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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 158-15 Liberty Avenue<br>Jamaica, NY 11433<br>(718) 340-7000 Ext:5301 Fax:(718)662-5661 | 5/6/2019-6/25/2019*<br>FEI NUMBER<br>3008231170 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Estee Altman, CEO

| FIRM NAME | STREET ADDRESS |
|---|---|
| Infusion Options, Inc. | 5924 13th Ave |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Brooklyn, NY 11219-4934 | 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 WE OBSERVED:**

## OBSERVATION 1

Drug products are not stored under appropriate conditions of temperature and humidity so that their identity, strength, quality, and purity are not affected.

Specifically, on 05/16/2019, we observed (b)(4) coolers with drug products within expiry that require temperature-controlled conditions (e.g. 2°-8°C) stored on the floor of the warehouse bathroom that appeared to be actively used as such. Your firm failed to store drug products under sanitary and temperature-controlled conditions. Some of the products found under these conditions include but not limited to:

- (b) (4) (bevacizumab) 400mg/16mL (25mg/mL), Lot#(b) (4), Exp: 02-2021
- (b) (4) Rituximab) 100mg/10mL (10mg/mL), Lot#(b) (4), Exp:07-2021
- (b) (4) (carfilzomib) 60mg/vial, Lot#(b) (4), Exp: 01-2021
- (b) (4) (Infliximab) 100mg/vial, Lot#(b) (4), Exp: 10-2021

Note: Due to your firm's lack of document control for the receival, inventory, storage and use of these drug products there is no assurance on how long these drug products were exposed to the conditions aforementioned.

## OBSERVATION 2

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

Specifically, during the aseptic processing of sterile drug products we observed the following aseptic technique deficiencies:

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| | Jose O Hernandez, Investigator<br>Kevin J Flessa, Chemist/Biologist | X Jose O Hernandez Investigator Signed By Jose O. Hernandez-guzman -S Date Signed 07-08-2019 13 15 12 | 7/8/2019 |

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1) During compounding of Penicillin G, batch # PEN250508190800 on 05/08/2019:

   a. The operator moved her arms and hands over bottles, bags, syringes and needles multiple times (over 10 times) during the manufacturing process, disrupting the ISO-5 HEPA airflow over the compounded product and materials below her arms.

   b. The operator wiped the injection port of the 5% Dextrose Injection, USP, 100 ml bags, ((b) (4) bags) for disinfection, however the ports stayed in direct contact with the ISO-5 counter surface, leaving the ports exposed to any particulate or bacteria flushed by the vertical airflow onto the BSC work surface.

   c. After wiping the injection port with an (b) (4) the operator did not allow enough contact time for disinfection and the port to dry, then he immediately proceeded to inject the penicillin into the 5% Dextrose Injection, USP, 100ml bags.

2) During the priming of sodium chloride bags for chemotherapy drug production on 05/07/2019 the operator conducted the following deficiencies:

   a. After cleaning the sodium chloride bags with (b) (4) the operator threw the bags into ISO 5 LAF instead of placing them in, which causes fast disruption of airflow that could cause contamination of the materials and LAF surfaces.

   b. While priming the injection line, the operator sprayed (b) (4) directly into the injection port and did not allow enough contact time for disinfection, then he immediately proceeded to make a connection with (b) (4) still on the ports.

3) During the aseptic processing of Chemo Therapy product Fluorouracil 780mg/15.6 ml IVP Rx:(b) (6) on 05/07/2019, the operator conducting aseptic dispensing of materials moved her arms and hand out of the ISO-5 BSC without disinfecting her gloves prior to continuation of compounding. We observed her repeat the process over 5 times.

