

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772		DATE(S) OF INSPECTION 8/24/2026-9/3/2026* FEI NUMBER 3011967886			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Raymond Robert Carlson , 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 WE OBSERVED: OBSERVATION 1 Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic and sterilization process. Specifically, A. Your firm conducted Airflow Visualization (AFV) studies (smoke studies) for ISO 5 Laminar Flow Hood (b) (4) (LFH (b) (4)) and Laminar Flow Hood (b) (4) (LFH (b) (4)) under both static and dynamic conditions in August 2025 and February 2026. No formal study reports or supporting documentation were available for review for either study. The records lacked the following critical study elements: the type of smoke sources, the stated study purpose, targeted test locations, and personnel activities performed during dynamic conditions, real-time observations, and conclusions. Although video recordings of the AFV studies were captured, they were not accompanied by written protocols, contemporaneous documentation, or summary reports sufficient to contextualize, interpret, or substantiate the visual findings. B. Discrepancies were identified in the Airflow Visualization (AFV) records (videos) for ISO 5 Laminar Flow Hood (b) (4) (LFH (b) (4)) and Laminar Flow Hood (b) (4) (LFH (b) (4)) from studies completed in August 2025 and February 2026. The following deficiencies were observed: i. Incomplete Coverage of Critical Production Steps Across both August 2025 and February 2026 AFV studies, the dynamic airflow visualization did not encompass all critical steps performed during commercial production operations. For example, the following steps were not captured in either study period: • Drawing drug product from vials into a (b) (4) mL syringe using (b) (4) needle, syringe preparation, cap preparation, opening of syringe and cap boxes (trays of (b) (4) units),					
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> EMPLOYEE(S) SIGNATURE Kara J Wright, Investigator Pushpa S Jayasekara, Investigator Jeremy T Dautrich, Investigator </td> <td style="width: 40%; vertical-align: top; text-align: center;"> X Jeremy T Dautrich Investigator Signed By: JEREMY T. DAUTRICH -S Date Signed: 09-03-2026 16:50:10 </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Kara J Wright, Investigator Pushpa S Jayasekara, Investigator Jeremy T Dautrich, Investigator	X Jeremy T Dautrich Investigator Signed By: JEREMY T. DAUTRICH -S Date Signed: 09-03-2026 16:50:10
EMPLOYEE(S) SIGNATURE Kara J Wright, Investigator Pushpa S Jayasekara, Investigator Jeremy T Dautrich, Investigator	X Jeremy T Dautrich Investigator Signed By: JEREMY T. DAUTRICH -S Date Signed: 09-03-2026 16:50:10				
		DATE ISSUED 9/3/2026			

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772		DATE(S) OF INSPECTION 8/24/2026-9/3/2026* FEI NUMBER 3011967886			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Raymond Robert Carlson , 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			
picking up and attaching caps to filled syringes, and the capping process. • Only the filling of each (b) (4) mL syringe to the 0.07 mL mark was consistently captured. This deficiency was observed across multiple video records. ii. Stationary Fogger Wand and Absence of Airflow Visualization Over Critical Work Zones In multiple video records from February 2026, the fogger wand was held stationary rather than maneuvered to cover all critical work surfaces and product-contact areas. For example: • In the provided video (LFH (b) (4) Repacking, dynamic), no airflow visualization was observed over the syringe to be filled or cap containers from T= (b) (4) to T= (b) (4), and no AFV was observed over the filling area at T= (b) (4). • In the provided video (LFH (b) (4) Sterile (b) (4), dynamic), the fogger wand was stationary, and no airflow visualization was captured over the initial collection of drug product from the (b) (4) container into the syringe (T= (b) (4) to T= (b) (4)). • In the provided video (LFH (b) (4), Repacking, dynamic), the fogger wand remained stationary throughout the entire video, with no airflow visualization captured over the syringe and cap containers at any point during the study. iii. Absence of AFV During Dynamic (Operational) Conditions In the provided video (LFH (b) (4)) (February 2026), airflow visualization was observed only under static conditions (T= (b) (4) to T= (b) (4)). Once the operator began preparation for production, no AFV was conducted during the dynamic phase (T= (b) (4) to T= (b) (4)), despite dynamic studies being required to reflect actual operational conditions. iv. Absence of Active Air Sampling During AFV Studies In all three August 2025 video records covering both LFH (b) (4) and LFH (b) (4) no active air sampling was performed concurrent with the AFV studies. Active air sampling during AFV studies is necessary to assess and document the microbiological quality of the environment under simulated or actual operational conditions.					
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%;"> EMPLOYEE(S) SIGNATURE Kara J Wright, Investigator Pushpa S Jayasekara, Investigator Jeremy T Dautrich, Investigator </td> <td style="width: 40%; text-align: center; vertical-align: bottom;"> Jeremy T Dautrich Investigator Signed By: JEREMY T. DAUTRICH -S Date Signed: 09-03-2026 16:50:10 X </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Kara J Wright, Investigator Pushpa S Jayasekara, Investigator Jeremy T Dautrich, Investigator	Jeremy T Dautrich Investigator Signed By: JEREMY T. DAUTRICH -S Date Signed: 09-03-2026 16:50:10 X
EMPLOYEE(S) SIGNATURE Kara J Wright, Investigator Pushpa S Jayasekara, Investigator Jeremy T Dautrich, Investigator	Jeremy T Dautrich Investigator Signed By: JEREMY T. DAUTRICH -S Date Signed: 09-03-2026 16:50:10 X				
		DATE ISSUED 9/3/2026			

