

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

DISTRICT ADDRESS AND PHONE NUMBER

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Baltimore, MD 21215  
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Industry Information: [www.fda.gov/oc/industry](http://www.fda.gov/oc/industry)

DATE(S) OF INSPECTION

03/09/2015 - 03/11/2015

FEI NUMBER

3003432602

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

**TO: Meredyth C. Nelson, Chief, Pharmacy Service**

FIRM NAME

Hunter Holmes McGuire Veterans Admin  
Medical Center

STREET ADDRESS

1201 Broad Rock Blvd

CITY, STATE, ZIP CODE, COUNTRY

Richmond, VA 23224

TYPE ESTABLISHMENT INSPECTED

Producer of Sterile Drugs

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**

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and written.

Specifically, smoke studies have not been conducted (under dynamic conditions) to ensure that there is laminar flow of air in ISO 5 and 7 areas to include documentation that operators and equipment do not have detrimental effects on the laminar flow of air, and also showing that turbulence and stagnant air are not the condition in critical areas.

When media fill (process simulation) is conducted, media used and incubated does not include a positive control to show media can promote growth, nor are Lots of media tested at receipt to ensure that it will encourage growth. And, specifically, the media selected is not demonstrated at your facility to support growth of gram-negative & gram-positive bacteria, yeast and mold.

**OBSERVATION 2**

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Although spore-forming microorganisms (such as bacillus) have been identified in processing areas from environmental monitoring conducted, sporicidal cleaning agents are not used.

A multi-use wet mop was found used to clean floors in ISO 7 areas lacking assurance that repeated use of the same mop stored wet in a bucket does not add to the bioburden of areas cleaned.

Disinfection/cleaning procedures do not include directions and schedules for cleaning ceilings and walls in ISO 7 areas, and the use of all cleaning agents, such as non-sterile (b) (4) used in cleaning ISO 7 areas, are not included.

**SEE REVERSE  
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Michael A. Charles, Investigator  
Zachery L. Miller, Investigator

DATE ISSUED

03/11/2015

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**OBSERVATION 3**

Written records are not made of investigations into unexplained discrepancies.

Specifically, there are not written procedures established in order to ensure that discrepancies are thoroughly investigated. For example, no investigation was conducted when:

Personnel environmental surface samples were taken on 5/24/2014 but no results were recorded. No investigation was conducted to determine why this discrepancy happened and what the results might be, nor were there documented actions to correct and prevent this discrepancy from recurring.

When a tray below ISO 5 Hood <sup>(b)(4)</sup> was found with a surface sample result of 1 CFU on 1/17/2014, results for the tray on ISO 5 Hood <sup>(b)(4)</sup> having the same configuration and the possibility of similar resulting analytical values, were not recorded/documented and no written investigation was conducted.

When colonies <10 CFU were found on a sink surface in a support (Ante) area on 11/19/2014, no documented investigation to pursue root cause was conducted, and corrective/preventative actions, as well as follow-up, were not recorded.

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Michael A. Charles, Investigator Zachery L. Miller, Investigator	DATE ISSUED 03/11/2015
		