

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

DISTRICT ADDRESS AND PHONE NUMBER 6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax: (513) 679-2772	DATE(S) OF INSPECTION 1/22/2018-1/26/2018*
	FEI NUMBER 3013995728

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Tonya K. Sutton, General Manager

FIRM NAME Infusion Partners, LLC	STREET ADDRESS 4137 Boardman Canfield Rd Ste LL04
CITY, STATE, ZIP CODE, COUNTRY Canfield, OH 44406	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**

The ISO 5 classified aseptic processing areas had visibly dirty equipment or surface.

Specifically, the HEPA filter guards in all (b) (4) ISO 5 laminar airflow hoods had visible whitish and rust-colored residue in and around the holes in the guards. In addition, the (b) (4) HEPA filter guards in the ISO 7 cleanroom had flaking paint and rust-colored discoloration on multiple areas of each guard.

OBSERVATION 2
Disinfectant contact time (also known as "dwell time") and coverage of the item being disinfected were insufficient to achieve adequate levels of disinfection.

Specifically, the contact time for the (b) (4) used as a sporicide in the ISO 5 laminar airflow hoods used to produce sterile drugs and the supporting ISO 7 and ISO 8 cleanrooms is (b) (4) minutes, which is estimated by the employee, after which the hood is washed with (b) (4) to remove the (b) (4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Matthew B Casale, Investigator Lauren N Howard, Investigator	Matthew B Casale Investigator Signed By: Matthew B. Casale -S Date Signed: 01-26-2018 13:40:53 X	DATE ISSUED 1/26/2018

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DISTRICT ADDRESS AND PHONE NUMBER 6751 Steger Drive Cincinnati, OH 45237-3097 (513)679-2700 Fax: (513)679-2772		DATE(S) OF INSPECTION 1/22/2018-1/26/2018*
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OBSERVATION 3

Personnel conducted aseptic manipulations and placed equipment/supplies in an area that blocked the movement of first pass air around an open unit, either before or after it was filled with sterile product.

Specifically,

- 1) The (b) (4) laminar airflow hoods used to produce all non-chemotherapeutic sterile drugs have sagging HEPA guards with (b) (4) (b) (4), resulting in approximately 1/3 of the HEPA airflow being blocked by a (b) (4) (b) (4) before it can reach the critical area. There are no visually recorded smoke studies to demonstrate that the airflow is not interrupted by these obstacles.
- 2) There are no velocity measurements for airflow in the ISO 7 cleanroom or the ISO 5 laminar airflow hoods to show that ISO 7 airflow does not negatively impact the laminar flow of the ISO 5 hoods despite the fact that the HEPA filters in the ISO 7 room are located partially over the openings to the ISO 5 hoods.
- 3) Employees were observed pulling solutions from vials and injecting them into IV bags and similar containers in an area of the ISO 5 laminar airflow hood in front of the HEPA filters that is not covered by laminar airflow, and then placing the filled containers down on the work surface that is located in the same part of the hood and is not exposed to laminar airflow.
- 4) Employees were observed placing their hands over the tops of vials used in sterile drug production in the ISO 5 vertical laminar airflow hoods, blocking first-pass airflow over the vial stoppers on multiple occasions during production.

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OBSERVATION 4

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, on different occasions, employees engaged in the production of sterile drugs in ISO 5 laminar airflow hoods were observed exiting the ISO 5 hood area and touching items in the ISO 7 cleanroom, including a keyboard, telephone, nonsterile IV bag packages, paperwork, a computer monitor, and pushing down discarded nonsterile packaging in the garbage can, and then returning to the ISO 5 area without sanitizing or replacing their gloves.

OBSERVATION 5

Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically, employees were observed taking non-sterile IV bags and vials into the ISO 7 room from the pass-through originating in an unclassified room and then putting them directly into the ISO 5 laminar airflow hood without any decontamination step.

OBSERVATION 6

Personnel did not disinfect and change gloves frequently enough to prevent contamination.

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Specifically, an employee was observed donning sterile gloves and then touching multiple items and performing multiple tasks in the ISO 7 area, including pushing down trash in the trash can, using the telephone, taking multiple items from the pass-through originating in an unclassified room, typing on a keyboard, and using a touchscreen, before putting her hands into the ISO 5 laminar airflow hood to start sterile production without changing her gloves.

OBSERVATION 7

Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically, gowning for employees involved in sterile drug production in the ISO 5 laminar airflow hoods consists of sterile gloves, non-sterile masks, non-sterile hooded body suits that are taken off and re-used throughout the day, and no eye-covering, resulting in exposed skin around the eyes, despite the fact that the employee's entire upper body must enter the ISO 5 hood to properly produce sterile drug products.

OBSERVATION 8

Your facility design allowed the influx of poor quality air into a higher classified area.

Specifically, the pass-through into the ISO 7 cleanroom used to pass all components, containers, and closures for sterile drug production into the cleanroom originates in an unclassified room, has doors that do not seal, has unused screw holes that contain expose particle board inside the pass-through, has rust

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colored discoloration on the hinges on the ISO 7 side, and has visible dust in a gap between the pass-through and the wall on the ISO 7 side.

OBSERVATION 9

Personnel moved rapidly in the vicinity of open sterile units and instruments, which disrupted the airflow and increased the risk of bringing lesser quality air into the ISO 5 classified aseptic processing area.

Specifically, an employee was observed unfolding a black trash bag and then shaking it in a vigorous manner directly in front of and less than a foot from the work surface of the ISO 5 laminar airflow hood being used to produce sterile total parenteral nutrition while ingredient vials and IV bags for production were staged, cleaned and ready for production, and directly in front of and approximately three feet from the work surface of the ISO 5 laminar airflow hood being used to produce sterile home infusion systems while production was in progress.

OBSERVATION 10

You produced beta-lactam drugs without providing adequate containment and segregation to prevent cross-contamination.

Specifically, multiple sterile penicillin and cephalosporin drugs are produced in the same positive pressure ISO 5 laminar airflow hoods that are used to produce all sterile non-chemotherapeutic drugs, and there is no procedure to specify how spills are to be cleaned.

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***DATES OF INSPECTION**

1/22/2018(Mon), 1/23/2018(Tue), 1/24/2018(Wed), 1/26/2018(Fri)

X Lauren N Howard
Investigator
Signed By: Lauren N. Howard -S
Date Signed: 01-26-2018 13:40:42

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