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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 8050 Marshall Drive, Suite 205<br>Lenexa, KS 66214<br>(913)495-5100 Fax:(913)495-5115 | 3/10/2025-3/27/2025*<br>FEI NUMBER<br>3013927023 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
James M. Krogman, President, CEO

| FIRM NAME | STREET ADDRESS |
|---|---|
| Apollo Care, LLC | 3801 Mojave Ct Ste 101 |
| CITY, STATE, ZIP CODE, COUNTRY<br>Columbia, MO 65202-4042 | TYPE ESTABLISHMENT INSPECTED<br>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

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

A) Your quality unit failed to evaluate and approve removal ~~and relocation~~ of the handwashing sink from the ISO 8 Hallway/Anteroom. Facility construction within your ISO classified cleanroom was not conducted per SOP CQI002 Management of Change Authorization (MOCA).

B) Your written procedure, PRC002 Facility Cleaning Procedure, Rev 15, Effective Date 03/01/2025, instructs documentation of (b) (4) cycles in Logbook (b) (4) This record of decontamination/cleaning is deficient, such that it does not capture details to demonstrate the specifications of each (b) (4) cycle meet those established during performance qualification/ validation. Details of each cycle are instead captured in vendor supplied application software accessed through a mobile device. You lack documented validation showing that the application software that generates and stores details of (b) (4) cleaning/decontamination meet Part 11 requirements for electronic records.

## OBSERVATION 2

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| | Jolanna A Norton, Investigator<br>X Jolanna A Norton Investigator Signed By: Jolanna A. Norton -S Date Signed: 03-27-2025 18:58:51 | 3/27/2025 |

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

Specifically,

A) Your firm lacks assurance that non-sterile in-process bulk drug solutions exposed to cleaning agents during ISO 8 Anteroom cleaning do not alter the quality and purity of sterile compounded finished drug product produced from exposed bulk drug solution. Your firm performs cleaning of the ISO 8 Hallway/ Anteroom while non-sterile in-process bulk drug solution is stored there.

- On 03/18/2025 I observed storage of non-sterile bulk drug solution, Phenylephrine HCL 100 mcg/mL, Lot (b) (4) in a (b) (4) Liter beaker loosely covered with aluminum foil in the ISO 8 classified Hallway/ Anteroom during operator gowning and area cleaning. Cleaning agents included sterile sporicidal ((b) (4) ) and sanitizer ((b) (4) ). I observed your operator repeatedly sprayed a microfiber mop head with cleaning agents near the beaker containing bulk drug solution. On the same day the bulk drug solution was (b) (4) and filled as finished drug product, Phenylephrine HCL 100 mcg/mL in 10 mL Syringe, Lots (b) (4) and (b) (4) .

B) Your firm's Hallway/Anteroom is classified as ISO 8 per your cleanroom certifications. However, you use it as both ISO 8 and "ISO 7" area: for example, during non-sterile bulk formulation, this area is treated as an extension of the ISO 8 rooms (Storage (b) (4) . Required gowning and gloves are non-sterile. After formulation, the hallway undergoes a "full clean" with bulk formulation stored in the hallway during cleaning. After this cleaning, the hallway is treated as an extension of your ISO 7 areas and used for cleanroom gowning and operator/material movement during (b) (4) in Lab (b) (4) Lab) and aseptic filling in Lab (b) (4) ((b) (4) Fill Lab).

C) Prior to August 2024, written procedure, SOP CQI003 Clean Room, Rev 22, Effective Date 07/08/2024, established inadequate specifications for microbiological recoveries from Support Compounding operator sleeves that enter the ISO 5 to ensure compounded drug products purported to be sterile were produced in aseptic conditions (specification: (b) (4) )). You failed to investigate 1 CFU

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microbiological contamination recovered from sleeves of Primary Support Compounders that entered critical ISO 5 LAH during compounding operations. 1 CFU microbiological recoveries were not documented as deviations and were not investigated to determine root cause or to evaluate product impact. From October 2023 to June 2024 your firm approved and distributed compounded drug products that were produced with 1 CFU recoveries found on ISO 5 operator gowning gloves or sleeves. For example,

