DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1
Personnel touched equipment or other surfaces located outside of the ISO 5 classified aseptic processing area with gloved hands and then engaged in aseptic processing without changing or sanitizing gloves.

Specifically, on 07/14/21 we observed the operator fail to sanitize their gloves after touching equipment located on the ISO 7 mixing room table and before returning their gloves to handle materials within the ISO 5 Biological Safety Cabinet (BSC) during (b) (4) of compounded inhalation drug product, Albuterol/Ipratropium Bromide 2.5 mg/0.75 mg Solution for Nebulizer, Lot 071421-1, BUD 01/10/2022.

OBSERVATION 2
Personnel in an area that blocked the movement of first pass air around an open unit, either before or after it was filled with sterile product.

Specifically, on 7/14/21 we observed the operator place an IV bag containing (b) (4) drug product over the ISO 5 BSC air return vents, blocking downward airflow for approximately ten (10) seconds following (b) (4) of compounded inhalation drug product, Albuterol/Ipratropium Bromide 2.5 mg/0.75 mg Solution for Nebulizer, Lot 071421-1, BUD 01/10/2022.

*DATES OF INSPECTION
7/12/2021(Mon), 7/13/2021(Tue), 7/14/2021(Wed), 7/15/2021(Thu), 7/16/2021(Fri), 7/19/2021(Mon), 7/21/2021(Wed), 7/22/2021(Thu), 7/23/2021(Fri)
Dylan A. Herr, Vice President Quality and Compliance

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Producer of Sterile Drugs

Jolanna A Norton, Investigator  
Gunneet Kaur, Investigator

7/23/2021
The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."