DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	12/10/2024-12/18/2024* FEI NUMBER 3013236711

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Richard L. Crockett, Medical Center Director

FIRM NAME	STREET ADDRESS
Overton Brooks VA Medical Center	510 E Stoner Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Shreveport, LA 71101-4243	Producer of Sterile and Non-Sterile Products

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

Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically,

During production of Fluorouracil 50mg/ml in your firm's hazardous clean room on 12/11/2024, your firm's pharmacist inadvertently threw away the drug product from the ISO-5 hood prior to adding the total amount needed to the finished product. Your pharmacist retrieved the drug product from the hazardous waste bin located under the ISO-5 hood, wiped the vial with sterile (b) (4), then proceeded to use the product to finish producing. This hazardous waste bin was approximately 3/4th full of various hazardous products when the pharmacist retrieved the Fluorouracil. Your pharmacist was on their way to put the finished product in the pass through for use when I stopped them to ask what they planned to do with the product. Your pharmacist then decided to remake the product.

In addition, your pharmacist did not perform decontamination and deactivation cleaning steps in the ISO-5 work area after introducing product from the hazardous waste bin. Your pharmacist proceeded to remake the drug product which was administered to an immunocompromised veteran.

OBSERVATION 2

Personnel infrequently changed and sanitized gloves to prevent contamination.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Logan T Williams, Investigator	X Logan T Williams Investigator Signed By: 2002955055 Date Signed: 12-18-2024 14:21:29	12/18/2024

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During production on 12/11/2024, I observed the following instances of infrequent glove changes/sanitation:

- ☐ During production of leucovorin 10mg/ml in the chemo buffer room, I observed your pharmacist remove vials and packaging components from the ISO-5 workspace to make room to work. After disposing of the vials and components in the trash bin and hazardous bin, the pharmacist returned to production in the ISO-5 hood without sanitizing their gloved hands. This leucovorin product was administered to a veteran.
- ☐ During production of leucovorin 10mg/ml in the chemo buffer room, I observed your pharmacist remove their hands from the ISO-5 environment to verify a label outside of the ISO-5 environment. The pharmacist returned to the ISO-5 hood without sanitizing their hands. This leucovorin product was administered to a veteran.
- ☐ During production of enfortumab vedotin-ejfv 10mg/ml in the chemo buffer room, I observed your pharmacist remove their hands from the ISO-5 hood, adjust their face mask, then return to production activities. The pharmacist adjusted their face mask a second time in the same manner approximately one minute later and returned to the ISO-5 hood. The pharmacist did not sanitize their hands in either instance. Thie enfortumab vedotin-ejfv product was administered to a veteran.
- ☐ During production of fluorouracil 50mg/ml in the chemo buffer room, your pharmacist's shoe cover fell off. They replaced the shoe cover by picking it up off the floor. The pharmacist then proceeded to the pass through and opened it. The pharmacist did not sanitize their hands prior to touching the pass through door. In addition, the pharmacist did not change their glove prior to returning to the ISO-5 environment. This fluorouracil product was administered to a veteran.
- ☐ During production activities on 12/11/2024 in the chemo buffer room, your pharmacist changed gloves twice over approximately three hours. During these glove changes, your pharmacist used the old outer glove in a manner that would contaminate the new glove by touching sterile areas of the new glove.

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☐During production of fluorouracil 50mg/ml, your pharmacist lowered their mask to allow lip reading by personnel from outside the chemo buffer room during production while they were standing in the ISO-7 environment. The pharmacist did not change gloves after lowering their mask and the pharmacist did not sanitize their gloves until they reentered the ISO-5 environment. This fluorouracil product was administered to a veteran.

OBSERVATION 3

Failure to conduct media fills that closely simulate aseptic production operations under the worst-case, most-challenging, and stressful conditions.

Specifically,

Media fills are performed filling (b) (4)) media into vials. Your firm does not produce any products in vials. The most common final packaging is IV Bag followed by syringe. Your firm's current media fill protocol requires operators to perform (b) (4) sets of (b) (4) transfers into a final vial container. During production of on 12/11/24, I observed up to ten or more transfers. (b) (4) vials were reconstituted and then each vial's contents were filled into an IV bag during production of enfortumab vedotin-ejfv 10mg/ml in the chemo buffer room.

***DATES OF INSPECTION**

12/10/2024(Tue), 12/11/2024(Wed), 12/12/2024(Thu), 12/13/2024(Fri), 12/16/2024(Mon), 12/17/2024(Tue), 12/18/2024(Wed)

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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."