OBSERVATION 1

Sporicidal agents are not used in your facility's cleanrooms and/or ISO 5 area.

Specifically, the firm does not use a sporicidal agent to clean the surfaces in the ISO 5 laminar flow hoods or the ISO 5 IV Room and ISO 6 Chemo Room floors, walls, and ceilings. The firm is required to use (b)(4)(b)(4) to clean the ISO 5 laminar flow hoods (b)(4) operations and (b)(4) work orders and the cleanroom floors (b)(4) with (b)(4). The (b)(4) cleaning of the ISO 5 laminar flow hoods and cleanrooms includes cleaning with (b)(4) solution. On 06/14/2016, viable air monitoring was conducted in the firm's facility. The ISO 6 Chemo Room sample location received out-of-compliance test results and Bacillus species were recovered from the sample. On 12/01/2016, viable air monitoring was also conducted in the firm's facility. The ISO 6 Chemo Room sample location received growth of microorganisms and Bacillus species were recovered.
OBSERVATION 2

Beta-lactam drugs were produced without providing adequate containment, segregation, and cleaning of work surfaces and personnel to prevent cross-contamination.

Specifically,

The firm produces both penicillin drug products and other sterile human drug products in (b) (4) laminar flow hood. On 07/06/2017, I observed the firm's sterile drug production technician produce the following products in (b) (4) laminar flow hood: Ceftriaxone 2gm in 20ml SWFI-IVP; Vancomycin 1.25gm in 250ml 0.9% NaCl; Mercopenem 500mg in 100ml 0.9% NaCl and Oxacillin 2gm Q6hr (16g/300ml sterile water). The firm's current cleaning practice is to only use (b) (4) in the laminar flow hood (b) (4) different products, and (b) (4) On 07/06/2017, I observed the firm's technician produce Oxacillin 2gm Q6hr (16g/300ml sterile water) which resulted in spillage of the finished drug product on the work surface. The technician only wiped down the work surface with (b) (4) after the completion of the work order. On 07/18/2017, I observed that the technician did not wipe down the laminar flow hood with any cleaning agent between work orders for sterile Vancomycin 1.5gm in 250ml 0.9% NaCl and Ceftriaxone 2gm in 100ml 0.9% NaCl.

OBSERVATION 3

Non-microbial contamination was observed in your production area.

Specifically,

On 07/18/2017, I observed that the top metal ceiling grate in the ISO 5 laminar flow hood in the Chemo Room had a reddish-brown residue on the holes of the ceiling grate. This laminar flow hood is used for the production of sterile chemotherapy drug products.