- NDC 71170-950-25 Fentanyl 500mcg (2mcg/mL) & Ropivacaine 250mg (1mg/mL) in 250 NS (Epidural Use Only), Lot (b) (4) , Exp 04/06/2024; 4 CFU (Bacillus sp., Staphylococcus sp. coagulase negative) on Left Sleeve and 1 CFU (Staphylococcus sp. coagulase negative) on Right Glove of Support Compounder, (b) (6), (b) No documented investigation or risk assessment was conducted for the (b) (4) action limit recovery.
- NDC 71170-050-05 Ketamine 50mg (10mg/mL) 5mL Syringe, Lot (b) (4) , Exp 04/27/2024; 1 CFU (Micrococcus luteus) on Right Sleeve of Support Compounder, (b) (6), (b)
- NDC 71170-020-05 Succinylcholine 100mg (20mg/mL) 5mL Syringe, Lot (b) (4) , Exp 05/27/2024; 1 CFU (Staphylococcus sp. coagulase negative) on Left Glove of Support Compounder, (b) (6), (b)
- NDC 71170-550-25 Norepinephrine 8mg in 250 NS IV bag, Lot (b) (4) , Exp 12/17/2024; 1 CFU (Micrococcus luteus) on Right Sleeve of Support Compounder, (b) (6),

D) Your smoke studies were inadequate. For example, during the review of your May and November 2024 static smoke studies, I observed that static smoke studies were conducted in either empty hoods for LAHs (b) (4) , (b) (4) and (b) (4) ) or with only a repeater pump placed in the hood. These conditions do not represent all equipment present in the LAH during routine production. Additionally, generated smoke appeared turbulent near and around the repeater pump and the volume and/or location of the generated smoke was not sufficient to adequately visualize the airflow pattern.

## OBSERVATION 3

Equipment and utensils are not cleaned, maintained and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

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Specifically,

A) Written procedure, PRC002 Facility Cleaning Procedure, Rev 15, states that no high particle shedding materials may enter the cleanroom suite. Your cleaning processes within the ISO classified cleanroom suite include use of disposable sterile polyester cleaning pads and microfiber mop heads, which appeared to be shedding.

- 1) On 3/10/2025 I observed white fiber-like particles and debris on the floor of ISO 7 (b) (4) following (b) (4) area cleaning that included equipment, ceilings, walls, and floors. (b) (4) ISO 5 (b) (4) Laminar Airflow Hoods ((b) (4) ) where (b) (4) of compounded bulk drug product is located in the (b) (4) .
- On 3/18/2025 I observed white fiber-like particles on the floor of the ISO 8 Hallway/ Anteroom following area cleaning that included equipment, walls and floors. Non-sterile compounded bulk drug solution for Phenylephrine HCL 100 mcg/mL, Lot (b) (4) in the (b)(4) Liter beaker loosely covered with aluminum foil was stored in the Hallway/Anteroom during cleaning

B) In 2024 as part of your firm's Mold Risk Mitigation strategy in response to the 2023 mold issue, your firm instituted the practice of (b) (4) (b) (4) in your ISO classified cleanroom suite and finished product storage areas. Your firm does not have scientific rationale to justify holding in-process material inside classified areas while performing (b) (4)

- 1) Your firm failed to demonstrate that storage bags filled with in-process (b) (4) bulk drug solution are compatible with the (b) (4) used in your facility. For example, in-process bulk solution for Vancomycin 100 mg/mL, Lot (b) (4) , compounded on 02/05/2025, was stored in the ISO 7 (b) (4) and exposed to (b) (4) cycle on 02/10/2025. The storage bag manufacturer claims it can withstand exposure up to (b) (4) Your (b) (4) cycle uses a (b) (4) solution. You have not demonstrated that stored bulk drug solution is not altered by the higher concentration solution. The following distributed sterile compounded finished drug product lots were filled from the bulk drug solution exposed to (b) (4) Lot (b) (4) : Vancomycin 1g in Normal Saline, 250 mL IV bag, Filled on (b) (4) , and Lot (b) (4) : Vancomycin 1.25 g in Normal Saline, 250 mL, Filled on (b) (4)

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- 2) You do not document all (b) (4) cycles where in-process bulk solution was exposed to (b) (4). On 03/10/2025 during facility walk-through I observed storage of (b) (4) in-process bulk drug solution, Vancomycin 100 mg/mL Bulk Stock Solution, Lot (b) (4). An ongoing (b) (4) cycle in the ISO 7 (b) (4) was stated as reason why walk-through could not include the ISO classified suite. Review of cleaning records found no documented record of the (b) (4) cycle observed on 03/10/2025. Your Director of Quality stated that the observed (b) (4) cycle was not documented in the cleaning record because the cycle was stopped before completion. Your firm does not document partial (b) (4) cycles or exposure times of stored in-process bulk drug solution related to incomplete (b) (4) Hence, in-process bulk solution can be exposed to partial and completed decontamination cycles across their holding period without documentation.

