DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	8/27/2019-9/12/2019* FEI NUMBER 3012907473

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Brett C. Riddle, Pharmacist-In-Charge

FIRM NAME	STREET ADDRESS
Innoveix Pharmaceuticals Inc	3790 Arapaho Rd
CITY, STATE, ZIP CODE, COUNTRY Addison, TX 75001-4311	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-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

Un-protected product intended to be sterile was exposed to lower than ISO 5 classified aseptic processing area quality air.

Specifically,

Your firm's Pharmacist-In-Charge left vials of sterile drug product, Human Chorionic Gonadotropin, (b) (4) Units, Lot #INX575, Production Date 07/26/2019, inside your (b) (4) brand name "(b) (4) (b) (4) ", model (b) (4) , pending sterility testing results.

Your firm's Pharmacist-In-Charge executes all capping and crimping of all sterile drug products outside of your ISO 5 biosafety cabinet. Your firm caps and crimps sterile drug products in the non-classified area of the general pharmacy.

OBSERVATION 2

Your facility design allowed the influx of poor quality air into a higher classified area.

Specifically,

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On 08/27/2019, I observed your firm's ISO 5 area to be a HEPA filtered area outside of your biosafety cabinet and your ISO 5 area is separated from the ISO 7 I.V. Buffer room (b) (4) (b) (4) I witnessed your firm's failure to monitor differential pressure between the ISO 5 areas and the ISO 7 I.V. Buffer area. Your firm only monitors pressure differentials between the ISO 7 I.V. Buffer area, your ISO 8 Anteroom, and the general pharmacy area. Your firm's third-party ISO 5 environment qualification company, does not perform smoke studies under dynamic conditions for any classified areas at your facility, including your ISO 8 Anteroom, ISO 7 I.V. Buffer area, and most importantly your ISO 5 biosafety cabinet. None of the unidirectional airflows in your facility's ISO 5 environments are characterized, in order to prevent influx of poor quality air into your higher classified areas.

In addition, your firm turns off the airflow in your biosafety cabinet, brand name "(b) (4) ", model (b) (4) (b) (4) , serial number #(b) (4) , while not in use. This allows for potential influx of poor quality air into your biosafety cabinet's higher classified environment. Your firm produces (b) (4) drug products intended to be sterile in your biosafety cabinet. Your firm's ISO 7 I.V. Buffer room failed qualifications on 05/15/2018 due to exceeding maximum air fungal counts (Alternaria Species, (b) (4) and on 08/04/2017 due to exceeding maximum air fungal counts (Yeast, (b) (4) . Your firm had a sterility failure on 01/01/2016 for your drug product, Sermorelin w/GHRP2, Lot SER125.

OBSERVATION 3

Personnel touched equipment or other surfaces located outside of the ISO 5 classified aseptic processing area with gloved hands and then engaged in aseptic processing without changing or sanitizing gloves.

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On 08/28/2019, during the production of Human Chorionic Gonadotropin, (b) (4) Units, Lot # SIM580, Production Date 08/28/2019, your firm's Pharmacist-in-Charge touched an exterior alarm switch eight times (located on front of the biosafety cabinet), with gloved hands, and failed to disinfect his gloved hands prior to reentry into the ISO 5 biosafety cabinet. In addition, the firm's Pharmacist-in-Charge rested his arms on the front of the ISO 5 biosafety cabinet during production of Lot #SIM580.

OBSERVATION 4

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

Specifically,

On 08/27/2019, your firm failed to allow adequate contact times for cleaning agents in your biosafety cabinet, brand name '(b) (4) ", model (b) (4) , serial number #(b) (4) ISO 5 environment. Your firm's Pharmacist-In-Charge allows for a contact time of (b) (4) for your sporicidal cleaning agent, (b) (4) The manufacturer's recommendations for contact time to achieve sporicidal activity for (b) (4) is (b) (4) .

OBSERVATION 5

Equipment was not disinfected prior to entering the aseptic processing areas.

