OBSERVATION 1
The ISO classified area underwent a change in air equipment and you continued to produce and distribute sterile drugs.

Specifically, you replaced the air to the sterile suite on February 6, 2019, due to issues with maintaining the coolness of the air on multiple occasions. Your firm continued to produce and distribute sterile drugs while and after the air to the sterile suite was replaced without adequate cleaning and recertification following the installation.

OBSERVATION 2
Inadequate pressure differentials between higher quality air room and lower quality air rooms were observed.

Specifically, you had negative or zero pressure for short periods of time in the buffer room (ISO 7) and anteroom (ISO 8) on January 2, 2019. Additionally, there were multiple times on twenty-one days when the pressure was lost in the room from November 28, 2018 to December 28, 2018. You have no pressure data for January 24, 2019 to February 7, 2019 between the anteroom and room as well as when the room was being changed.
OBSERVATION 3
The use of sporidical agents in the cleanrooms and ISO 5 area is inadequate or infrequent.

Specifically, you do not use a sporidical cleaner at a minimum monthly.

OBSERVATION 4
Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worse-case activities and conditions that provide a challenge to aseptic operations.

Specifically, your media fills include (b) (4) with minimal manipulations and do not include syringes at all or the number of syringes produced for stock solutions.

OBSERVATION 5
Personnel donned gowning apparel improperly, that may have caused the gowning apparel to become contaminated.

Specifically, you don non-sterile face masks in an uncontrolled environment which do not cover your entire face and lean into the ISO 5 hoods during aseptic operations.