DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	9/10/2018-9/19/2018* FEI NUMBER 3013446837

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Stacy E. Bryant-Wimp, Operations Director

FIRM NAME	STREET ADDRESS
Accurate RX Pharmacy Consulting LLC	103 Corporate Lake Dr Ste B
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Columbia, MO 65203-7290	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 I OBSERVED:

OBSERVATION 1

The ISO 5 classified aseptic processing area was located within a non-classified room (segregated production area).

Specifically,

A. Your ISO 5 (b) (4) , (b) (4) , which is utilized to produce human sterile drug products that are administered with Beyond Use Dates greater than 12 hours, is in a non-classified segregated room. For example, the following prescriptions for human sterile drug products were produced in the ISO 5 (b) (4) between 6/10/2018 – 9/10/2018:

- Vancomycin 225 mg/NS 45 mL for Rx (b) (6) on 8/09/2018. BUD = 14 days refrigerated.
- Gammagard S/D Less IgA 30 g/600 mL for Rx (b) (6) on 8/14/2018. BUD = 3 days refrigerated after reconstitution.

B. The ISO 5 (b) (4) , (b) (4) , is (b) (4) in the open position during cleaning and (b) (4) certification operations, exposing both ISO 5 chambers (ante & main) to unclassified air from within the non-classified room. Additionally, technicians do not don sterile gowning garb when performing such operations inside the ISO 5 (b) (4)

This was observed on 9/11/2018 during post-cleaning of the ISO 5 (b) (4) after the production of

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	Constantin Y Philopoulos, Investigator X Constantin Y Philopoulos Investigator Signed By Constantin M. Philopoulos -S Date Signed 09-19-2018 14 52 06	9/19/2018

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Gammagard S/D Less IgA 30 g/600 mL for Rx (b) (6) and on 9/13/2018 during (b) (4) certification of the ISO 5 (b) (4)

C. Your ISO 5 (b) (4) (b) (4), does not always maintain a positive pressure differential ((b) (4)" wc) between the main chamber and the ante chamber during material-transfer processes from the surrounding non-classified room into the ante chamber. On 9/11/2018 and 9/13/2018, the pressure differential between the ante chamber and the main chamber was observed to be compromised (<0.02" wc) at times during material-transfers to produce Gammagard S/D Less IgA 30 g/600 mL for Rx (b) (6) and when performing the ISO 5 (b) (4) (b) (4) certification, respectively. Additionally, the ISO 5 (b) (4) is periodically turned off when not in use, thus not always maintaining a positive pressure differential with the surrounding non-classified room, as reported by management.

OBSERVATION 2

Disinfecting agents and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically,

You utilize the following non-sterile cleaning products to clean the ISO 5 (b) (4) (b) (4) (b) (4), which is utilized to produce human sterile drug products:

- (b) (4) spray solution (germicidal)
- (b) (4) cleaning wipes (lint-free)

On 9/11/2018, after production of Gammagard S/D Less IgA 30 g/600 mL for Rx (b) (6), you

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used the aforementioned non-sterile cleaning products during post-cleaning of the ISO 5 (b) (4) . These non-sterile cleaning products are also used to clean the ISO 5 (b) (4) at the beginning of each work day, as evidenced in your cleaning logs and referenced in your Policy SOP, PO-10 *Hood Cleaning Policy and Log*.

OBSERVATION 3

Sporicidal agents were not used in your facility's cleanrooms and/or ISO 5 classified aseptic processing area.

Specifically,

The germicidal agent, (b) (4) used when cleaning the ISO 5 (b) (4) (b) (4) (b) (4), before and after aseptic processing of human sterile drug products, is not considered to be a sporicidal agent.

***DATES OF INSPECTION**

9/10/2018(Mon), 9/11/2018(Tue), 9/12/2018(Wed), 9/13/2018(Thu), 9/19/2018(Wed)

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	Constantin Y Philopoulos, Investigator	X Constantin Y Philopoulos Investigator Signed By: Constantin M. Philopoulos -S Date Signed: 09-19-2018 14:52:06	9/19/2018