4) During review of video camera footage of the Ante Room ISO-8 area that directly connects with the ISO-7 compounding rooms for the period of 05/08/2019 to 05/16/2019, multiple aseptic process deficiencies were observed. For example:

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a. Employees which included management personnel were seen entering the ISO 7 and ISO 8 rooms either completely ungowned or partially gowned.
b. ISO 7 doors were being opened with bare hands.
c. Line of demarcation between gowned and un-gowned area in ISO 8 room does not appear to be considered. (e.g. Employees were observed going back and forth between the gowned and ungowned areas, while ungowned and in many cases wearing street clothing.)
d. Personnel gowning did not prevent gown apparel from touching the floor during the gowning process.
e. Inadequate cleaning/disinfection: transfer carts were not wiped completely (tops, bottoms, legs and wheels) prior to transferring between ISO areas, also carts were touched with bare hands while being cleaned, inadequate amount of cleaning/sanitizing agent ((b) (4)) was used to ensure an appropriate wet contact time on floors.
f. When used, the doors to material transfer areas were left open for prolonged periods of time.
g. Inadequate material transfer: firm is not using the material transfer areas to move materials from the ISO 8 to ISO 7 rooms, items are not being sanitized as they are transferred.
h. It was observed multiple times an employee carrying an armful of IV bags into an ISO 7 room with bare-arms (wearing short sleeves, no gowning).

5) On 06/14/2019, I observed the following:
a. A technician in the process of gowning while in the ISO 8 anteroom. I observed that while she was standing beyond the demarcation line, inside the "clean" portion of the room that she was wearing the pre-covered street shoes without first donning the sterile booties.
b. The same technician described in Observation 2, 5a was inside the demarcation area without protective goggles. While in the demarcation area, she attempted to put them on, then dropped them on the floor and she proceeded to pick them up and put them on, instead of leaving them on the floor and getting a new pair of goggles.
c. In the Intra Venous (b) (4) ISO-7 room, I observed a technician gowned inadequately, where his hood was not worn in a manner that covered his face exposing facial skin while he helped with the

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priming of IV bags to be used in the (b) (4) compounding room for chemo therapy drugs. The exposure of facial skin could lead to cell shedding during aseptic processes.

**OBSERVATION 3**

Unauthorized personnel have access to enter areas of the buildings and facilities designated as limited access areas.

Specifically, during the review of video camera footage of the Ante Room ISO-8 area (b) (4) rooms for the period of 05/08/2019 to 05/16/2019, we observed personnel with no documented training and or education on conducting processes in these areas. (e.g. it was observed an Infusion Options Inc. driver entering the aseptic areas ungowned and carrying compounding materials and products into the ISO-7 areas).

**OBSERVATION 4**

Written production and process control procedures are not followed in the execution of production and process control functions.

Your firm's pharmacist and technician failed to identify and collect adequate compounding materials prior to the compounding of Rx#(b) (6)- Piperacillan-Tazobactam 4.5gm/100ml D5W IV. Specifically, on 6/7/2019, it was observed (b)( bags of expired Dextrose 5% IV bags lot # (b) (4) Exp: May 2019 used for the preparation of (b) (4) add-a-vials Intra Venous drugs.

**OBSERVATION 5**

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

Specifically:

a) Your firm does not conduct continuous non-viable particulate testing in the ISO 5 areas, during aseptic processing. Currently your firm conducts the non-viable particulate testing every (b) (4) during the equipment certifications.
b) The HEPA filters on the ISO-5 (b) (4) Benches: (b) (4) and (b) (4)

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(b) (4) were observed with what appeared to be rust stains and signs of deterioration.

c) The upper light cover of (b) (4) Bench (b) (4) ISO-7 area used for the compounding of IV bag drug products contained what appeared to be dried and peeling off drug material.

**OBSERVATION 6**

Aseptic processing areas are deficient in that walls are not smooth and/or hard surfaces that are easily cleanable.

Specifically, the wall in the (b) (4) room ISO 7 grade, which are used for aseptic processing of Total parenteral nutrition (TPN) products, had paint peeling under the thermostat making this area porous and irregular.

**OBSERVATION 7**

Samples taken of drug products for determination of conformance to written specifications are not representative.

