

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 4/17-19/2018 and 4/23-25/2018 FEI NUMBER 3014124903
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Lee R. Boyd, General Manager

FIRM NAME Infuscience Inc	STREET ADDRESS 2915 Waters Rd Ste 110
CITY, STATE AND ZIP CODE Eagan, MN 55121-1562	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile Drug Products

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

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

Specifically,

On 04/18/2018 during aseptic processing of TPN Prescription Number (b) (6) a large area of brown residue was observed on the HEPA filter grate of an ISO 5 hood being used. Firm management could not identify the nature or source of the residue.

OBSERVATION 2

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

Specifically,

On 4/17/2018, a pharmacy technician performing sterile production of Ertapenem 1 gm/100 ml .45% NaCl for Prescription Number (b) (6) Rifampin 300 mg/400 ml D5W eclipse for Prescription Number (b) (6) Methylprednisolone 1 gram /100 ml NS HP for Prescription Number (b) (6) and Azithromycin 500 mg/100 ml NS Eclipse for Prescription Number (b) (6) in Hood (b) (4) continuously demonstrated rapid hand movements including opening instruments, picking up syringes, picking up vials, moving trash around the table, and repeatedly waving hands around inside the hood after sanitizing.

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,

On 4/18/2018, during sterile production of TPN Prescription Number (b) (6) in Hood (b) (4) a pharmacy technician manipulated sterile connections (b) (4) such that (b) (4) in the ISO5 space blocked the exposed sterile connections from first pass air.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>Emilie E. Kahn</i> <i>James K. Ireland</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Emilie E. Kahn, Investigator James K. Ireland, Investigator	DATE ISSUED 04/25/2018
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OBSERVATION 4

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

- 1) On 4/18/2018, a pharmacy technician moved a box, containing a calibration weight for the (b) (4) (b) (4) from the top of the Hood (b) (4) to the bench inside the ISO-5 processing area, without wiping the box with a sporicidal or sanitizing agent. The pharmacy technician performed the calibration, returned the box to the top of Hood (b) (4) and proceeded to produce several TPN drug products, including one for Prescription Number (b) (6)
- 2) On 4/18/2018, a pharmacy technician placed a bin, used to transport materials used in sterile production, directly into the ISO 5 aseptic processing area without wiping the bin with a sporicidal or sanitizing agent. The pharmacy technician proceeded to remove syringes, vials, and other materials, and produce Ceftriaxone 2 grams in 65 ml .45% NaCl for Rx (b) (6) Ceftriaxone 2 gm in 20 ml in syringe for Prescription Number (b) (6) and Vancomycin 1400 mg in 250 ml .9% NaCl for Prescription Number (b) (6)
- 3) On 4/18/2018, a pharmacy technician picked up several IV bags off a cart and held them with both arms against a non-sterile bunny suite before directly placing all bags into Hood (b) (4) an ISO 5 processing area, and proceeding to produce several TPN drug products, including one for Prescription Number (b) (6)

OBSERVATION 5

Personnel engaged in aseptic processing were observed with exposed hands.
Specifically,

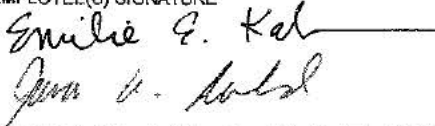
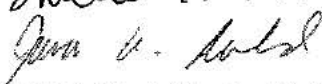
On 4/17/2018, we observed the sterile pharmacy technicians glove bare hands under Hood (b) (4) and Hood (b) (4) prior to cleaning with (b) (4) and producing sterile drug product. Several TPN products were subsequently produced in Hood (b) (4) and Ertapenem 1 gm/100 ml .45% NaCl for Prescription Number (b) (6) Rifampin 300 mg/400 ml D5W eclipse for Prescription Number (b) (6) Methylprednisolone 1 gram /100 ml NS HP for Prescription Number (b) (6) and Azithromycin 500 mg/100 ml NS Eclipse for Prescription Number (b) (6) were produced in Hood (b) (4)

Additionally, on 4/18/2018, we observed the following:

- 1) While preparing Hood (b) (4) for sterile production, a sterile pharmacy technician used bare hands to remove the (b) (4) that had been left inside the hood from previous drug production.

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<p>The technician did not use a sporicide before proceeding with sterile production of Ceftriaxone 2 grams in 65 ml .45% NaCl for Prescription Number (b) (6) Ceftriaxone 2 gm in 20 ml in syringe for Prescription Number (b) (6) and Vancomycin 1400 mg in 250 ml .9% NaCl for Prescription Number (b) (6) in Hood^{(b) (4)}</p> <p>2) A sterile pharmacy technician performed cleaning activities, leaning into the ISO 5 classified space with a bunny suit that was not fully zipped, exposing neck and chest skin. This technician immediately proceeded with sterile production of Ceftriaxone 2 grams in 65 ml .45% NaCl for Prescription Number (b) (6) Ceftriaxone 2 gm in 20 ml in syringe for Prescription Number (b) (6) and Vancomycin 1400 mg in 250 ml .9% NaCl for Prescription Number (b) (6) in Hood^{(b) (4)}</p>			
<p>OBSERVATION 6</p> <p>ISO 5 classified areas were not certified under representative dynamic conditions.</p> <p>Specifically,</p> <p>Smoke studies performed in the ISO 5 laminar flow hoods were not performed under dynamic conditions that represent your aseptic processing practices. During routine TPN production, (b) (4) and storage carts of materials are rolled in front of exhaust vents for the clean room. However, these routine conditions were not replicated during the smoke studies.</p>			
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