DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse, Rm 900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Fax:(215) 597-0875 Industry Information: www.fda.gov/oc/industry	12/01/2014 - 12/05/2014 FEI NUMBER 3011127887

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Louise A. Balla, General Manager

FIRM NAME	STREET ADDRESS
Infusion Partners (subsidiary of Bio Scrip)	311 23rd Street Ext Suite 500
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sharpsburg, PA 15215	Producer of Sterile Drugs

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 designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

Specifically,

1. On 12/01/14, the production of Rx# 140651666 (Total Parenteral Nutrition (TPN) 3-in-1 1270ml) was observed taking place in the ISO 6 Compounding Room and not under ISO 5 conditions. Three (3) ampoules of Addamel (lot 12G1B20) were opened and exposed in the ISO 6 environment at the beginning and the continued staging of materials and components in preparation for compounding. Additionally, components were staged in a manner requiring the technician to extend arms and upper torso over the opened and exposed ampoules.

2. On 12/2/14, during the production of Rx# 014651945 (Vancomycin 1.5g/250ml NS bag) and Rx# 0140651917 (Cefepime 1g/10 ml syringe), technicians were observed vigorously shaking product after addition of a diluent to aid in dissolution of lyophilized powder.

3. Technicians were observed making frequent contact using gloved hands with nonsterile components and surfaces, such as door handle, trash bag, scissors and packaging material, prior to initiating aseptic processing without the application of sterile 70% isopropyl alcohol to sanitize hands.

4. On 12/2/2014, during the setup of the B. Braun Pinnacle TPN Management System (Part Number 60084, Serial number 1233), the technician was observed reusing the same sanitizing sterile pad over 15 times on tops of stoppered vials and the connections to the "6-Lead Transfer Set (Vented) for the use with Pinnacle TPN Management System" tubing which was labeled as sterile. During the reuse of the

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sanitizing sterile pad, the technician was observed rewetting the pad with sterile 70% isopropyl alcohol.

5. There is no evidence that media fills are performed under the most stressful or challenging conditions. The firm uses an aseptic technique validation kit which doesn't utilize equipment and containers used in normal processing.

6. Technicians were observed not practicing good aseptic technique while performing aseptic manipulations in the ISO 5 critical area. For example:

a. On 12/3/14, a technician was observed applying non-sterile Alcare Foamed Antiseptic Handrub to sterile gloves prior to initiating aseptic processing in the ISO 5 area.

b. On 12/2/14, a technician was repeatedly observed immediately wiping gloved hands with non-sterile wipes after sanitizing with sterile 70% isopropyl alcohol prior to initiating aseptic processing in the ISO 5 area, thereby not allowing for sufficient contact time of the isopropyl alcohol.

c. During the production of the Rx 0140649338 (TPN), the technician was observed picking up paper trash from the floor. The technician immediately resumed aseptic processing of the TPN drug product without sanitizing his hands.

OBSERVATION 2

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

1. The (TPN) workbench and Chemo Biological Safety Cabinet where sterile injectable products are produced are deficient in their ISO 5 classification in that these areas have not been properly qualified through the performance of airflow studies (smoke studies) to assure unidirectional airflow under static and dynamic conditions.

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2. Technicians were observed throughout the time moving in a manner that did not appear measured, slow, or deliberate. The technicians freely move in the entire ISO 6 area without restriction. There was no clear line of demarcation between the ISO 5 and ISO 6 environments except for a clear plastic liner which hangs down approximately 3 feet from the 9 foot ceiling.

OBSERVATION 3

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

Specifically,

1. Your firm has not conducted cleaning efficacy studies to assure the suitability and effectiveness of non-sterile Accel TB (0.5% hydrogen peroxide), bleach solution mixed 1:10 dilution with potable water, and sterile 70% isopropyl alcohol used to clean and disinfect ISO 5 areas, Compounding Room, Chemo Room and ante room.

2. The firm does not use a sporicidal agent to disinfect the clean room including the ISO 5 area. Daily cleaning of the ISO 5 critical areas consists of Sterile 70% isopropyl alcohol.

3. On 12/1/14, a spray bottle labeled "water" was observed on a tray in the ISO 6 Compounding Room. The firm reported that the spray bottle contains Sterile Water For Irrigation used to clean up crystallized drug residue resulting from spills in the ISO 5 area that cannot be removed using sterile 70% isopropyl alcohol. The spray bottle is non-sterile but sanitized externally using sterile 70% isopropyl alcohol prior to entry into the ISO 6 Compounding Room.

OBSERVATION 4

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

Specifically,

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1. Environmental monitoring of surfaces for microbial contamination is not performed during routine processing of sterile injectable drug products in the ISO 5 area. Your firm only performs such monitoring on a monthly basis. Additionally, the product information sheet for the Hycon YM contact plates used for yeast and mold growth promotion requires incubation parameters of 3-7 days at 20-25° C. Review of documentation relevant to plates for surface contamination identifies incubation parameters of 35° C for 3 days.

2. Technician's gloves are not monitored for microbial contamination during routine processing of sterile drug products. Glove tips are monitored on an annual basis for current employees and 3 times during a two week period for new hires as part of qualification.

3. Environmental monitoring for non-viable particulates and viable air counts is not performed during routine production of sterile injectable drug products. Such monitoring is performed on a semi-annual basis during cleanroom certification by an outside vendor.

4. Pressure gauges in the ISO 6 Compounding Room and ISO 7 Ante Room are not continuously monitored for air pressure differential. Instead personnel perform a daily visual inspection of the pressure gauges to verify they are reading within the specification of 0.02-0.05psi.

OBSERVATION 5

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

Specifically,

Gowns/coveralls, facemasks, bouffant hair nets and goggles worn by operators working inside ISO 5 zones are not sterile. Additionally, the technician's face and neck are not fully covered allowing exposed facial skin and hair over the ISO 5 critical area.

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