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772	DATE(S) OF INSPECTION 8/24/2026-9/3/2026*
	FEI NUMBER 3011967886

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Raymond Robert Carlson , 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

The AFV studies for ISO 5 LFH^{(b) (4)} and LFH^{(b) (4)} conducted in both August 2025 and February 2026, were incomplete and did not adequately simulate or represent actual commercial production operations, including critical manual steps and interventions. These deficiencies indicate that unidirectional airflow protection over open product and product-contact components during critical production steps have not been adequately characterized or verified, which poses a risk to sterility assurance and the quality of the drug product.

C. Media fills were not representative of routine production. Review of the media fills revealed the following discrepancies:

- i. Your firm's two most recent media fill runs were conducted, spanning from (b) (4) and (b) (4), with personnel rotation across all (b) (4) employees over a period of up to (b) (4) days. Review of the records revealed that on media fill run days, your firm simultaneously conducted commercial production lots, producing up to (b) (4) lots per day across LFH^{(b) (4)} and LFH^{(b) (4)} operating across (b) (4) shifts and (b) (4), for a total of (b) (4) shifts per day. The media fill runs did not represent the worst-case production scenario, as they failed to account for all shift changes and the associated line clearances performed between production runs. For example, during both of the past two media fill runs, (b) (4) covered per media fill run, thereby not simulating all (b) (4) shifts or the corresponding line clearances and shift transitions that occur during commercial operations.
- ii. Review of the past two media fill batch records revealed that the records contained no directions specifying the required number of air samples an operator must collect or the prescribed time intervals at which sampling must occur. Consequently, all media fill batch records reviewed contained (b) (4), and none of the records included lot numbers for the associated media plates used during the runs. This is in contrast to commercial production, during which (b) (4) active air samples are taken per (b) (4).

Your firm's media fill program does not adequately simulate worst-case aseptic processing conditions, as it fails to incorporate all shift changes, associated line clearances, and representative environmental monitoring practices observed during commercial production. This deficiency, compounded by

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Kara J Wright, Investigator Pushpa S Jayasekara, Investigator Jeremy T Dautrich, Investigator	Jeremy T Dautrich Investigator Signed By: JEREMY T. DAUTRICH -S Date Signed: 09-03-2026 16:50:10	DATE ISSUED 9/3/2026
	X		

