DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	3/15/2022-4/13/2022* FEI NUMBER 3014577316

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Jacqueline A. Biery, Manufacturing Pharmacy Manager

FIRM NAME	STREET ADDRESS
Providence Health and Services Washington Dba Providence Infusion Hospital Services	3333 S 120th Pl Ste 100c
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Tukwila, WA 98168-5134	Outsourcing Facility

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

The flow of components, drug product containers, closures and in-process materials through the building is not designed to prevent contamination.

Specifically,

On 03/17/2022, during the production of ceFAZolin 3 gram per 30mL Syringe, Lot: (b) (4) a compounding technician used a (b) (4) cabinet to transfer the compounded sterile drug product from your ISO 7 classified Cleanroom (b) (4) to an unclassified Room (b) (4) during filling operations multiple times.

In addition, your firm management stated that the (b) (4) cabinet leading from the unclassified Room (b) (4) to the ISO 7 classified Cleanroom (b) (4) was used to move items needed for the sterile drug production of ceFAZolin (b) (4) times from 01/01/2021 to 03/20/2022.

For instance, your firm produced ceFAZolin 2g per 20mL Syringe, Lot: (b) (4) on 02/11/2022. During the production of this lot of ceFAZolin your management stated the (b) (4) cabinet was used to transfer items used in the sterile drug production.

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*DATES OF INSPECTION

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Kenneth O Gee, Investigator X Kenneth O Gee Investigator Signed By: 2001873861 Date Signed: 04-13-2022 15:48:36	4/13/2022

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3/15/2022(Tue), 3/16/2022(Wed), 3/17/2022(Thu), 3/18/2022(Fri), 3/21/2022(Mon), 3/22/2022(Tue), 3/23/2022(Wed), 3/24/2022(Thu), 3/25/2022(Fri), 3/28/2022(Mon), 3/29/2022(Tue), 3/30/2022(Wed), 4/01/2022(Fri), 4/04/2022(Mon), 4/05/2022(Tue), 4/06/2022(Wed), 4/07/2022(Thu), 4/13/2022(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Kenneth O Gee, Investigator	X Kenneth O Gee Investigator Signed By: 2001873861 Date Signed: 04-13-2022 15:48:36	4/13/2022

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."