DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, New York 11433-1034 (718) 340-7000 Industry Information: www.fda.gov/oc/industry	04/09, 10, 11, 14, 16, 23/2014
	FEI NUMBER 3008231170

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Nabil Kass-Gergi, Director of Pharmacy

FIRM NAME	STREET ADDRESS
Infusion Options, Inc.	5924 13th Avenue
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Brooklyn, New York 11219	Outsourcing Facility

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 (WE) OBSERVED:

OBSERVATION 1

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

Specifically:

a). Smoke studies were not performed under dynamic conditions to verify that operators, processing equipment or activities of the ISO 7 clean room do not alter or impede the unidirectionality of air from the HEPA filters to the (b) (4) ISO 5 laminar flow benches where products are aseptically processed.

b). The wall mounted room pressure monitors used to monitor differential air pressures of the (b) (4) clean rooms and surrounding areas are not monitored periodically during production. It is only done (b) (4) . Also, alarms generated by these monitors are not reviewed.

c). Entry for materials used in sterile processing to one of the firm's (b) (4) clean rooms (ISO 7) is directly from an unclassified area.

OBSERVATION 2

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

• Sterile drug products are aseptically manipulated by the cleanroom operators who were observed wearing non-sterile gowns, non-sterile glasses/goggles, non-sterile footwear, and non-sterile facial masks.

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• The procedure operators use to put on sterile gloves used at the chemo ISO 5 work area is performed in a way as to risk contamination, since non-sterile gloves are used to handle sterile gloves.

• The operator's face and head are not fully covered and allows exposed facial skin and hair over the critical ISO 5 laminar flow areas.

• Gowning apparel is composed of particle shedding material.

OBSERVATION 3

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

Specifically,

a. Environmental monitoring for viable air counts in the ISO 5 zones is not performed at least daily during periods of production. The firm has never monitored viable air counts.

b. Environmental monitoring for non-viable particulates in the ISO 5 zones is not performed under dynamic conditions. This was last performed on 10/18/13 and 11/26/13.

c. 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. This monitoring is only performed [redacted] (b) (4) It is done after disinfecting the work surfaces and during the processing of a batch.

d. Operators' gloves are not tested for microbial contamination at least daily. Glove fingertips are only monitored [redacted] (b) (4)

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OBSERVATION 4

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

Specifically,

a. Sterile wipes which are used to disinfect the ISO 5 hoods' sterile processing surfaces are composed of particle shedding material.

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

c. In the disinfection of the (b) (4) chemotherapy ISO5 hoods, non-sterile wipes are used to remove cytotoxic drugs from the processing surfaces. This is done after the hoods are disinfected with sterile wipes and (b) (4) [redacted]

OBSERVATION 5

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

No media fills/process simulations have been performed under the most stressful or challenging conditions/worst case scenarios and according to a written protocol. In the absence of a media fill record and having not defined the frequency of interventions, type of interventions, the target amounts of units to fill, the minimum duration of filling simulations, amount of employees inside the room for a given period of time, there is a lack of a demonstration that you have fulfilled the purpose of your media fill process. The rationale chosen for the conditions and activities simulated during the media fill are neither written nor defined.

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Additionally, testing conducted in lieu of media fills/process simulations to ensure that parenteral solutions are sterile, is not performed per the firm's procedure titled "Quality Control of Parenteral Solutions".

a. Product or preparation samples are not used.

b. The pharmacist does not check for turbidity daily.

c. A [redacted] (instead of 14 days) incubation period is used without justification.

d. The incubation temperature used [redacted]) differs from the test kit manufacturer's recommendation of 22.5 +/- 2.5 degrees C.

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, given the observed inadequate environmental controls, testing is deficient in that:

a. Your firm has not conducted sterility testing for any batches (totaling [redacted] units) of outsourced sterile drugs since the registration date of 01/24/14.

b. Endotoxin testing has not been performed for any outsourced sterile drug products produced.

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OBSERVATION 7

The operations relating to the processing and packing of penicillin are not performed in facilities separate from those used for other drug products for human use.

Specifically, your firm is processing Penicillin-type drugs, such as Nafcillin IVPB and Oxacillin IVPB, in the same cleanroom with your 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.

OBSERVATION 8

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

Specifically, there are no separate facilities, for processing operations, to prevent contamination from beta-Lactam non-penicillin drugs, such as Cefazolin IVPB, Ceftazidime IVPB, Meropenem IVPB, and others. These beta-Lactam powders, which are contained in glass vials, are processed in the same clean room as sterile non beta-Lactam drugs. There is no assurance that a potential breakage of the glass vial and consequent powder spill would not contaminate other sterile drug products.

OBSERVATION 9

Any unexplained discrepancy or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated, whether or not the batch has already been distributed.

Lot number 0806121600 of Heparin 5000 Units/1L NS was tested on 08/14/12 and found to be "Not Sterile" at Day 0. There was no investigation conducted to determine the cause and impact of this result.

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OBSERVATION 10

Containers and closures are not reviewed for conformance with all appropriate written procedures.

Specifically,

Your firm does not receive or review certificates of analysis showing sterility for the sterile containers, such as IV bags, used for sterile drug products.

Purchased sterile equipment, such as transfer tubing, are accepted into inventory and used for sterile drug processing without reviewing the manufacturer's certificate of analysis to assure sterility.

OBSERVATION 11

For each batch of drug product, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the drug product.

Specifically, visual checks of sterile drugs for clarity/discoloration or particulates/contaminants are not performed against a contrasting background.

OBSERVATION 12

There shall be written procedures designed to assure that correct labels, labeling, and packaging materials are used for drug products; such written procedures shall be followed. These procedures shall incorporate the following features: Identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch.

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Dexamethasone 10mg in 50mL of 0.9% NaCl and Dexamethasone 20 mg in 50mL of 0.9% NaCl were both processed on 3/28/14. Both lots were assigned the same lot number, 0328141330.

Observation 13

The labels of your firm's drug products do not include information required by section 503B(a)(10) of the Act.

a. The following drug product label does not contain the following: the statements "This is a compounded drug," "Not for Resale," and "Office Use Only;" the address and phone number of the applicable outsourcing facility; inactive ingredient; and information to facilitate adverse event reporting (www.fda.gov/medwatch and 1-800-FDA-1088): Vancomycin Oral Solution 125 mg in 5 mL syringe [not sterile].

b. The following labels do not contain the dosage form; route of administration and the statement "Office Use Only":

Dexamethasone 10 mg in 50 mL of 0.9% NaCl bag

Dexamethasone 20 mg in 50 mL of 0.9% NaCl bag

Diphenhydramine 25 mg in 50 mL of 0.9% NaCl bag

Diphenhydramine 50 mg in 50 mL of 0.9% NaCl bag

Heparin 1000 units in 500 mL 0.9% Sodium Chloride bag

Heparin 2000 units in 1000 mL 0.9% Sodium Chloride bag

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Heparin 2500 units in 500 mL 0.9% Sodium Chloride bag

Heparin 5000 units in 1000 mL 0.9% Sodium Chloride bag

Oxytocin 10 Units added to 1000 mL Lactated Ringers Injectable Bag

Oxytocin 20 Units added to 1000 mL Lactated Ringers Injectable Bag

Oxytocin 60 Units added to 1000 mL Lactated Ringers Injectable Bag

Vancomycin 1 gram added to 250 mL 0.9% Sodium Chloride Injectable Bag.

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."