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772		DATE(S) OF INSPECTION 8/24/2026-9/3/2026* FEI NUMBER 3011967886			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Raymond Robert Carlson , 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			
unresolved sterility failures and incomplete investigation findings, raises significant concerns regarding your firm's ability to assure the sterility of its aseptically re-packaged drug product. D. The following inadequate aseptic technique behaviors were observed: Your procedure, SOP 65, Maintaining Sterile Environment, effective 04/08/2026, is deficient. For example, per this procedure, your sterile gloving and gowning must be performed (b) (4) entering the ISO 8 anteroom, which should be designated solely for pre-gowning activities, including the donning of head covers, masks, and shoe covers. However, it was observed that operators enter the ISO 8 anteroom directly from the labeling room wearing street garments and initiate aseptic gowning within the ISO 8 area itself. No physical or spatial separation exists within the ISO 8 room to support or delineate a gowning zone. ii. Prior to initiating production, operators in sterile gowning exited the ISO 7 cleanroom and entered the ISO 8 anteroom to collect media plates and components, then re-entered the ISO 7 area to begin production at the ISO 5 LFH, thereby exposing sterile gowning, including head covers and goggles, to a less-controlled environment before aseptic operations commenced. iii. During filling operations, after completing approximately the first half of the finished batch of filled syringes of Avastin in the ISO 5 LFH, operators exited the cleanroom and entered the ISO 8 anteroom carrying the filled syringes, placing them on the ISO 8 surface. Operators then collected additional drug vials, re-entered the ISO 7 cleanroom, and completed the remaining half of the lot. Upon re-entry to the ISO 5 LFH, operators changed only their sterile gloves and sleeve covers, without performing a full gown change following exposure to the ISO 8 anteroom environment. Additionally, during syringe filling, operators were observed leaning into the ISO 5 LFH such that their head covers and goggles extended into the ISO 5 work zone. Given that operators exited and re-entered the cleanroom multiple times during aseptic filling — exposing their sterile gowning to less-controlled environments —re-engaging in ISO 5 LFH operations constitutes a repeated and unmitigated breach of aseptic technique.					
SEE REVERSE OF THIS PAGE		<table style="width: 100%; border: none;"> <tr> <td style="border: none; vertical-align: top;"> EMPLOYEE(S) SIGNATURE Kara J Wright, Investigator Pushpa S Jayasekara, Investigator Jeremy T Dautrich, Investigator </td> <td style="border: none; vertical-align: top; text-align: center;"> DATE ISSUED 9/3/2026 </td> </tr> </table> Jeremy T Dautrich Investigator Signed By: JEREMY T. DAUTRICH -S Date Signed: 09-03-2026 16:50:10 X		EMPLOYEE(S) SIGNATURE Kara J Wright, Investigator Pushpa S Jayasekara, Investigator Jeremy T Dautrich, Investigator	DATE ISSUED 9/3/2026
EMPLOYEE(S) SIGNATURE Kara J Wright, Investigator Pushpa S Jayasekara, Investigator Jeremy T Dautrich, Investigator	DATE ISSUED 9/3/2026				

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772		DATE(S) OF INSPECTION 8/24/2026-9/3/2026*
		FEI NUMBER 3011967886
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Raymond Robert Carlson , 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	

E. Your Firm's environmental monitoring (EM) program for the cleanroom area is deficient.

Per SOP 57, *Testing of Sterile Environment*, effective date 04/09/2026, operators are required to perform personnel sampling of fingertips and gown sleeves (b) (4). However, personnel sampling of the sterile head/face covers and face goggles is not included in the sampling protocol. As described in the previous Observation 1D, operators exit and re-enter the ISO 7 cleanroom through the ISO 8 anteroom multiple times during the filling/repackaging operation and place their head/face coverings and goggles into the ISO 5 critical area during the filling process. The absence of head/face cover and google sampling therefore leaves a significant gap in personnel contamination monitoring.

- ii. Personnel sampling for fingertips and gown sleeves is performed only (b) (4), not after completing the first half. The firm's current sampling practice, therefore, does not adequately represent the full fingertip and gown sleeve contamination exposure throughout the filling/repackaging cycle. This practice does not adequately represent the full fingertip and gown sleeve contamination exposure throughout the filling/repackaging cycle, as the first half of the lot is completed prior to the ISO 8 anteroom exit and is not captured by (b) (4) sampling.
- iii. Your firm does not perform surface sampling in the ISO 8 anteroom on a routine basis; (b) (4) collected every (b) (4) as part of the ISO room qualification program. Additionally, while your firm conducts (b) (4) active air sampling, the selected sampling frequencies and locations are not supported by a documented risk assessment based on your historical environmental data.
- iv. Your firm monitors non-viable particulates (NVP) in the ISO 5 laminar flow hood (LFH), ISO 7, and ISO 8 classified areas using (b) (4) NVP equipment assigned (Manufacturer: (b) (4), Model # (b) (4)) in each classified space. Active air samplers (SAS) are also (b) (4) in LFH (b) (4) and LFH (b) (4). The following deficiencies were noted regarding equipment location selection and orientation for both NVP and SAS equipment:

