Equipment, materials, and/or supplies are not disinfected prior to entering the aseptic processing areas.

Specifically, inadequate aseptic practices were observed while transferring materials on 4/18/2017 during the aseptic processing of 7 units of Ertapenem 1 gm/100 ml Rx [0(6), 0(7),0] including the following:

-Pharmacy technicians wiped down IV bags with sterile IPA but without gloves prior to putting bags in prep room (ISO-8) and then directly moving bags from the prep room (ISO-8) into the hood (ISO-5) without disinfesting the bags;

-Vials of sterile drug products were removed from product boxes and were not cleaned. These vials were subsequently placed directly under the hood (ISO-5) without being disinfected;

Additionally, while bins that are used for transferring all of the components and ingredients for sterile drug production are wiped down on the inside; these bins are routinely stacked on top of each other with the components such as vials inside. Therefore, vials of active ingredients are touching the bottom of a bin while being transferred from the prep room (ISO-8) to the compounding room (ISO-7) and these vials are subsequently placed directly under the hood (ISO-5) without being disinfected.

OBSERVATION 2

The use of sporicidal agents in the cleanroom and/or ISO 5 area is inadequate.

Specifically, the adequacy of cleaning frequency has not been appropriately assessed to ensure potential contaminants are removed from surfaces in the ISO-5 classified area. For example, sporicidal agents that are used on a monthly basis are insufficient to assure the prevention of spores when, on a daily basis, intake materials are
not disinfected prior to being placed under the ISO-5 hood. In addition, your firm does not have data to support that the current established contact time of 10 minutes is sufficient to remove sporicidal activity.

OBSERVATION 3
Beta-lactam drugs are produced without adequate cleaning procedures to prevent cross contamination. Your firm’s cleaning procedures are limited to use of sterile water and IPA (70%). There is no dedicated area for processing Beta-lactam products. Your firm has two ISO-5 hoods and beta-lactam products are processed in both. For example, 7 units of Ertapenem 1 gm/100 ml Rx were processed under the same hood on 4/18/2017.

This is a repeat observation.

OBSERVATION 4
Aseptic environmental conditions are not assured by current monitoring practices.

Specifically,

The dynamic smoke study video that we viewed demonstrated an operator standing at the hood making manipulations with one IV bag at the top of the hood. This was not representative of aseptic processing operations observed from 04/17-19/2017. We observed your staff aseptically processing on the bench, with components, equipment (such as the TPN mixer or the repeater pump), and other items which can affect laminar air flow.