DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Detroit District Office 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	04/17-20/2017; 04/25-26/2017
	FEI NUMBER 3004593468

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Bryan O'Neill, Director of Quality

FIRM NAME	STREET ADDRESS
Coram Healthcare Corporation of Indiana	1290 Arrowhead Court
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Crown Point, Indiana 46307	Producer of 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) (WE) OBSERVED:

OBSERVATION 1

Equipment, materials, and/or supplies are not disinfected prior to entering the aseptic processing areas.

Specifically, inadequate aseptic practices were observed while transferring materials on 4/18/2017 during the aseptic processing of 7 units of Ertapenem 1 gm/100 ml Rx (b) (6), (b) (7)(C) including the following:

-Pharmacy technicians wiped down IV bags with sterile IPA but without gloves prior to putting bags in prep room (ISO-8) and then directly moving bags from the prep room (ISO-8) into the hood (ISO-5) without disinfecting the bags;
-Vials of sterile drug products were removed from product boxes and were not cleaned. These vials were subsequently placed directly under the hood (ISO-5) without being disinfected;

Additionally, while bins that are used for transferring all of the components and ingredients for sterile drug production are wiped down on the inside; these bins are routinely stacked on top of each other with the components such as vials inside. Therefore, vials of active ingredients are touching the bottom of a bin while being transferred from the prep room (ISO-8) to the compounding room (ISO-7) and these vials are subsequently placed directly under the hood (ISO-5) without being disinfected.

OBSERVATION 2
The use of sporicidal agents in the cleanroom and/or ISO 5 area is inadequate.

Specifically, the adequacy of cleaning frequency has not been appropriately assessed to ensure potential contaminants are removed from surfaces in the ISO-5 classified area. For example, sporicidal agents that are used on a monthly basis are insufficient to assure the prevention of spores when, on a daily basis, intake materials are

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Emilie E. Kahn Sarah E Rhoades	Emilie E, Kahn, Investigator Sarah E. Rhoades, Investigator	04/26/2017

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not disinfected prior to being placed under the ISO-5 hood. In addition, your firm does not have data to support that the current established contact time of 10 minutes is sufficient to remove sporicidal activity.

OBSERVATION 3

Beta-lactam drugs are produced without adequate cleaning procedures to prevent cross contamination. Your firm's cleaning procedures are limited to use of sterile water and IPA (70%). There is no dedicated area for processing Beta-lactam products. Your firm has two ISO-5 hoods and beta-lactam products are processed in both. For example 7 units of Ertapenem 1 gm/100 ml Rx (b) (6), (b) (7)(C) and 21 units of Vancomycin 1.5 gm/250 ml Rx (b) (6), (b) (7)(C) were both processed under the same hood on 4/18/2017.

This is a repeat observation.

OBSERVATION 4

Aseptic environmental conditions are not assured by current monitoring practices.

Specifically,

The dynamic smoke study video that we viewed demonstrated an operator standing at the hood making manipulations with one IV bag at the top of the hood. This was not representative of aseptic processing operations observed from 04/17-19/2017. We observed your staff aseptically processing on the bench, with components, equipment (such as the TPN mixer or the repeater pump), and other items which can affect laminar air flow.

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