LFH (b) (4) (b) (4) wide) and LFH (b) (4) (b) (4) wide) operate with (b) (4) airflow. The NVP (b) (4) sample (b) (4) and SAS units in both LFHs are positioned (b) (4) to the LFH

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Kara J Wright, Investigator Pushpa S Jayasekara, Investigator Jeremy T Dautrich, Investigator	DATE ISSUED 9/3/2026
	Jeremy T Dautrich Investigator Signed By: JEREMY T. DAUTRICH -S Date Signed: 09-03-2026 16:50:10	

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772		DATE(S) OF INSPECTION 8/24/2026-9/3/2026* FEI NUMBER 3011967886	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Raymond Robert Carlson , 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	
airflow and are located near the end corners of the respective hoods, rather than in close proximity to the filling/repackaging station, with no scientific justification. Likewise, the SAS orientation and placement in both LFHs have not been justified. The NVP^{(b) (4)} sample^{(b) (4)} in LFH^{(b) (4)} is located near the ^{(b) (4)} end corner, approximately 2–2.5 feet from the filling/repackaging station. Particulate monitor placement must be representative of and in close proximity to the active filling/repackaging process to yield meaningful monitoring data. ^{(b) (4)} installed in each of the ISO 7 and ISO 8 rooms. The location selection rationale for these instruments was based primarily on practical considerations — such as proximity to a ^{(b) (4)} connection — rather than on a risk assessment derived from historical environmental data. Your firm's environmental monitoring program contains multiple significant deficiencies in personnel sampling coverage, surface and air sampling frequency, and the placement and orientation of particulate monitoring and active air sampling equipment. None of these practices are supported by documented risk assessments. Collectively, these deficiencies compromise your firm's ability to detect and respond to potential microbial and particulate contamination during sterile filling/repackaging operations, posing a risk to product sterility assurance and patient safety.			
OBSERVATION 2 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, Sterility test failure investigations for aseptically re-packaged Avastin 1.25 mg/0.05 mL were inadequate and failed to identify probable root causes. Since October 2025, the firm has rejected four batches due to sterility			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Kara J Wright, Investigator Pushpa S Jayasekara, Investigator Jeremy T Dautrich, Investigator DATE ISSUED 9/3/2026	
		Jeremy T Dautrich Investigator Signed By: JEREMY T. DAUTRICH -S Date Signed: 09-03-2026 16:50:10 X	

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772	DATE(S) OF INSPECTION 8/24/2026-9/3/2026*
	FEI NUMBER 3011967886

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Raymond Robert Carlson , 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

failures. Despite the rejection of these batches, other batches manufactured on the same day and in the same laminar flow hood in the table below were released without a scientifically sound justification or supporting data demonstrating adequate risk mitigation.

Fill date	Rejected lot #	Released lot manufactured in the same hood	Released lots manufactured in the 2 nd hood
10/17/2025	20251017-01A42E	20251017-0FFE8B	20251017-6D87A8 20251017-03F240 20251017-235C2A
10/21/2025	20251021-01F7A1	20251021-8CC0D9 20251021-5C30B4	20251021-1BEBE6 20251021-817D6D
3/09/2026	20260309-8FE1A0	20260309-141A33	20260309-3645AC 20260309-80AC52
6/15/2026	20260615-4D607D	20260615-812D57	20260615-7E9720 20260615-42D2D3

Your firm's failure to identify probable root causes for sterility test failures raises significant concerns regarding the robustness of the aseptic filling operations and the integrity of the contamination control strategy. The release of concurrent batches — manufactured under the same conditions as the rejected lots — without adequate scientific justification or documented risk mitigation poses a direct risk to patient safety, as those products may not meet sterility assurance requirements.

OBSERVATION 3

Separate or defined areas to prevent contamination or mix-ups are deficient regarding the manufacturing and processing operations.

