your company's product.

**Explain the tasks involved in performing these tests.**

*The results of the test fail the acceptance criteria because 10 of the 3,000 vials filled are contaminated.*

**How do you identify the source of the problem, and what suggestions do you make to your group?**

### WORKPLACE SETTING FOR THIS SCENARIO

- A) Generic (Applies to B, C, D)
- B) Research and Development ◆
- C) Manufacturing ◆
- D) Clinical Laboratory

### KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication • Documentation/Tracking
- Quality Systems (QC, QA)
- Troubleshooting Equipment Failure
- Troubleshooting Methods Failure

### TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

- B-1 Follow SOP and batch record (protocol or procedure)
- B-2 Obtain raw material
- B-3 Set up equipment according to process requirements
- B-4 Perform cleaning (manual/CIP) and sterilize (autoclave/SIP)

- B-5 Prepare buffers and solutions
- B-6 Start up production
- B-8 Obtain, process, and store product samples (applies to all manufacturing steps)
- B-10 Formulate, fill, and inspect product
- C-5 Handle, transport, store sample, including legal requirements
- F-1 Check calibration and perform system diagnostics
- F-2 Validate processes, equipment, facilities, kits, vendor products
- F-3 Perform or schedule preventive maintenance
- F-4 Clean work area according to SOPs
- F-5 Sample environment
- F-6 Implement systems updates
- F-7 Maintain equipment logs
- F-8 Troubleshoot and repair equipment (work order)
- F-9 Label equipment and facilities
- F-10 Ensure clean room integrity
- H-1 Follow regulations: FDA (GMPs and GLPs)
- I-6 Monitor production lines
- I-9 Participate in proficiency testing
- K-2 Coordinate tasks with coworkers
- N-1 Participate in training and cross-training
- N-6 Document training

### TASKS FOR SOLVING PROBLEM(S)

- B-3 Set up equipment according to process requirements
- B-4 Perform cleaning (manual/CIP) and sterilize (autoclave/SIP)
- B-8 Obtain, process, and store product samples (applies to all manufacturing steps)
- F-2 Validate processes, equipment, facilities, kits, vendor products
- F-4 Clean work area according to SOPs
- F-5 Sample environment
- F-8 Troubleshoot and repair equipment (work order)
- F-10 Ensure clean room integrity
- H-1 Follow regulations: FDA (GMPs and GLPs)

- H-2 Check, verify integrity of the product, procedure, specimen
- I-4 Maintain QA logs
- J-1 Collect data
- J-2 Perform calculations
- J-3 Perform basic statistical analysis
- J-4 Evaluate validity of results
- J-5 Identify abnormal results
- J-6 Document and report test results
- J-7 Obtain written or verbal verification
- K-1 Interact with vendors, colleagues, and clients
- K-2 Coordinate tasks with coworkers
- K-3 Write or update protocols, procedure manuals, and reports for validation
- K-4 Write memos or letters
- K-5 Make oral presentations
- K-6 Process information using computers
- K-7 Notify appropriate persons about problems and observations
- L-3 Maintain laboratory notebook
- N-5 Read technical literature
- N-8 Maintain professional demeanor

### SKILLS, KNOWLEDGE, ATTRIBUTES

#### General Work Skills

Basic Math (Fractions, Percentages, Metric System)  
 Communication (Electronic, Oral, Written)  
 Critical Thinking  
 Decision-Making  
 Organization Skills  
 Prioritizing Tasks  
 Resource Management  
 Teamwork  
 TQM/Total Quality Management

#### Industry-Related Knowledge

Engineering  
 Microbiology/Lab  
 Quality Control and Quality Assurance Practices  
 Regulatory Standards  
 Safety Systems  
 Scientific Method

#### Industry-Related Skills

Aseptic Technique

Identifying Irregular Results  
 Maintaining Records, Logs, Protocols  
 Performance Consistency  
 Troubleshooting Ability  
 Upkeep of Equipment/Work Area

#### Attributes

Alertness  
 Common Sense  
 Conscientiousness  
 Creativity  
 Handles Constructive Criticism  
 Handles Failure  
 Honesty  
 Integrity  
 Interest in Work  
 Leadership  
 Meticulousness  
 Observant  
 Responsibility  
 Thoroughness  
 Works Well with Many Different People