DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410)779-5455 Fax:(410)779-5707	7/23/2019-7/30/2019* FEI NUMBER 3013352224

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ms. Regina N. Smeraglinolo, Pharm D, Pharmacy Manager

FIRM NAME	STREET ADDRESS
InfuScience, Inc. dba Bioscrip Infusion Services	4151 Lafayette Center Dr., Suite 600
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Chantilly, VA 20151-1220	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 I OBSERVED:

OBSERVATION 1

You produced beta-lactam drugs without providing adequate segregation, cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

Specifically,

A. On July 25, 2019, a portion of "Meropenem 1 g/ 50 ml NS IVP Q8H" (Rx(b) (6)) spouted out of the syringe onto the working surface of the ISO 5 classified area of laminar flow hood 1 during production. Upon completion of producing the product, cleaning was performed by wiping the exposed working surface of the laminar flow hood with a sterile wipe and sterile(b) (4) . Following, two additional beta-lactam products were produced with subsequent cleaning of the exposed working surface of the laminar flow hood with a sterile wipe and sterile(b) (4) . Immediately after, a non-beta-lactam product, "0.9% NaCL 500 ml IV daily via HP" (Rx (b) (6)) was produced without cleaning to prevent cross-contamination from a beta-lactam product. Rx (b) (6) was released and distributed.

B. On July 23, 2019, "Cefepime 1gm/ 10ml NS Q24H IVP" (Rx (b) (6)) was produced while a non-beta-lactam product, unsealed vials of "Vancomycin 1000 mg/100 ml NS Q12H EP" (Rx (b) (6)), remained in the same ISO 5 classified area laminar flow hood, hood(b) (4) Rx (b) (6) was released and distributed.

OBSERVATION 2

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

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	Sena G Dissmeyer, Investigator	X Sena G Dissmeyer Investigator Signed By: Sena G. Dissmeyer -S Date Signed: 07-30-2019 14:10:28	7/30/2019

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Specifically, on July 23 – 26, 2019, the rear HEPA filter (b) (4) of (b) (4) laminar air flow hoods (b) (4) were observed with white "staining." The (b) (4) supplies the ISO 5 classified production area with (b) (4) HEPA airflow. The "staining" was not removed before or in between aseptic processing of all products produced in those hoods, such as "TPN 3-in-1 4000 mL, over 13 hours," (Rx (b) (6)). Management stated that all total parenteral nutrition (TPN) products are produced in those (b) (4) hoods.

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,

A. On July 25, 2019, during sterile production of "TPN 3-in-1 1055mL IV over 8 hrs" (Rx (b) (6)), in hood (b) (4) a technician manipulated sterile connections between an IV lipid bag and the (b) (4) compounder such that IV bags hanging in the ISO 5 classified area blocked the exposed sterile connection from first pass air.

B. On July 26, 2019, during sterile production of "TPN 3-in-1 4000 mL, over 13 hours," (Rx (b) (6)), in hood (b) (4) another technician manipulated sterile connections between an "(b) (4) ((b) (4))" IV bag and the (b) (4) compounder in front of the (b) (4) equipment such that the exposed sterile connection was blocked from first pass air in the ISO 5 classified area.

OBSERVATION 4

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

Specifically,

A. On July 23, 2019, a technician reached with a gloved hand and forearm into a trash receptacle in the ISO 7 classified "IV Compounding Room" to push down trash and returned to aseptic processing of "TPN 3-in-1 1800 mL, over 12 hours, QD" (Rx (b) (6)) in the ISO 5 classified laminar flow hood without

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changing or sanitizing gloves and coveralls.

B. On July 23, 2019, technicians repeatedly reached back and forth between the ISO 7 classified "IV Compounding Room" and the ISO 5 classified laminar flow hoods, such as to obtain materials from their respective stock carts and to use a(b) (4), without changing or sanitizing gloves. Personnel touched surfaces located outside of the ISO 5 classified aseptic processing area with gloved hands and engaged in aseptic processing during production of "Cefazolin 2 g / 20ml in Sterile Water syringe" (Rx (b) (6)) in hood(b) (4), "TPN 3-in-1 1750 mL IV 12 Hours" (Rx (b) (6)) in hood(b) (4), and "TPN 3-in-1 2100 mL" (Rx (b) (6)) in hood(b) (4) with infrequent glove sanitization.

OBSERVATION 5

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

Specifically, on July 23, 2019, technicians brought materials such as product vials, syringe pouches, and IV bags from the ISO 7 classified "IV Compounding Room" into the ISO 5 classified laminar flow hoods without disinfecting the outer surfaces. Transfers of materials without being disinfected were observed during production of "Cefazolin 2 g / 20ml in Sterile Water syringe" (Rx (b) (6)) in hood(b) (4), "TPN 3-in-1 1750 mL IV 12 Hours" (Rx (b) (6)) in hood(b) (4), and "TPN 3-in-1 2100 mL" (Rx (b) (6)) in hood(b) (4).

OBSERVATION 6

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

Specifically,

S7D 07-30-19

A E. On July 25, 2019, during (b) (4) cleaning(b) (4) production operations, the use of "(b) (4) Disinfectant Solution" sterile germicidal disinfectant in the ISO 5 classified laminar flow hoods(b) (4) did not dwell to achieve your required contact time of(b) (4). Some areas of the hood had a drying time of less than five seconds.

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B D. On July 23 – 26, 2019, upon usage of your disinfectant, sterile(b) (4), on exposed working surfaces of ISO 5 classified laminar flow hoods in between production of different products, your

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required contact time for bactericidal activity of (b) (4) was not achieved. Cleaning of some hoods had a sterile (b) (4) drying time of less than five seconds.

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C. On July 25, 2019, during (b) (4) cleaning (b) (4) production operations, your disinfectant, sterile (b) (4), was not used in ISO 5 classified laminar flow hoods (b) (4). Furthermore, sterile (b) (4) disinfectant was not used during (b) (4) cleaning operations in hood (b) (4) the previous production day, July 24, 2019. Sterile production operations were commenced in hoods (b) (4).

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D. On July 24, 2019, during (b) (4) cleaning operations, use of "(b) (4) Disinfectant Solution" sterile germicidal disinfectant on the ISO 7 classified "IV Compounding Room" floor did not dwell to achieve your required contact time of (b) (4). Some areas of the floor had a drying time of less than five seconds.

OBSERVATION 7

ISO 5 classified areas were not certified under dynamic conditions.

Specifically, unidirectional airflow was not verified under dynamic operational conditions representative of your aseptic processing practices. Smoke studies performed in the (b) (4) ISO 5 classified laminar flow hoods did not demonstrate unidirectional airflow, for example, around IV bags hung in each hood and the presence of a repeater or (b) (4) pump.

OBSERVATION 8

The facility design was observed to allow the influx of poor quality air into a higher classified area.

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Specifically, there are (b) (4) located (b) (4) the unclassified (b) (4) general pharmacy area and the ISO 7 classified "IV Compounding Room." All production materials are exchanged (b) (4) (b) (4) permitting unclassified air to enter the ISO 7 classified area.

***DATES OF INSPECTION**
7/23/2019(Tue), 7/24/2019(Wed), 7/25/2019(Thu), 7/26/2019(Fri), 7/30/2019(Tue)

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