Specifically,

- A. Personnel and material flow into and out of the ISO 7 and ISO 8 classified areas occurs through a single shared pathway that passes directly through the visual inspection and labeling room. Gowning,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Kara J Wright, Investigator Pushpa S Jayasekara, Investigator Jeremy T Dautrich, Investigator	Jeremy T Dautrich Investigator Signed By: JEREMY T. DAUTRICH -S Date Signed: 09-03-2026 16:50:10 X	DATE ISSUED 9/3/2026

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772	DATE(S) OF INSPECTION 8/24/2026-9/3/2026* FEI NUMBER 3011967886
---	--

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Raymond Robert Carlson , 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

degowning, and material transfer — including finished product exiting the cleanroom and incoming components entering — all traverse the same corridor used for labeling and visual inspection of previously released product, creating a convergence of traffic that is inconsistent with unidirectional flow principles.

Specifically, operators completing shoe covers, head covers, masks, and hand washing in the non-classified area must traverse this shared labeling room pathway to reach the ISO 8 entry door. Upon degowning, operators must similarly walk from ISO 7, through ISO 8, and through this same labeling room, where other staff are actively performing packaging, labeling, and visual inspection activities, to reach an outside corridor. No designated degowning area exists within the ISO 8 anteroom. Additionally, no physical or spatial separation exists within the ISO 8 anteroom to support or delineate a gowning zone, and operators were observed leaning against ISO 8 walls and tables for stability during gowning, introducing a potential source of contamination to sterile garments.

- B. Within this same access route, a (b) (4) door handle providing passage between the ISO 7 and ISO 8 classified areas and the labeling room was observed to be visibly degraded due to repeated exposure to cleaning and disinfecting agents. Furthermore, the curved geometry of the handle prevents adequate cleaning and disinfection of all contact surfaces.
- C. Airflow vents in the ISO 7 cleanroom and ISO 8 anteroom are obstructed. For example, multiple items — including storage containers, a table, and (b) (4) bottles — were observed blocking the air vents in the ISO 8 anteroom.

The shared personnel and material pathway through the visual inspection and labeling room, the absence of a designated gowning and degowning zone, a deteriorating and inadequately cleanable door handle, and obstructed airflow vents collectively represent significant deficiencies in contamination control infrastructure. These conditions compromise the environmental integrity of the ISO 7 and ISO 8 classified areas and present a risk of cross-contamination to finished product, released materials, and ongoing sterile production operations.

OBSERVATION 4

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Kara J Wright, Investigator Pushpa S Jayasekara, Investigator Jeremy T Dautrich, Investigator	DATE ISSUED 9/3/2026
	Jeremy T Dautrich Investigator Signed By: JEREMY T. DAUTRICH -S Date Signed: 09-03-2026 16:50:10 X	

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772	DATE(S) OF INSPECTION 8/24/2026-9/3/2026* FEI NUMBER 3011967886
---	--

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Raymond Robert Carlson , 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

There is a lack of written procedures assigning responsibility, providing cleaning schedules and describing in sufficient detail the methods, equipment and materials to be used for sanitation.

Specifically,

- A. Your firm's cleaning procedure is inadequate.
 - i. Your firm stated that only the ISO 5 laminar flow hood receives cleaning (b) (4). However, your firm failed to clean the ISO 7 classified area (b) (4) leaving cleaning to the end of production for the day.
 - ii. Your firm lacks scientifically established and data-supported cleaning intervals for the cleanroom. A review of cleaning records revealed a 49-day gap between the (b) (4) deep cleaning performed on 02/09/2026 and the subsequent cleaning on 03/30/2026. Furthermore, your firm acknowledged that scheduling cleaning on a (b) (4) basis — rather than at fixed intervals — could permit up to (b) (4) between cleaning events. Cleaning intervals of this duration, without scientific justification or validated hold-time data, present an unacceptable risk of microbial proliferation and environmental contamination in a classified cleanroom, potentially compromising the sterility and quality of drug products manufactured therein.

OBSERVATION 5

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

Specifically,

Your firm has not performed temperature mapping under the worst-case conditions for your critical equipment during equipment qualification.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Kara J Wright, Investigator Pushpa S Jayasekara, Investigator Jeremy T Dautrich, Investigator	DATE ISSUED 9/3/2026
	Jeremy T Dautrich Investigator Signed By: JEREMY T. DAUTRICH -S Date Signed: 09-03-2026 16:50:10 X	

