

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

New Orleans District Office

404 BNA Dr., Bldg. 200, Ste. 500

Nashville, TN 37217-2597

615) 366-7801 Fax: (615) 366-7802

DATE(S) OF INSPECTION

02/06-10/2017; 02/13-17/2017

FEI NUMBER

3013236711

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

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Richard L. Crockett, Interim Medical Center Director

FIRM NAME

Overton Brooks VA Medical Center

STREET ADDRESS

510 E Stoner Ave

CITY, STATE, ZIP CODE, COUNTRY

Shreveport, LA 71101-4243

TYPE ESTABLISHMENT INSPECTED

Producer of Sterile Drug Products

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OBSERVATION 1

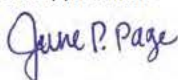
The system for cleaning and disinfecting the aseptic processing areas are deficient.

Specifically,

1. (b) (4) cleaning within the pharmacy cleanrooms were done sporadically.
 - a. The Environmental Management Service (EMS) department is responsible for conducting (b) (4) cleanings ((b) (4) cleanings) and (b) (4) cleanings (mopping floors and cleaning door handles). For example, 2016 pharmacy cleaning records document:
 - i. No (b) (4) cleanings occurred (b) (4).
 - ii. No (b) (4) cleanings occurred (b) (4).
 - b. Pharmacy staff is responsible for conducting (b) (4) cleanings of the (b) (4) Laminar Air Flow Workspace LAFW (ISO 5 Hood) and (b) (4) (ISO 5). For example, 2016 pharmacy cleaning records document:
 - i. (b) (4) cleanings did not occur (b) (4) for the (b) (4) (ISO 5).
 - ii. (b) (4) cleanings did not occur (b) (4) for the LAFW (ISO 5 Hood).
2. Housekeeping personnel stated they have entered into the ISO 7 areas to mop and empty the trash while a pharmacist or pharmacy technician is actively performing aseptic operations.
3. Visible discoloration that appears to be rust was observed:
 - a. on the (b) (4) staging shelf, located approximately 3 feet from the LAFW (ISO 5 Hood);
 - b. on the outside wall on the left side of the LAFW (ISO 5 Hood); and
 - c. on the return air vents.
4. Visibly discolored HEPA filters were observed in the LAFW (ISO 5 Hood), located in the IV Buffer room. According to your firm, the HEPA filters have not been replaced since at least 2012.

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DATE ISSUED

02/17/2017

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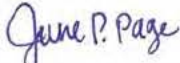

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5. Visible signs of debris and residue build-up were observed in the following ISO 5 areas located in the IV Buffer Room:
 - a. underneath the "grate" (return air slots) located on the edge of the LAFW (ISO 5 Hood);
 - b. on the florescent light cover located on ceiling of LAFW (ISO 5 Hood);
 - c. around the bolts where the HEPA (b) (4) meets the LAFW (ISO 5 Hood);
 - d. on and under the (b) (4), used in the (b) (4) process, located on the LAFW (ISO 5 Hood).
6. Visible signs of debris and residue build-up were observed in the following ISO 7 areas located in the IV Buffer Room:
 - a. underneath the supply shelf, located approximately 1½ feet from the LAFW (ISO 5 Hood);
 - b. on the automatic light switch, located approximately 1½ feet from the LAFW (ISO 5 Hood); and
 - c. alongside the (b) (4), located approximately 5 inches from the LAFW (ISO 5 Hood).
7. A thread-like material that appeared to be from a mop head was observed on the wheel of the (b) (4) (ISO 5) located in the ISO 7 area of the IV Chemo room.
8. Lint-free cloths used for cleaning in the LAFW (ISO 5 Hood) and (b) (4) (ISO 5) are not sterile.
9. On 02/10/2017, in the IV chemo buffer room (ISO 7), a chair was observed to not be suitable as a cleanroom chair; and appears to be not easily cleanable, and may not ensure aseptic cleaning.

OBSERVATION 2

Your firm continued producing sterile drug products while construction was ongoing within your facility without establishing adequate controls to prevent contamination of the production environment.

Specifically, your firm produced sterile drugs on 06/10/2010 and did not have adequate controls in place to protect the production environment within these areas. The initial air certification for the clean rooms (ISO 7 and ISO 8 areas), LAFW (ISO 5 Hood) and (b) (4) (ISO 5) were completed on (b) (4). However, the occupancy release date for the clean rooms was (b) (4). Furthermore, additional construction occurred in the general pharmacy area during this time and was not completed until 02/01/2011. Your firm continued to produce sterile drug product in the Chemo Buffer Room and IV Buffer Room.

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OBSERVATION 3

The system for monitoring and maintaining environmental conditions in the aseptic processing areas was deficient.

Specifically, the air and surface samples lack meaningful data. For example,

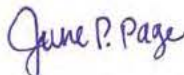

1. Your firm used (b) (4) to conduct in-house surface sampling, air sampling, and personnel fingertip sampling. According to the manufacturer's recommendations, this media requires incubation in a controlled environment. Your firm failed to place the (b) (4) in an appropriate controlled environment.
2. In 2016, surface and air sampling was not performed in the (b) (4) (ISO 5).
3. In 2016, your firm failed to conduct fingertip sampling on approximately 27% of your pharmacist and approximately 43% of your pharmacy technicians.
 - a. In addition, recorded growth for *Staph*, was documented on 09/13/2012 for (b) (4), (b) (6), who performs aseptic operations. According to your firm, (b) (4), (b) (6) continued to perform aseptic operations.
 - b. On 02/01/2017, your firm used an outside contractor to conduct viable surface and non-viable air samples. However, the contractor's sampling plan did not represent worst-case activities and conditions that provide a challenge to aseptic operations. For example, according to your firm, the sampling was not performed under dynamic conditions in the (b) (4) (ISO 5).

