DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	8/18/2025-8/28/2025* FEI NUMBER 3011967886

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Raymond R. Carlson, RPh, Owner	
FIRM NAME RC Outsourcing, LLC	STREET ADDRESS 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 I OBSERVED:

OBSERVATION 1

Investigations of a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy.

Specifically, Lot # #20250428-488A81 of Avastin® (bevacizumab) re-packaged on April 28, 2025, failed sterility testing. Non-Conformance Report NCR-2 identified the potential root cause as a medical condition the technician who re-packaged the lot was experiencing and failed to report. Your investigation resulted in the rejection of this lot. You did not extend the investigation to other lots re-packaged by the same technician. From April 21, 2025 to July 21, 2025, the technician re-packaged approximately (b) (4) lots of Avastin® (bevacizumab), including the lot that failed sterility testing. In addition, your firm failed to implement appropriate corrective action in that once you were informed of the issue you allowed the technician to continue working in the cleanroom before resolution of the medical condition.

OBSERVATION 2

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

Specifically, your firm has not developed an environmental monitoring plan based upon sound scientific methods to include appropriate sampling frequency and timing. Your firm has no

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documentation to demonstrate that the environmental sampling performed is representative of the entire process. For example,

a) Your firm is taking (b) (4) active viable air(b) (4) towards the (b) (4) of filling. Filling operations for Avastin® (bevacizumab) can take (b) (4) In addition, the active air sampler is placed outside of the laminar flow hood facing into the flow of the air. Your firm has no documentation to demonstrate that this sampling method is representative of ISO 5 conditions within the laminar flow hood.

This is a repeat observation from the 09/17-27/2024 inspection.

b) On August 18, 2025, I observed the passive air plates were placed in the far corner of each laminar flow hood. In Hood (b) (4) which is a (b) (4) hood, the plate was placed in the far left corner, approximately 3-4 feet away from where aseptic manipulations occur. In Hood (b) (4) the plate was placed in the far right corner, approximately 1.5ft away from where aseptic manipulations occur. Your firm has no documentation to demonstrate that the location of these passive settle plates will provide meaningful environmental monitoring data. In addition, your firm is using (b) (4) plates for the passive air sampling. (b) (4) plates are designed for surface sampling and are not typically used as settle plates.

SOP 57 Testing of Sterile Environment, version 4.0 effective 2025-07-16, states under section 5.6 Passive Air Sampling Protocol, that a passive air sample is collected (b) (4) in the ISO 5 and that a (b) (4) plate is opened and placed in the ISO 5 space in a location where it will not interfere with compounding activities".

c) SOP 57 Testing of Sterile Environment, version 4.0 effective 2025-07-16, does not define a maximum amount of time that a settle plate can be open. Section 5.6.3 states that "the (b) (4) plate will remain open until compounding is completed". Filling operations can last(b) (4) .

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d) On August 18, 2025, I watched two technicians working in the cleanroom perform personnel monitoring. One technician lightly touched the plate to their sleeves and did not use a (b) (4) (b) (4) while performing the sampling. The other technician pushed the plate more firmly to their sleeve but did not use a(b) (4) while performing the sampling. The technique used may not provide meaningful personnel monitoring data.

Work Instruction WI-18 Microbiological Media Sampling, version 1.0 effective 2024-10-08, states under section D. Collecting Gown Sleeve Samples: "Using a (b) (4) , choose a spot in the defined area mentioned above on the right sleeve and (b) (4) exposed media with moderate (b) (4) to assure full contact with the sleeve".

e) Your firm has no documentation justifying the action level for personnel monitoring of the sleeves of the technicians' sterile gowning. Your firm has set an action limit of (b) (4) per sleeve. Since October 1, 2024, your firm personnel have had approximately 43 instances of microbial recovery on sleeves. These include four (4) instances where 3CFU were recovered and one (1) instance where 2CFU were recovered. None of these recoveries have been investigated since they were (b) (4) your action limit. On August 18, 2025, I observed the filling/re-packaging of Avastin® (bevacizumab) in StaClear® Syringes. I observed the technicians' arms being fully inside the ISO 5 laminar flow hood while filling the syringes.

OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically, from October 1, 2024 to present your firm personnel have had approximately 43 instances of microbial recovery on sleeves. These include four (4) instances where 3CFU were recovered and one (1) instance where 2CFU were recovered. All others were 1CFU.

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None of these recoveries have been investigated since they were (b) (4) your action limit. Your firm failed to identify and investigate this adverse trend in personnel monitoring.

OBSERVATION 4

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

Specifically, tips and caps for dropper bottles are placed directly onto the surface of the LFH when filling Povidone-Iodine (re-packaging Betadine).

Work Instruction WI-22 Production Protocol for Repackaging Betadine (povidone-iodine) 5% Ophthalmic Solution in Sterile Dropper Bottles, version 3.0 effective 2025-02-14, states under section 5.3 Production Tasks: "6. Open (b) (4) of the dropper bottles. Remove (b) (4) (b) (4) (b) (4) from the package. Remove the (b) (4)

The batch record for the filling of Povidone-Iodine (re-packaging Betadine) also states under one of the Production Tasks to "Remove dropper bottles from the package and (b) (4) (b) (4) and set them with the (b) (4) to the (b) (4) of the holders".

This is a repeat observation from the 09/17-27/2024 inspection.

OBSERVATION 5

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.

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Specifically, test methods used by your contract testing lab for determining assay for the Lidocaine 23%-Tetracaine 7% ointment (LT), Lidocaine, USP 20%-Tetracaine, USP 6%-Phenylephrine, HCl 2% ointment (LTP), and the Benzocaine 20%-Lidocaine 6%-Tetracaine 4% ointment (BLT) are not validated. The Certificate of Analysis (CoA) from the contract testing lab states for the analysis of Tetracaine, Benzocaine and Phenylephrine that the potency method(s) used passed system suitability requirements for "non-cGMP analysis" and that "product specific method validation is not available for this sample and specification(s) are for informational purposes only". Since October 1, 2024, your firm has made approximately (b) (4) lots of the BLT stock, (b) (4) lots of the LT stock, and (b) (4) lots of the LTP stock.

OBSERVATION 6

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without performing at least one specific identity test on each component and establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Specifically, your firm is compounding Lidocaine HCl 2% Solution injection, Lidocaine 23%-Tetracaine 7% ointment (LT), Lidocaine, USP 20%-Tetracaine, USP 6%-Phenylephrine, HCl 2% ointment (LTP), and the Benzocaine 20%-Lidocaine 6%-Tetracaine 4% ointment (BLT) from bulk drug substances. Your firm does not perform any testing, including an identity test, on the incoming bulk drug substances or excipients used to make these products.

OBSERVATION 7

Routine calibration of automatic, mechanical and electronic equipment is not performed according to a written program designed to assure proper performance.

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Specifically, your firm is not calibrating the balances used to weigh bulk drug substances and excipients used to make Lidocaine HCl 2% Solution injection, Lidocaine 23%-Tetracaine 7% ointment (LT), Lidocaine, USP 20%-Tetracaine, USP 6%-Phenylephrine, HCl 2% ointment (LTP), and the Benzocaine 20%-Lidocaine 6%-Tetracaine 4% ointment (BLT). Your personnel perform a verification before use using uncalibrated weights. Of the three (3) technicians I spoke to, each performed this verification in a manner that was not consistent with WI-16 Calibration and Operation of a Precision Balance, version 1.0 effective 2024-10-28. In addition, the verification performed when making the Lidocaine 2% Solution injection is not documented. No other calibration of the balances is performed.

OBSERVATION 8

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically, your firm is not recording all pertinent information regarding raw materials, equipment and consumables used during the compounding of drug products. For example,

a) Your firm does not record the lot number of the sterile disposable beakers used to make the Lidocaine 2% Injection.
b) Your firm did not record in the batch record the lot number of the (b) (4) used for lot #20240725-0C03FA of Lidocaine 2% Solution injection.

***DATES OF INSPECTION**

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8/18/2025(Mon), 8/19/2025(Tue), 8/20/2025(Wed), 8/21/2025(Thu), 8/22/2025(Fri), 8/25/2025(Mon), 8/26/2025(Tue), 8/28/2025(Thu)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."