Specifically, your firm does not collect samples for testing that are representative of the entire aseptic processes. (e.g. During mfg. of Penicillin G, batch # PEN250508190800 we observed that your firm manufactured (b)(4) bags of product from (b)( separate bottles of (b) (4) Penicillin G, however collected the last mixed (b) bags as samples for testing from the last of the (b) bottles of Penicillin G.)

**OBSERVATION 8**

Written records of major equipment cleaning, maintenance and use are not included in individual equipment logs.

Specifically, your firm does not maintain usage/maintenance logs for any of the Laminal Air Flow and Bio Safety Cabinets used for the manufacturing of drug products, to document when the equipment was used, the products manufactured and cleaning and maintenance of the equipment.

**OBSERVATION 9**

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Your outsourcing facility did not submit a report to FDA identifying the drugs compounded during the previous six month period.

Therefore, failing to comply with section 503B(b)(2)(A). Specifically, the following products were compounded and not identified on your report dated December 2018:

- Daptomycin 800 MG/ 50 ML 0.9% NACL IV- (e.g. Rx#(b) (6) dated 8/1/2018)
- Heparin 30 units/3 mL flush Syringe - (e.g. Rx# (b) (6) dated 6/26/2018)
- Ferric Carboxymaltose 750 mg/50 mL NS- (e.g. Rx# (b) (6) dated 7/25/2018)
- Bortezomib 2.25 MG / 0.9 mL SQ Syringe- (e.g. Rx# (b) (6) date 7/25/2018)
- Bevacizumab 691 MG / 100 ML NS IVPB- (e.g. Rx# (b) (6) date 9/18/2018)

**OBSERVATION 10**

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 failed to conduct endotoxin testing on intrathecal drug products aseptically processed in your facility such as but not limited to:

- Rx#(b) (6)- Methotrexate 15 mg QS 6 mL NS IT, date 11/06/2018
- Rx#(b) (6)- Methotrexate 15 mg QS 6 mL NS IT, date 05/16/2019
- Rx#(b) (6)- Cytarabine 70 mg QS 3 mL PF NS Syringe, date 07/17/2018
- Rx#(b) (6)- Cytarabine 100 mg QS 6 mL PF NS Syringe, date 05/23/2019

**OBSERVATION 11**

Written records are not made of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications.

Specifically, your firm does not conduct and document investigations when drug product fails to meet specifications such as potency, sterility and endotoxin. For example:

a. Cefazolin Sodium 2mg- Lot# CEFAZ20306180900, Mfg. date 3/6/2018- (b) (4) -

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Sample # (b) (4) - Potency Laboratory results- 89.0% (Specification (b) (4)%)

b. Penicillin G 2.5 Million Units/ 100mL Dextrose 5%- Lot# PEN250516180810, Mfg. date 5/16/2018- (b) (4) - Sample # (b) (4) - Potency Laboratory results- 89.6% (Specification (b) (4)%)

c. Penicillin G 2.5 Million Units/ 100mL Dextrose 5%- Lot# PEN250518180810, Mfg. date 5/18/2018- (b) (4) - Sample # (b) (4) - Potency Laboratory results- 86.0% (Specification (b) (4)%)

## OBSERVATION 12

The labels of your outsourcing facility's drug products are deficient.

They do not include information required by section 503B(a)(10)(A). The statements, "This is a compounded drug" and "Not for resale," the lot or batch number, and the date the drug was compounded are not on your drug product labels. Labels for the following drug products do not contain these statements:

- Rx# (b) (6) - Daptomycin 1000 mg/50 mL 0.9% NACL IV, discard date: 05/16/19
- Rx# (b) (6) - Heparin 30 units/3 mL flush syringe, discard date: 08/05/19
- Rx# (b) (6) - Vancomycin 1000 mg/250 mL D5W IVPB, discard date: 05/16/19
- Rx# (b) (6) - Ferric Carboxymaltose 750 mg/50 mL NS, discard date: 05/08/19
- Rx# (b) (6) - Pembrolizumab 200 mg/100 mL NS IVPB, discard date: 04/30/19

## OBSERVATION 13

The container labels of your outsourcing facility's drug products are deficient.

