DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237-3097 (513)679-2700 Fax:(513)679-2772	3/27/2017-3/31/2017
	FEI NUMBER 3011967886

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Raymond R. Carlson , Owner

FIRM NAME	STREET ADDRESS
RC Outsourcing LLC	102 E Water St
CITY, STATE, ZIP CODE, COUNTRY Lowellville, OH 44436-1117	TYPE ESTABLISHMENT INSPECTED 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

There is a failure to thoroughly review any unexplained discrepancy and 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,

1) Between 2/14/2016 and 3/10/2017, 22 positive results of fingertip, (b) (4), and surface sampling were recorded that exceeded (b) (4) colony forming unit. Only 5 investigations were completed; 2 of which resulted in an additional (b) (4) cleaning and the remaining 3 had no action taken. The organism obtained was only identified in one investigation. The results obtained included the following: 2 colony forming units on the ISO 5 surface (b) (4) taken on 3/10/17, 5 colony forming units on the ISO 5 surface (b) (4) taken on 1/23/17, 1 colony forming unit (recorded as "bigger") on the ISO 5 surface (b) (4) taken on 03/07/16, 10 colony forming units on the fingertip (b) (4) taken on 10/03/16, 2 colony forming units (recorded as covering the plate) on the fingertip (b) (4) taken on 08/25/16, 10 colony forming units on the fingertip (b) (4) taken on 04/27/16, 20 colony forming units on the (b) (4) taken on 03/30/16, and "multiple" and "many" colony forming units on the fingertip (b) (4) taken on 03/18/16.
2) During your media fill intended to represent Avastin production on (b) (4), your (b) (4) taken for sterile fingertip and (b) (4) testing after production resulted in (b) (4) colony forming unit, with no action or investigation undertaken.

This is a Repeat Observation from FDA inspection ending on 2/09/2016.

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Matthew B Casale, Investigator Jazmine N Still, Investigator	3/31/2017 X Matthew B Casale Matthew B Casale Investigator Signed by: Matthew B. Casale -S	3/31/2017

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

Specifically,

1) During cleaning on (b) (4), you cleaned the outside of the ISO 5 hood and then the inside top of the hood with same cloth.
2) During cleaning on (b) (4), you cleaned ISO 8 side of door between the ISO 7 cleanroom and ISO 8 anteroom, and then cleaned the ISO 7 side of the door with same cloth.
3) During cleaning on (b) (4), the door between the ISO 7 cleanroom and ISO 8 anteroom rooms was left open repeatedly during cleaning and then to air out the ISO 7 room after cleaning.
4) During cleaning on (b) (4), you repeatedly moved from the ISO 8 anteroom to the ISO 7 cleanroom and back again, without changing gowning or gloves.
5) While preparing to enter the ISO 7 cleanroom to repackage Avastin on 3/27/17, you (b) (4) (b) (4) with (b) (4) and then put a second tub containing more syringes and (b) (4) which had been sitting on a wire rack in the ISO 8 anteroom, on top of the syringes in the first tub.

OBSERVATION 3

Clothing of personnel engaged in the manufacturing, processing and packing of drug products is not appropriate for the duties they perform.

Specifically,

1) During sterile gowning to produce Avastin syringes on 3/27/17, you donned your sterile gown before sitting on a non-sterile bench in the ISO 8 anteroom, donned your sterile boots, washed your hands with tap water after pushing up the sleeves of your sterile gown, removed your mask, donned your sterile hood and goggles with the neck of the hood on top of the gown, donned your sterile gloves, and then touched the chest of the gown, the hood, and your goggles with your sterile gloves.

2) During production of Avastin syringes on 3/27/17, you placed the tub of empty syringes, which had previously been sitting on a wire rack in the ISO 8 anteroom, in your lap on top of your sterile gown without disinfecting the outside of the tub.

OBSERVATION 4

Each batch of drug product purporting to be pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically,

There is no routine testing for endotoxin of sterile parenteral drug products manufactured at your firm, including products manufactured using non-sterile active pharmaceutical ingredients, such as vancomycin, phenylephrine, absolute alcohol, and dexamethasone ocular injections.

This is a Repeat Observation from FDA inspection ending on 2/09/2016.

OBSERVATION 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and written.

Specifically,

6) There is no growth promotion on media prepared by your firm during media fills intended to validate aseptic sterile drug processes to demonstrate that the media can support microbial growth.
7) The (b) (4) used to sterilize and depyrogenate glassware and the (b) (4) used to sterilize and depyrogenate (b) (4) used in sterile parenteral drug production has not been demonstrated to remove endotoxin, despite the fact that the items are (b) (4) that has been poured into a non-sterile spray bottle, and then (b) (4)

(b) (4) in an unclassified room. In addition, no (b) (4) are used to verify (b) (4) .

8) No hold times have been established for the depyrogenated sterilized glassware (b) (4) and (b) (4) stored in tubs in the ISO 8 anteroom that are intended to be used in sterile parenteral drug production.

This is a Repeat Observation from FDA inspection ending on 2/09/2016.

OBSERVATION 6

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

Specifically,

9) Non-viable particulate monitoring is performed (b) (4) and is not performed under dynamic conditions.
10) Active air sampling is performed (b) (4) and is not performed under dynamic conditions.

This is a Repeat Observation from FDA inspection ending on 2/09/2016.

OBSERVATION 7

Test procedures relative to appropriate laboratory testing for sterility are not followed.

Specifically,

The sterility test you use to test each batch of sterile parenteral drug product you produce uses only (b) (4) media; you have not tested any product using (b) (4) media to date.

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OBSERVATION 8

The accuracy and reproducibility of test methods have not been established and documented.

Specifically,

You do not have a program to qualify employees to perform visual inspection for container defects and particulates on finished sterile parenteral drug products.

OBSERVATION 9

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

Visual inspection for container defects and particulates on finished sterile parenteral drug products is performed by staring at the container directly in front of an (b) (4) with employees performing the examination complaining of the light hurting their eyes and causing headaches.

3/31/2017

X Jazmine N Still

Jazmine N Still
Investigator
Signed by: Jazmine Still -S

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	Matthew B Casale, Investigator Jazmine N Still, Investigator 3/31/2017 X Matthew B Casale Matthew B Casale Investigator Signed by: Matthew B. Casale -S	3/31/2017