Specifically,

On 08/28/2019, Your firm's Pharmacist-In-Charge failed to adequately disinfect equipment prior to entering your biosafety cabinet, brand name '(b) (4) ", model (b) (4) , serial number

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#(b) (4) , ISO 5 environment. Your firm's electric connection cable to the repeater pump, brand name "(b) (4)", serial #(b) (4), was disinfected in the ISO 7 I.V. Buffer Room area, but was dragged on the ISO 7 I.V. Buffer Room's floor into the ISO 5 area prior to entry into the firm's biosafety cabinet. This cable was not disinfected prior to entry into the firm's biosafety cabinet, during the production of Human Chorionic Gonadotropin, (b) (4) Units, Lot # SIM580, Production Date 08/28/2019.

OBSERVATION 6

Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically,

On 08/28/2019, your Pharmacist-In-Charge (PIC) failed to properly don the sterile gown and execute proper aseptic technique. While sterile gowning, the firm's Pharmacist-in-Charge allowed his sterile gown's arm sleeves and head hoodie to touch the floor of the anteroom and materials staging tables in the anteroom. This was prior to the production of Human Chorionic Gonadotropin, (b) (4) Units, Lot # SIM580, Production Date 08/28/2019. Your firm's PIC introduced this gown into the ISO 5 biosafety cabinet without disinfecting it. Your firm's PIC placed his head inside the biosafety cabinet during the set up of the repeater pump.

OBSERVATION 7

The ISO 5 classified aseptic processing areas had particle-generating and visibly dirty equipment or surface.

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On 08/27/2019, your firm failed to adequately clean your biosafety cabinet, brand name "(b) (4) ", model (b) (4) , serial number #(b) (4) ISO 5 environment. Your firm's Pharmacist-In-Charge left empty syringes, vials, gloves, syringe wrappers, sterile wipe wrappers, and an open bottle of water in your biosafety cabinet overnight. Your firm produces (b) (4) drug products intended to be sterile in the biosafety cabinet.

Additionally, your firm's Pharmacist-In-Charge left vial stoppers in your firm's (b) (4) overnight. This (b) (4) utilized to transfer all materials from your anteroom (ISO 8 classified) into your I.V. Buffer Room (ISO 7 classified) and then further transferred into your ISO 5 classified environments.

OBSERVATION 8

Your facility was designed and/or operated in a way that permits poor flow of personnel and materials.

Specifically,

On 08/28/2019, I witnessed your firm's lack of adequate space in your anteroom area to allow your Pharmacist-In-Charge to properly sterile gown and stage materials prior to the production of Human Chorionic Gonadotropin, (b) (4) Units, Lot # SIM580, Production Date 08/28/2019. I observed your firm's PIC touching items and surfaces in the ISO 8 anteroom without gloves.

OBSERVATION 9

The (b) (4) (b) (4)) used for (b) (4) terilization of product intended to be sterile were not lethal to (b) (4) microorganisms.

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Specifically,

On 08/27/2019, I witnessed your firm's failure to establish effective sterilization (b) (4) for your (b) (4), brand name "(b) (4)". The (b) (4) to your firm's (b) (4) does not securely close and must be propped shut by a yellow bucket, therefore all (b) (4) are not guaranteed to be maintained. Your firm does not utilize (b) (4) (b) (4) to verify the efficacy of your (b) (4) sterilization (b) (4) The firm utilizes the (b) (4) to sterilize glassware equipment utilized during production of drug products intended to be sterile.

In addition, during the use of your firm's (b) (4) brand name (b) (4) model (b) (4) serial # (b) (4), your firm does not utilize (b) (4) to verify the efficacy of your (b) (4) sterilization (b) (4) Your firm uses your (b) (4) to sterilize tongs and stoppers used during production of drug products intended to be sterile. Your firm does not maintain documentation for (b) (4) (b) (4) monitoring for both your (b) (4) and (b) (4).

***DATES OF INSPECTION**
8/27/2019(Tue), 8/28/2019(Wed), 8/29/2019(Thu), 8/30/2019(Fri), 9/02/2019(Mon), 9/03/2019(Tue), 9/04/2019(Wed), 9/05/2019(Thu), 9/06/2019(Fri), 9/09/2019(Mon), 9/10/2019(Tue), 9/11/2019(Wed), 9/12/2019(Thu)

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