OBSERVATION 4

Personnel were observed touching equipment or other surfaces located outside of the ISO 5 area with gloved hands and then proceeding with aseptic processing without changing or sanitizing gloves.

Specifically,

1. On 02/06/2017, Investigator JPP observed your pharmacy technician gathering drug components and supplies, located outside the ISO 5 area, without changing or sanitizing their gloved hands 47 times within a 29 minute timeframe and then proceeding with aseptic drug processing of Vancomycin, Remicade, Cetuximab, Micafungin, and Furosemide.
2. On 02/06/2017, Investigator JPP observed the same pharmacy technician touching the plunger of a syringe during the transfer of sterile-to-sterile drug products.

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OBSERVATION 5 Personnel were observed conducting aseptic manipulations or placing equipment/supplies in an area that blocked the movement of first pass air around an open unit, whether before or after it is filled with sterile product. Specifically, during aseptic operations, a pharmacy technician was observed placing their hands in the path of unidirectional airflow under the LAFW (ISO 5) over open units with sterile product, therefore blocking the movement of first pass air. Additionally, on 02/06/2017, your pharmacy technician was observed to be moving rapidly in the vicinity of open sterile units, which disrupted the airflow and increased the risk of bringing lesser quality air into the ISO 5 area.			
OBSERVATION 6 Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated. Specifically, on 02/06/2017, prior to conducting aseptic operations, Investigator JPP observed your pharmacy technician touching the outside of the glove with their ungloved hand, compromising the sterility of the glove.			
OBSERVATION 7 Equipment, materials, and/or supplies are not disinfected prior to entering the aseptic processing areas. Specifically, Investigator JPP observed the movement of materials, utilized for sterile drug production, from a dirty area to a cleaner area without being disinfected. For example, a (b) (4) components from an unclassified area to the Anteroom (ISO 8) and from the Anteroom (ISO 8) into the IV Buffer room (ISO 7), was not disinfected.			
OBSERVATION 8 Your firm did not conduct smoke studies of the aseptic processing area under dynamic conditions. Specifically, during the (b) (4) recertification, unidirectional airflow was not verified under operational conditions under the (b) (4) (ISO 5).			
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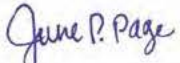

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OBSERVATION 9

There is inadequate HEPA filter coverage or airflow over the area to which sterile product is exposed.

Specifically,

1. Your firm failed 4 consecutive re-certifications (on (b) (4), respectively) for the HEPA filters located in the Air Handling Unit (AHU). The AHU supplies clean air into all the clean rooms. This air does not pass through additional HEPA filters before entering the IV Buffer Room (ISO 7) and Chemo Buffer Room (ISO 7). In addition, your firm did not conduct the scheduled re-certification test for (b) (4). Your firm did not provide any documentation supporting these failures were corrected.
2. A leak was detected on 1 (b) (4) during the re-certification of your LAFW (ISO 5 Hood), located in the IV Buffer Room. Your firm did not provide any documentation supporting this leak was corrected.
3. Your firm failed to re-certify the clean rooms after maintenance and repairs were conducted on the HEPA filters in the AHU on 01/14/2016, 10/31-11/01/2016, and 02/02-03/2017. However, your firm continued to perform aseptic operations.
4. The room certification report, dated (b) (4), documents the Chemo Buffer Room's pressure was recorded at (negative) - 0.118. According to your firm's criteria, the acceptance range is between (b) (4). Your firm continued to perform aseptic operations.
5. Inadequate pressure differentials between higher quality air rooms and lower quality air rooms were observed.
 - a. For example, in 2015 - 2016 out-of-specifications were recorded on your firm's IV Quality Assurance Log:
 - i. Approximately 69% of the time in the Anteroom (ISO 8)
 - ii. Approximately 96% of the time in the Chemo Buffer Room (ISO 7)
 - iii. Approximately 14% of the time (b) (4) Room (ISO 7)
 - iv. Approximately 69% of the time IV Buffer Room (ISO 7)

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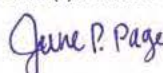

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OBSERVATION 10

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition.

Specifically,

1. The gasket that (b) (4) located on the ceiling directly above the (b) (4) (ISO 5) located in the Chemo Buffer Room and directly above the LAFW (ISO 5 Hood) located in the IV Buffer Room is frayed.
2. Multiple ledges are present in the IV Buffer Room and Chemo Buffer Room (i.e. base boards; (b) (4))
 - a. What appears to be sheet rock dust was observed on the baseboard located approximately 2 feet from the LAFW (ISO 5 Hood) in the IV Buffer room.
3. A crack, approximately 4 inches long, which created a gap, was observed on the florescent light cover located on ceiling of LAFW (ISO 5 Hood).
4. A missing bolt was observed underneath the return air slot, creating approximately a 2mm gap.

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