The container of your outsourcing facility's drug products does not include information required by section 503B(a)(10)(B). Specifically, your outsourcing facility's drug product container labels do not contain information to facilitate adverse event reporting: http://www.fda.gov/medwatch and 1-800-FDA-1088. Container labels for the following drug products do not contain this information:

- Rx# (b) (6) - Daptomycin 1000 mg/50 mL 0.9% NACL IV, discard date: 05/16/19
- Rx# (b) (6) - Heparin 30 units/3 mL flush syringe, discard date: 08/05/19
- Rx# (b) (6) - Vancomycin 1000 mg/250 mL D5W IVPB, discard date: 05/16/19

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- Rx# (b) (6) - Ferric Carboxymaltose 750 mg/50 mL NS, discard date: 05/08/19
- Rx# (b) (6) - Pembrolizumab 200 mg/100 mL NS IVPB, discard date: 04/30/19

## OBSERVATION 14

The written stability testing program is not followed.

Specifically, your firm does not conduct stability studies on your prescription drug products such as but not limited to:

- Rx# (b) (6) - Daptomycin 1000 mg/50 mL 0.9% NACL IV, discard date: 05/16/19
- Rx# (b) (6) - Heparin 30 units/3 mL flush syringe, discard date: 08/05/19
- Rx# (b) (6) - Vancomycin 1000 mg/250 mL D5W IVPB, discard date: 05/16/19
- Rx# (b) (6) - Ferric Carboxymaltose 750 mg/50 mL NS, discard date: 05/08/19
- Rx# (b) (6) - Pembrolizumab 200 mg/100 mL NS IVPB, discard date: 04/30/19

## OBSERVATION 15

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

Specifically, your firm does not conduct potency and sterility testing for all prescription drug product aseptically processed at your facility such as:

- Rx# (b) (6) - Daptomycin 1000 mg/50 mL 0.9% NACL IV, discard date: 05/16/19
- Rx# (b) (6) - Heparin 30 units/3 mL flush syringe, discard date: 08/05/19
- Rx# (b) (6) - Vancomycin 1000 mg/250 mL D5W IVPB, discard date: 05/16/19
- Rx# (b) (6) - Ferric Carboxymaltose 750 mg/50 mL NS, discard date: 05/08/19
- Rx# (b) (6) - Pembrolizumab 200 mg/100 mL NS IVPB, discard date: 04/30/19

## OBSERVATION 16

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Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically, your firm failed to maintain separate storage areas out of the ISO-7 areas. Currently your firm is using refrigerators in the (b) (4) ISO-7 room for the storage of commercial drug products used in the aseptic processing of drug products.

Note: Refrigerators are particle generators that can affect the ISO-5 and ISO-7 area, that could affect product quality.

**OBSERVATION 17**

Your outsourcing facility compounds drug products that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective.

Specifically,

- Ondansetron 24 mg/50 mL D5W IVPB

***DATES OF INSPECTION**

5/06/2019(Mon), 5/07/2019(Tue), 5/08/2019(Wed), 5/09/2019(Thu), 5/10/2019(Fri), 5/16/2019(Thu), 5/17/2019(Fri), 5/20/2019(Mon), 5/29/2019(Wed), 5/30/2019(Thu), 5/31/2019(Fri), 6/03/2019(Mon), 6/05/2019(Wed), 6/06/2019(Thu), 6/07/2019(Fri), 6/10/2019(Mon), 6/12/2019(Wed), 6/13/2019(Thu), 6/14/2019(Fri), 6/25/2019(Tue)

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X Kevin J Flessa
Chemist/Biologist
Signed By: Kevin J. Flessa -S
Date Signed: 07-08-2019 13:15:51

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