DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax:(404) 253-1202 Industry Information: www.fda.gov/oc/industry	05/12/2015 - 05/15/2015 FEI NUMBER 3011515831

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Chirag A. Patel, General Manager

FIRM NAME	STREET ADDRESS
InfuScience a subsidiary of Bioscrip	462 Wando Park Blvd Ste A
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Mount Pleasant, SC 29464-7906	Sterile Drug Producer

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

Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

Specifically,

On 11/24/14, your firm was notified of an adverse event associated with a dose of hydromorphone administered to a patient and produced by your firm. Your firm failed to notify the Corporate Clinical Services Department of the incident as delineated in procedures CLIN-PH107: Drug and Product Defect Reporting, effective 03/01/07, and ADMOPS15: Adverse Event Reporting, effective 03/01/07. The issue was noted in an electronic chart and a replacement was sent to the patient.

OBSERVATION 2

Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically,

a) Sterile drugs are aseptically manipulated by the cleanroom operators who were observed wearing non-sterile gowns, caps, and face masks. Non-sterile eye protection may be used in the event of splashes.

b) The operator's area around the eyes is not fully covered allowing exposed facial skin over the critical ISO 5 laminar flow areas where sterile injectable drug products are processed.

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

a) Environmental monitoring for viable and non-viable air counts in the ISO 5 zones is not performed at least daily during periods of production. The firm only monitors viable and non-viable air counts during the (b) (4) cleanroom certification by an outside vendor; lastly on 03/18/15.

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b) The work surfaces, inside the ISO 5 hoods, are not tested for microbial contamination at least daily during periods of production and at the end of operations. The monitoring is only performed (b) (4)

c) Operators' gloves are not tested for microbial contamination at least daily during periods of production. Glove fingertips are only monitored (b) (4)

d) The two ISO 7 clean rooms and the ISO 7 anteroom are not continuously monitored for air pressure differentials during production.

e) The gauge monitoring the pressure differential between the clean room and the anteroom showed a reading of approx. zero inches W.G. on 05/12/15. The operator stated readings must be captured with doors open but was not able to explain how this disturbance would provide accurate readings.

OBSERVATION 4

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

a) Non-sterile wipes are used to disinfect the ISO 5 hoods' sterile processing surfaces and they are composed of particle shedding material.

b) The firm does not use sporicidal agents to disinfect the ISO 5 surfaces.

c) A non-sterile liquid is used in disinfecting the ISO 5 surfaces.

d) No disinfectant efficacy studies have been performed to determine the disinfection procedures and disinfectants that are used can maintain an aseptic environment in the hoods.

e) On 05/12/15, operators were observed to wipe ISO 5 hood surfaces against the direction of the air flow.

OBSERVATION 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, and followed.

Specifically,

a) No media fills/process simulations have been performed under the most stressful or challenging conditions. Instead, the firm uses an (b) (4) which doesn't utilize equipment and containers used in normal processing.

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b) Operators were observed touching non-sterile items in the clean room such as the lining of the trash can (where disinfectants are maintained hanging) and a telephone. Gloves were not replaced after touching non-sterile surfaces.

c) On 05/12/15, operators were observed obstructing ISO 5 air flow patterns by placing vials in an random order on the surface and handling infusion bags one in front of another.

OBSERVATION 6

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically,

Your firm has not conducted any sterility testing for any products.

OBSERVATION 7

The separate or defined areas necessary to prevent contamination or mix-ups are deficient.

Specifically,

a) Your firm is processing Penicillin-type injectable drugs, such as Ampicillin, Penicillin and Nafcillin, in the same ISO 5 hood as for non-penicillin products. The absence of a structurally isolated area creates the potential that accidental breakage of vials of penicillin powders could contaminate your other sterile drug products.

b) There is no separate air handling unit for penicillin drugs.

c) Your firm is processing Beta-lactam non-penicillin injectable drugs, such as Cefazolin, Ceftazidime and Aztreonam, in the same ISO 5 hood as for non-beta-lactam products. The absence of a structurally isolated area creates the potential that accidental breakage of vials of beta-lactam powders could contaminate your other sterile drug products.

OBSERVATION 8

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically,

Your firm does not perform visual checks of sterile injectable drugs for clarity/discoloration and/or particulates/contaminants

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against contrasting backgrounds. In addition, visual inspections are not documented.

OBSERVATION 9

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

Your firm has not tested for sterility or potency over the assigned Beyond Use Dates (BUD) for any sterile injectable, all of which are preservative free. For example, your firm has not conducted any testing to support the BUDs such as 14 days refrigerated for Vancomycin or 14 days room temperature for Fluoracil. You have no data available to show that the sterility and potency will be maintained over the time period of the BUD.

OBSERVATION 10

Buildings used in the holding of a drug product are not maintained in a good state of repair.

Specifically,

Dust and debris were observed in the big warehouse which holds packaged materials and in a refrigerator utilized for holding packaged orders ready to be distributed. In addition, there was an approximate half an inch opening around the perimeter of the docking door in the big warehouse.

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