

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

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 3/8/2022-3/18/2022*
	FEI NUMBER 3017600845

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
William J. Kottmer, General Manager

FIRM NAME Optum Infusion Services 308, LLC	STREET ADDRESS 2555 W Fairview St Ste 104 Bldg D
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CITY, STATE, ZIP CODE, COUNTRY Chandler, AZ 85224-4708	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drug Products
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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

You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in the ISO 5 classified aseptic processing area during aseptic production.

Specifically, your firm failed to evaluate the potential impact of sterile drug products produced in your cleanroom after positive microbiological growth (bacterial/fungal growth) was found in ISO-5 hoods.

- A. EM/Microbiological growth excursion dated November 22, 2021: On 11/22/2021, your firm conducted (b) (4) environmental monitoring in ISO-5, ISO7, & ISO-8 areas and collected viable air and contact surface samples for testing. The EM samples were incubated, and growth (contact surface) was recovered from the keypad of a Repeater Pump (b) (4) located inside the ISO-5 (Hood (b) (4)) and (b) (4) in ISO-7 (b) (4) room. The positive plates were shipped to (b) (4) for ID test and on 12/3/2021 you were informed the identity of the organisms were Brevivacterium species, Micrococcus species, and Coagulase Negative Staphylococcus. On 12/4/2021, your firm placed hood (b) (4) out of commission until cleaning, re-sampling, and investigation is completed. Although your firm implemented remediation plan and corrective actions, you failed to evaluate the potential impact of (b) (4) sterile drug products produced and distributed to patients between 11/22/2021 to 12/04/2021.
- B. EM/Microbiological growth excursion dated August 16, 2021: On 8/16/2021, your firm conducted (b) (4) EM in cleanrooms and ISO-5 hoods and collected viable air and contact surface samples for testing. Incubation of EM samples confirmed growth (1CFU) found on the touchscreen of (b) (4) (in Hood (b) (4)). The positive plate was shipped to (b) (4) for ID test and preliminary finding of 1 CFU of mold was reported on 8/27/2021. On 8/30/2021, Aspergillus was reported. Hood (b) (4) was placed out of commission on 8/27/2021 until investigation and re-testing is completed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Truong X Nguyen, Investigator	Truong X Nguyen Investigator Signed By: Truong X. Nguyen -8 Date Signed: 03-18-2022 15:39:30 X	DATE ISSUED 3/18/2022

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Although your firm implemented remediation plan, you failed to evaluate the potential impact of over (b) (4) sterile drug products made and distributed to patients from 8/16 to 8/27/2021.

C. EM/Microbiological growth excursion dated May 4, 2021: On 5/4/2021, your firm conducted (b) (4) EM and collected viable air and surface samples for testing. Incubation of EM samples found growth (1CFU) on (b) (4) () of ISO-5 Hood (b) (4) and 1CFU on the (b) (4) room rack (ISO-7). The positive plates were shipped to (b) (4) for ID test and on 5/17/2021 confirmed 1CFU found in Hood # (b) (4) was Alternaria species (mold) and 1CFU of Paenibacillus species found in (b) (4) room rack. Hood (b) (4) was placed out of commission until further notice. Your firm failed to evaluate the potential impact of (b) (4) sterile drug products made and sent to patients from 5/4/2021 to 5/17/2021.

OBSERVATION 2

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

Specifically,

- A. On 3/8/2022, a compounding technician was observed opening sterile bags ((b) (4) ()) in ISO-7 (b) (4) area then moving the bags into ISO-5 Laminar Air Flow Hood (Hood (b) (4)) to make Rx# (b) (6) (SMOflipid 20% 500mL bag). The same technician was observed not sanitizing the gloved hands in ISO-7 environment before touching the DCA (Direct Compounding Area) inside the ISO-5 hood.
- B. On 3/10/2022, two technicians were observed with hair not fully covered (hair sticking out on back of head) while they were performing (b) (4) cleaning in the ISO-7 (b) (4) room and ISO-5 hoods.
- C. On 12/13/2021, video of (b) (4) cleaning was reviewed and I observed personnel storing sterile supplies (ex: sterile bags, tubes, syringes) in trash bags then placing the entire content of the trash bags (sterile supplies + trash bags) into cleanroom trash bins. Sterile supplies are used to make drug sterile products in ISO-5 hoods.

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D. On 2/14/2022, video of (b) (4) cleaning was reviewed and observed personnel touching dirty mop pads used to wipe the floor then resumed cleaning and touching others surfaces within the ISO-7 & ISO-5 without sanitizing or replacing their gloves.

OBSERVATION 3

Personnel engaged in aseptic processing were observed with exposed hair.

Specifically, on 3/11/2022, two technicians were observed with facial hair (beard) protruding out of their masks while producing sterile drug products. One technician was observed standing in front of the ISO-5 Hood (b) (4) while producing Rx# (b) (6) (CeFAZolin 2gm in 20mL). The other technician was observed standing in front of the ISO-5 Hood (b) (4) while producing Rx# (b) (6). Both sterile prescriptions listed above were released and distributed to patients.

OBSERVATION 4

The ISO 5 classified aseptic processing areas had particle-generating equipment or surface.

Specifically, your firm conducted (b) (4) certification of classified areas (ISO-5, ISO-7, & ISO-8) including smoke studies then resumed sterile operations on the same day without cleaning. Video recording shows static and dynamic smoke studies were performed on all ISO-5 hoods (hood # (b) (4)). Video recording also revealed actual drug products were used in dynamic smoke study for hood # (b) (4). Your firm failed to provide evidence showing that cleanroom areas and ISO-5 hoods were cleaned and disinfect after the certification process and smoke studies done on 4/16/2021. Prescription log shows that over (b) (4) sterile drug products were made and released for distribution to patients on 4/16/2021.

OBSERVATION 5

Vermin was observed in your production area.

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Specifically, your firm failed to implement effective remediation plan and pest control program resulting in three incidents of pest/insects found in the classified areas (ISO-5, ISO-7, ISO-8) where sterile drug products are made:

- One live gnat landed inside of ISO-5 Laminar Air Flow Hood # (b) (4) on 4/2/2021. Your firm failed to evaluate the potential impact to sterile drug products made in Hood (b) (4) on 4/2/2021.
- One live crane fly found in (b) (4) room (ISO-7) on 3/10/2021.
- One live fly found in the exit (b) (4) room (ISO-8) on 2/7/2022.

OBSERVATION 6

You had inadequate HEPA filter airflow over the area to which sterile product was exposed.

Specifically, the smoke study conducted under dynamic conditions for ISO-5 hoods (hoods # (b) (4), (b) (4)) performed on April 16, 2021 does not represent your actual work conditions of making sterile drug products and did not show the various techniques or equipment set in normal operations. For example the sterile drug production of TPN (Total Parenteral Nutrient) products using the Repeater Pump and (b) (4) equipment/machines.

***DATES OF INSPECTION**

3/08/2022(Tue), 3/09/2022(Wed), 3/10/2022(Thu), 3/11/2022(Fri), 3/14/2022(Mon), 3/15/2022(Tue), 3/16/2022(Wed), 3/18/2022(Fri)

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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."