Contamination Problem Example

Instructions:

1. Use this FDA 483 observation to perform and investigation and analysis using the DMAIC form and the blank fishbone diagram (the rest of the 483 is also available for download).
2. Use the CAPA form to document what could be done to correct and prevent this contamination from occurring in the future.

OBSERVATION 2

You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in an area adjacent to the ISO 5 classified aseptic processing area during aseptic production.

Specifically, eleven (11) colony forming units (cfus) were identified in your firm's Hazardous Buffer Room (ISO-7 Classified) during viable air sampling conducted on 18 September 2019 at location "Trailer-(b) (4) Hazard Room". The firm's Sample Analysis Results, dated 23 September 2019, documents the colony identifications are: Gram-positive rods; micrococcus; staphylococcus colagulase (-); and other fungi. According to your firm's sampling plan and the firm's Sample Analysis Results report, your firm has not resampled in this location ("Trailer-(b) (4): Hazard Room") ensuring the area is acceptable to continue aseptic operations prior to this FDA inspection. In addition, your firm did not consider inadequate facility designs (Please refer to **OBSERVATION 4 & 8**); the condensation unit or water evaporation tray of the refrigerators located in the ISO-7 Classified areas (Please refer to **OBSERVATION 4, 7, & 8**); inadequate cleaning practices (Please refer to **OBSERVATIONS 1, 3, 6**); non-sterile gowning, and/or exposed skin (Please refer to **OBSERVATION 5**). In addition, your firm's inpatient pharmacy supervisor stated (b) (4) cleanings are routinely scheduled to occur prior to EM sampling.

Your firm continued aseptic operations in this room from 18 September 2019 – present, with the exception of the following closures:

- 15 – 30 October 2019
- 04 – 18 December 2019

Your firm's vendor, (b) (4)., who performs Environmental Monitoring (EM) of your cleanrooms, has identified the following viable air sampling failures in 2019:

Date	Location	Colony Forming Unit (cfu) Count	Colony Identification
07/08/2019	Trailer-(b) (4) Hazard Room (corner – between BSCs)	1	Other Fungi
09/18/2019	Trailer-(b) (4): Hazard Room (corner – between BSCs)	11	Gram-positive rods; Micrococcus; Staphylococcus Colagulase (-); and Other Fungi
09/18/2019	Trailer-(b) (4) Hazard AnteRoom (Shelf)	18	Gram-positive rods; Micrococcus; Staphylococcus Colagulase (-)
09/30/2019	Trailer-(b) (4) Hazard Room Near (b) (4)	4	Gram-negative rods; Staphylococcus Colagulase (-); and Other Fungi
10/08/2019	Trailer-(b) (4): Hazard Room Near (b) (4)	3	Gram-negative rods; Staphylococcus Colagulase (-)
11/26/2019	Trailer-(b) (4) Hazard Room Near (b) (4)	1	Other Fungi

According to your firm's 6-month prescription log, your firm compounded approximately (b) (4) units of sterile drug products in your firm's Hazardous Room.