

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER

Division of Pharmaceutical Quality Operations I
10 Waterview Blvd, 3rd Floor
Parsippany, NJ 07054
ORAPharm1_responses@fda.hhs.gov

DATE(S) OF INSPECTION

02/05/2020-02/27/2020

FBI NUMBER

3011110195

Industry Information: www.fda.gov/oc/industry

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Vincent Immiti, MBA, FACHE, Medical Center Director

FIRM NAME

VA New Jersey Health Care System

STREET ADDRESS

385 Tremont Ave

CITY, STATE, ZIP CODE, COUNTRY

East Orange, NJ, 07018

TYPE ESTABLISHMENT INSPECTED

Producer of Sterile Drug 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 WE OBSERVED:

OBSERVATION 1

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

Specifically,

On 02/11/2020, pharmacy technician^{(b) (6)} was observed touching the plunger of the syringe 5 times during the production of Rituxamb.

OBSERVATION 2

Your firm produced drugs while construction was underway in an adjacent area without adequate controls to prevent contamination of the production environment and product.

Specifically,

A. The Hazardous Area (Room # 8-206A), containing the ISO 5 Classified Biological Safety Cabinet, where aseptic production is performed. The Ante room entrance door is located in a common hallway accessible to employees. On 02/07/2020, we observed approximately 2 to 3 maintenance personnel,

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Jana Bernard

DATE ISSUED

02/27/2020

2/27/2020

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<small>INDUSTRY INFORMATION: www.fda.gov/oc/industry</small> <small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Mr. Vincent Immiti, MBA, FACHE, Medical Center Director		<small>FBI NUMBER</small> 3011110195
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performing maintenance on the ceiling tiles in the hallway, while construction was being performed approximately 5 feet from the entrance of the Ante room door.

B. The Non-Hazardous Area, containing the ISO 5 Laminar Air Flow Hood, where aseptic production operations are performed. The Ante room entrance door is located in a common hallway accessible to employees. On 02/07/2020, we observed approximately 2 to 3 maintenance personnel, performing maintenance on the ceiling tiles in the hallway, while construction was being performed approximately 5 feet from the entrance of the Ante room door.

OBSERVATION 3

Vermin was observed in an area immediately adjacent to your sterile production area.

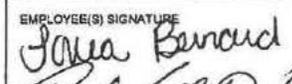
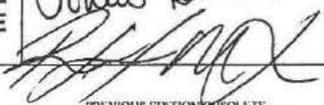
Specifically,

On 02/07/2020, while reviewing records in the pharmacy, a gnat was observed by the entry door of the Ante Room. The entry door is located approximately 2 feet from the Hazardous Room, which contains the Biological Safety Cabinet for the admixture of sterile intravenous (IV) drug products.

OBSERVATION 4

The ISO classified aseptic processing areas are difficult to clean and contained visibly dirty equipment or surfaces.

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We observed the following in your firm's ISO classified areas, where aseptic human drug production takes place (this includes, but is not limited to, the following observations in the areas designated below):

A. Inside your firm's Laminar Air Flow Hood and Biological Safety Cabinet (ISO 5 classified):

1.) On 02/07/2020, visible white cluster powder buildup was observed on the florescent light cover located on the ceiling of the Laminar Air Flow Hood (ISO 5 Hood). In addition, on 02/07/2020, we observed pharmacy technician producing the following drugs while the white cluster powder build-up was visibly present: Vasopressin, Ferric Gluconate, and Meropenem.

2.) On 02/11/2020, visible white dusty powder residue was observed on the stainless-steel rod located in the Biological Safety Cabinet (ISO 5 Cabinet). In addition, on 02/11/2020, we observed pharmacy technician^{(b) (6)} producing Cisplatin in the Biological Safety Cabinet while the white dusty powder residue remained on the stainless-steel rod in the Biological Safety Cabinet.

B. Visible reddish-brown discoloration that appears to be rust was observed in the Ante-Room, Non-Hazardous and Hazardous areas:

1.) On 02/07/2020, visible reddish-brown rust-like material appeared on the grating of the HEPA filters that face the work surface were observed in the Laminar Flow Hood (ISO 5 Hood)

2.) On 02/07/2020, visible brown stains were observed alongside the windowsills located in Non-Hazardous and Hazardous rooms. The windowsills are located approximately 2 to 5 feet away from Biological Safety Cabinet and Laminar Flow Hood.

3.) On 02/07/2020, visible reddish-brown rust-like material was observed on the sink located in the ante-room. The sink is used as a hand washing station.

C. Visible signs of debris and residue build-up were observed in the ante-room. The following are examples observed:

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<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Mr. Vincent Immiti, MBA, FACHE, Medical Center Director		
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- 1.) On 02/07/2020, dust accumulation located on the upper right corner of the main door entering the ante room.
- 2.) On 02/07/2020, dust on the air vent above the entry door in the ante room. The air vent is located approximately 5 feet from the Hazardous Room.
- 3.) On 02/14/2020, off-white residue on the sink faucet and on both computers, CPUs located in the ante room, which is approximately 3 to 5 feet away from the Hazardous Room.
- 4.) On 02/14/2020, dust, black dirt particles and a vial of Vancomycin 1 gm Lot #: 53100 EXP: 05/01/2017 were found underneath the "medication supply shelf and computer stations" located approximately 2 to 4 feet away from the Non- Hazardous Area.

OBSERVATION 5

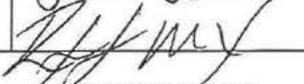
Use of cleaning and disinfecting agent past their expiry date.

Specifically,

On 02/07/2020, pharmacy technician (b) (6) was observed using (b) (4) Brush/Sponge (b) (4), lot # (b) (4) Exp: 2019-01 to disinfect his hands prior to the production of Vasopressin, Ferric Gluconate and Meropenem, despite the disinfecting agent being expired.

OBSERVATION 6

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

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	<small>FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE</small>	

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Specifically,

The firm utilizes (b) (4) (b) (4) non-sterile wipes for cleaning of the surfaces of ISO-5 area. The (b) (4) wipes are not labeled as sterile. On 02/11/2020, the non-sterile (b) (4) Wipes were observed being used by pharmacy technician (b) (6) to clean inside the Biological Safety Cabinet after production of Cisplatin on: 02/11/2020.

OBSERVATION 7

Sporicidal agents were not used in your facility's cleanrooms and/ or ISO 5 classified aseptic processing area.

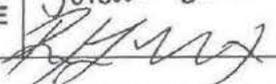
Specifically,

The firm does not use sporicidal agents to clean the interior surfaces of the ISO 5 areas. On 02/11/2020, the (b) (4) (b) (4) and (b) (4) Sterile (b) (4) (b) (4) Wipes were observed being used to clean inside of the Biological Safety Cabinet after production of Cisplatin. In addition, these wipes are not labeled sporicidal.

***DATES OF INSPECTION**

02/05/2020, 02/07/2020, 02/10/2020,02/11/2020,02/12/2020,02/14/2020, 02/27/2020

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