## OBSERVATION 4

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,

A) Your environmental monitoring recovered mold in ISO classified areas after implementing your firm's Mold Risk Mitigation strategies. Your mitigation strategies include (b) (4) of unclassified product storage areas. You have not investigated to determine a root cause for mold found in your ISO classified clean room suite and therefore lack assurance that your mold risk mitigation strategies are effective to ensure that your injection, infusion, and epidural sterile compounded drug products are produced in aseptic conditions. For example,

- On 08/30/2024 environmental monitoring surface sampling found fungi in your unclassified product storage areas, including Alternaria alternata, Acremonium variecolor, Cladosporium cladosporoides, and Fusarium solari.
- On 9/18/2024 environmental monitoring surface sampling of the ISO 8 Anteroom (b) (4) recovered 1 cfu fungi (Acremonim variecolor). On the same day you formulated non-sterile bulk drug solution,

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Vancomycin 100 mg/mL Stock Solution, Lot AC-016819, in the ISO 8 Anteroom (b)(4) That bulk solution was then used to produce distributed intravenous compounded finished drug products: NDC 71170-185-50 Vancomycin 1.5g in 250 mL NS, Lot (b) (4) , Exp 03/2025, and NDC 71170-254-25 Vancomycin 1g in 250 mL NS, Lot (b) (4) Exp 04/2025

B) Your firm failed to thoroughly investigate out-of-specification differential pressures and pressure reversals between ISO 7 cleanrooms and ISO 8 Hallway/Anteroom. Your written procedure, CQI017 Temperature, Humidity, Differential Pressure Monitoring, states a differential positive pressure specification of (b) (4) water column. From October 2024 to February 2025, differential pressure monitoring recorded approximately 100 events of out-of-specification differential pressures within your ISO classified cleanrooms where non-sterile bulk drug solutions and compounded finished drug products intended to be sterile were produced. For example,

- Differential pressuring monitoring in your ISO 7 Lab (b) ((b) (4) Lab (b)(4) documented four (4) out-of-specification readings (0.01), including a pressure reversal ((b) (4)) during filling of NDC 71170-020-05 Succinylcholine 100mg (20mg/mL) 5mL Syringe, Lot (b) (4) , Exp 04/30/2025. Your investigation record, D-25-005, concluded that the multiple OOS differential pressures had no adverse impact on the ISO 5 aseptic environment or product sterility. Your record does not include detailed steps of the investigation or the risk assessment used to justify the final determination. Lo(b) (4) was approved for released on 02/24/2025 and distributed from 02/26/2025 to 03/21/2025.

## OBSERVATION 5

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

A) On 03/18/2025, I observed an unsealed and loose ceiling tile within the ISO 7 (b) (4) Lab during (b) (4) of non-sterile bulk drug solution in the ISO 5 hood, Phenylephrine HCL 100 mcg/mL,

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Lot (b) (4) During setup and (b) (4) of the bulk drug solution, the ceiling tile repeatedly lifted, exposing the room to a lesser quality air that bypassed HEPA filtration. Operator gowning, which was exposed to lesser quality air in the ISO 7 (b) (4) Lab, was then worn by the ISO 5 Direct Compounder during syringe fill of Phenylephrine HCL 100 mcg/mL, Lot (b) (4), Exp 09/14/2025.

B) Audio speakers within ceiling tiles located in your ISO classified suite allow for potential entry of lesser quality air that bypasses HEPA filtration. A ceiling speaker is located in your ISO 8 Anteroom (b)/Hallway. A ceiling speaker is located in each of your ISO 7 Labs (b) (4)). Your critical ISO 5 laminar flow hoods, where compounded drug products intended to sterile are filled into syringes and IV bags, are located in ISO 7 Labs (b) (4) and (b) (4)

C) Wall panels overlayed on top of your ISO 8 Anteroom (b)/Hallway walls are not smooth. The textured surface is not easy to clean and may generate particles when other materials are rubbed against it.

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**OBSERVATION 6**

Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction and location to facilitate cleaning, maintenance, and proper operations.

Specifically,

Observation of exposed wood and wall insulation in warehouse storage areas where components and materials used in aseptic areas are stored. These surface**[s and]** materials are likely to generate particles and may harbor microbiological contamination within material storage areas. Examples of stored materials include: IV bags of normal saline and water for injection, packages holding syringe**[s]**, empty IV bags, (b) (4) bulk storage bags.

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***DATES OF INSPECTION**

3/10/2025(Mon), 3/11/2025(Tue), 3/12/2025(Wed), 3/13/2025(Thu), 3/14/2025(Fri), 3/17/2025(Mon), 3/18/2025(Tue), 3/19/2025(Wed), 3/20/2025(Thu), 3/26/2025(Wed), 3/27/2025(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."