Observation 1

Disinfecting agents and cleaning pads and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically, your firm cleans the interior of the ISO-5 classified located within your sterile cleanroom suite using non-sterile wipes prior to the aseptic production of drug products. Your firm uses non-sterile wipes to perform this cleaning process. There has been no assessment related to the use of non-sterile wipes in the ISO-5 classified area where aseptic processing occurs.

Observation 2

You had inadequate HEPA filter airflow over the area to which sterile product was exposed.

Specifically, on April 12, 2017, your firm performed an air pattern analysis (smoke study) of the sterile cleanroom suite and ISO-5 classified areas. The smoke studies conducted within the ISO-5 classified areas were inadequate as the smoke used was faint and intermittent. The ISO-5 classified areas were not...
certified under dynamic conditions and unidirectional airflow was not verified under operational conditions. The smoke studies did not include the transfer of starting components and materials into the ISO-5 classified areas, transfer of in-process products into a sterile (b)(4) or transfer of product into final container closure.

*DATES OF INSPECTION
2/06/2018(Tue), 2/08/2018(Thu), 2/09/2018(Fri), 2/12/2018(Mon), 2/13/2018(Tue), 2/15/2018(Thu), 2/21/2018(Wed), 2/27/2018(Tue)