DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	11/7-10, 28 & 29/2016 FEI NUMBER 3004513970

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Tae Sun Kim, Executive Director Manufacturing and Distribution

FIRM NAME	STREET ADDRESS
Resource Optimization & Innovation, LLC	2909 N. Neergard Ave.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Springfield, MO 65803	503B Compounding Pharmacy

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

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established or followed:

Specifically,

A. Your evaluation of the unidirectional air flow pattern (known as your smoke study), conducted (b) (4) of your ISO 5 Laminar Airflow Workbench documented (b) (4) (b) (4)

(b) (4)

B. The location of the settling plates appears to be inadequate to monitor the filling of the sterile product or the complete environment of the hood. (b) (4)

In addition, your firm doesn't conduct volumetric air sampling of your ISO 5 hood during your compounding operations.

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C. You do not perform environmental monitoring (EM) sampling in all appropriate locations. Specifically, in the (b) (4) Room, you perform surface sampling (b) (4) however, you do not perform surface sampling (b) (4) on all significant objects which are touched and/or handled during compounding operations. For example:

1. There are (b) (4) pumps which are used during compounding of sterile drug products and are located adjacent to the ISO Class 5 hood during compounding operations. These pumps are not included in your EM program.

2. You have (b) (4) electronic tablets (b) (4)) which are used throughout compounding operations. You use (b) (4) l during compounding which is included in your EM program. You have (b) (4) additional (b) (4) which are used interchangeably. You do not, however, have any identification information on them to document which (b) (4) has been used and/or monitored in your EM program.

OBSERVATION 2

The batch production and control records are deficient in that they do not include documentation of the accomplishment of each significant step in manufacturing and processing.

Specifically,

Your (b) (4) batch record does not include correct information on the actual date and time compounding operations occurred for your Phenylephrine products. It is unknown when this systemic problem started with your processing/batch records. For example (but not limited to) the following:

A. Phenylephrine 100 mg/mL lot no. 38824.The Compound History component of your batch record reports compounding operations occurred on (b) (7)(C), (b) (6), (b) (4) . Your media fill documentation records compounding operations do not occur for more than (b) (4) .

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B. Phenylephrine 100 mg/mL 10 mL, lot number 39124: The Compound History Record documents the Materials Handler (b) (7)(C), (b) (6) as the person who started compounding on 10/27/16 at 15:56 and at 16:36. The Material Handler is also listed as Starting Batch Setup and Ready for Batch Set Up Approval on 10/27/16 at 15:47 and 15:50, respectively. The Material Handler has not, however, been qualified to work in the sterile area and has not been trained in this area.

C. Phenylephrine 100 mg/mL 10 mL, lot number 39318: The Compound History Record does include information on the Pharmacy Technician who was involved in compounding operations for this batch on 11/10/16, which is documented in your Batch Traveler Record. The Compound History Record for this lot, however, documents compounding occurred on 11/14/16 by Pharmacist Technician (b) (7)(C), (b) (6) when compounding activities were reported to have been completed on 11/10/16.

D. Phenylephrine 100 mg/mL 10 mL, lot number 39316: The Compound History Record documents compounding started on 11/14/16 whereas your Batch Traveler Record documents compounding operations for this lot occurred on 11/3/16.

OBSERVATION 3

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

Specifically,

Your aseptic practices are inadequate as you do not clean from the top down and you do not always clean every area of the ISO 5 hood. For example, on 11/10/16 (but not limited to) your Pharmacist Technician did not clean the bar at the top of the ISO 5 Hood before compounding operations began on Phenylephrine 100 mg/mL 10 mL, lot number 39318.

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OBSERVATION 4

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

Your Registered Pharmacist stated they knew in June the label for your Phenylephrine HCl 100 mcg/mL 5 mL product did not contain the inactive ingredient information. You failed, however, to implement corrective actions to change your labels to include this information and yet continued to distribute this product with the missing inactive ingredient information.

OBSERVATION 5

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

Specifically,

You do not continuously monitor pressure throughout compounding operations for drug products compounded at your facility. Your SOP 01.ROI.MFr.IVC.014 "IVC Environmental Controls" requires you to read your pressure readings "at (b) (4) (b) (4) to get accurate readings".

OBSERVATION 6

Neither the label nor the container of your outsourcing facility's Phenylephrine 100 mcg per mL, 5 mL syringe drug product includes the following information required by section 503B(a)(10).

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Specifically,

Neither label nor the container for your Phenylephrine 100 mcg per mL, 5 mL syringe product contain a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

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