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772		DATE(S) OF INSPECTION 8/24/2026-9/3/2026*	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Raymond Robert Carlson , Owner		FEI NUMBER 3011967886	
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		
For example, your firm operates ^{(b) (4)} incubators ^{(b) (4)} ; and ^{(b) (4)} refrigerators ^{(b) (4)} all of which are used for product storage and environmental monitoring (EM) sample incubation. A review of the initial qualification records for these units revealed that temperature mapping was performed exclusively under empty-state conditions. When asked whether temperature mapping under operationally loaded conditions had been performed to reflect the units' current operational use, your firm confirmed that only the initial empty-state mapping had been completed and no subsequent studies have been initiated.			
OBSERVATION 6 Laboratory controls do not include the establishment of scientifically sound and appropriate specifications designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity. Specifically, Your firm continues to fail to provide a scientific rationale to support the established method and limits for subvisible particle testing of Avastin (bevacizumab) 1.75 mg/0.07 mL for intravitreal injection. Your firm releases this product using a subvisible particulate matter specification of ^{(b) (4)} particles/container at ^{(b) (4)} µm and ^{(b) (4)} particles/container at ^{(b) (4)} µm. All ^{(b) (4)} lots associated with endophthalmitis adverse events were released using this particulate matter specification. This observation is a repeat observation from the previous FDA 483, List of Observations, issued on 11/04/2024.			
OBSERVATION 7			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Kara J Wright, Investigator Pushpa S Jayasekara, Investigator Jeremy T Dautrich, Investigator		DATE ISSUED 9/3/2026 Jeremy T Dautrich Investigator Signed By: JEREMY T. DAUTRICH -S Date Signed: 09-03-2026 16:50:10

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772		DATE(S) OF INSPECTION 8/24/2026-9/3/2026* FEI NUMBER 3011967886	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Raymond Robert Carlson , 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	
Employees are not given training in the particular operations they perform as part of their function, current good manufacturing practices and written procedures required by current good manufacturing practice regulations. Specifically, A. Your firm does not conduct periodic CGMP training for employees. B. Not all personnel receive basic training on the theory and practice of the Quality Management System and Good Manufacturing Practices, as required, per SOP-6 <i>Training and Personnel</i>, v2.0, effective September 30, 2025, Section 5.2.1. C. Your firm has not established training or qualification requirements to ensure that personnel responsible for reading and interpreting EM plate results are able to accurately enumerate and differentiate microbial growth and surface colonization.			
OBSERVATION 8 Drug product expiration dates are not related to the storage conditions stated on the labeling, as determined by stability studies. Specifically, Your firm's product labels do not specify required storage temperature conditions, and the assigned (b) (4) beyond-use date (BUD) is not supported by stability testing. For example: your firm has failed to specify required storage temperature conditions on product labels, despite assigning a (b) (4) beyond-use date (BUD). For example, your firm stated that stability testing is not conducted for its non-sterile compounded products on the basis that the water activity content is less than (b) (4) %, with a (b) (4) - BUD assigned at a controlled room temperature of (b) (4). However, all three non-sterile product labels reviewed during the inspection indicated only "room temperature," without further qualification or specification			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Kara J Wright, Investigator Pushpa S Jayasekara, Investigator Jeremy T Dautrich, Investigator	
		DATE ISSUED 9/3/2026	
		Signature of Investigator X Jeremy T Dautrich Investigator Signed By: JEREMY T. DAUTRICH -S Date Signed: 09-03-2026 16:50:10	

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772	DATE(S) OF INSPECTION 8/24/2026-9/3/2026*
	FEI NUMBER 3011967886

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Raymond Robert Carlson , 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

of the required temperature range, which is inconsistent with your firm's stated storage conditions.

***DATES OF INSPECTION**

8/24/2026(Mon), 8/25/2026(Tue), 8/26/2026(Wed), 8/27/2026(Thu), 8/28/2026(Fri), 8/31/2026(Mon),
9/03/2026(Thu)

X Kara J Wright
Investigator
Signed By: 2004338119
Date Signed: 09-03-2026 15:50:56

X Pushpa S Jayasekara
Investigator
Signed By: Pushpa S. Jayasekara -S
Date Signed: 09-03-2026 15:51:30

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Kara J Wright, Investigator
Pushpa S Jayasekara, Investigator
Jeremy T Dautrich, Investigator

X Jeremy T Dautrich
Investigator
Signed By: JEREMY T.
DAUTRICH -S
Date Signed: 09-03-2026
16:50:10

DATE ISSUED

9/3/2026

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."