1. Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically,

On 09/20/2018, I observed an Operator donning a used disposable coverall. While donning, the legs of the coveralls contacted the floor of the Ante Room.

2. Disinfecting agents and cleaning pads or wipes used in the ISO 5 area [aseptic processing areas] are not sterile.

Specifically,

On 09/17/2018, I observed non-sterile wipes applied to surfaces within the ISO 5 area of the workbench in the non-hazard clean room, where aseptic processing of sterile products occurs. The wipes were identified as lint-free wipes. Products produced in the ISO 5 area workbench on 09/17/2018 include, but is not limited to the following:

- Milrinone 0.8mg/ml 165ml, Rx Number: (b) (6), Quantity: (b) (4)
- Methylprednisolone 1g/100ml, Rx Number: (b) (6), Quantity: (b) (4)