

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 1201 Main Street, Suite 7200 Dallas, TX 75202 (214) 253-5200 Fax: (214) 253-5314		DATE(S) OF INSPECTION 8/17/2026-9/9/2026* FEI NUMBER 3043120213	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Christopher W. McGarry, CEO			
FIRM NAME Greenwich Rx		STREET ADDRESS 9733 Fm 2902 Rd. Suite 100	
CITY, STATE, ZIP CODE, COUNTRY Tomball, TX 77375		TYPE ESTABLISHMENT INSPECTED Producer of sterile and non-sterile drug products	
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 Use of ingredients not intended for pharmaceutical use in sterile drug production. Specifically, your firm was found to use a reduced dietary supplement grade APIs in the compounding of finished sterile drug product, Glutathione Injection 200mg/mL. For example, the API, Glutathione (L) USP (Reduced) (Dietary Supplement Grade), Lot (b)(4), Expiry (b)(4) was used in the compounding of the finished sterile drug, Glutathione Injection 200mg/mL Lot 0060061826-1, BUD 09-26-2026. This lot was dispensed to fill patient-specific prescriptions. The firm continues to receive this grade of API based on a review of supplier provided COAs for Glutathione (L) USP.			
OBSERVATION 2 Your firm produced drugs while construction was underway in an adjacent area without adequate controls to prevent contamination of the production environment and product. Specifically, A. On 8/17/2026, during a site walk-through, I found construction with sheet rock in areas surrounding a newly constructed ISO Classified modular Cleanroom Suite (b)(4) occurring at the same time as compounding activities within ISO (b)(4) modular cleanrooms (Suites (b)(4)) located in the same general area separated by a wall not extended to the facility ceiling. Your firm's management reported construction activities had been occurring approximately three (3) weeks prior to the start of this FDA inspection. Your firm was compounding the sterile drugs, Tirzepatide 30mg/B12 0.5mg/mL (2.4mL) 30mg/0.5mg mg/mL, Lot number 0011081726-1			
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BUD 2026-11-25, Batch size (b)(4) vials and Semaglutide 10mg/B12 0.5mg/mL (1.3mL) 10mg/0.5mg, Lot number 0005081726-1, BUD 2026-11-25, Batch size (b)(4) vials.

- B. During my walk-through of your site, white foreign particulate matter and debris was observed within the vents of the ISO 8 Anteroom open to the non-controlled/unclassified area and through-out the construction area where the new ISO Classified Cleanroom Suite (b)(4) was under construction as a result of your firm's active construction and equipment installation.

OBSERVATION 3

Microbial contamination was present in the ISO 5 area and areas adjacent to production areas.

Specifically, during my review of your firm's environmental monitoring (EM) records, I found the following deficiencies:

- A. During a review of your firm's 2025 (b)(4) EM monitor sampling of the ISO Classified Cleanroom Suite (b)(4) I found two (2) different occurrences where 1 CFU was found during ISO 5 LAFC surface sampling (Acceptance Limits ISO Class 5: (b)(4)). These include:
1. 10/9/2025: ISO 5 (b)(4) Buffer Hood - 1CFU; Compounded sterile product include;
 - a. SEMAGLUTIDE 1MG, B12 0.5/ML, Lot 0002-100925-A, BUD 1/17/2026
 - b. SEMAGLUTIDE 1MG, B12 0.5MG/ML, Lot 0002 -100925-A
 - c. SEMAGLUTIDE 4MG, B12 0.5MG/ML, Lot 0003-100925-A
 - d. SEMAGLUTIDE 6MG, B12 0.5MG/ML, Lot 0004-100925-A
 - e. BPC-157 3mg/mL, Lot 019-100925-A
 - f. BPC157/TB500/KPV 3/3/3MG/ML (NO COPPER), Lot 0021-100925-A, BUD 1/17/2026
 - g. GHK-CU 10mg/mL, Lot 0027-100925-A, BUD 1/17/2026
 - h. BPC, TB500, KPV 3mg/3mg/3mg/mL, Lot 0021-100925-A
 - i. BPC-157 3mg/mL, Lot 0019-100925-A
 - j. TIRZEPATIDE 10MG, B12 0.5/ML, Lot 0007-100925-A

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k. TESMORELIN, IPAMORELIN-3MG/2MG/ML, Lot 0038-100925-A, BUD 1/17/2026 2. 12/11/2025: ISO 5 ^{(b) (4)} Buffer Hood - 1CFU; Compounded sterile product include; a. TIRZEPITIDE 15MG, B12 0.5/ML, Lot 0008-121125-1 b. TIRZEPATIDE 30MG, B12 0.5/ML, Lot 0011-121125-1, BUD 3/21/2026 c. TIRZEPITIDE 25MG, B12 0.5/ML, Lot 0010-121125-1 d. TIRZEPITIDE 20MG, B12 0.5/ML, Lot 0009-121125-1 e. Glutathione 200mg/mL, Lot 0060-121125-1, BUD 3/21/2026 f. TIRZEPATIDE 10MG, B12 0.5/ML, Lot 0007-121125-1 g. SEMAGLUTIDE 2MG, B12 0.5MG/ML, Lot 0002-121125-1 h. SEMAGLUTIDE 4MG, B12 0.5MG/ML, Lot 0003-121125-1 i. SEMAGLUTIDE 10MG, B12 0.5MG/ML, Lot 0005-121125-2 j. SEMAGLUTIDE 10MG, B12 0.5MG/ML, Lot 0005-121125-1 k. SEMAGLUTIDE 6MG, B12 0.5MG/ML, Lot 0004-121125-1 l. TIRZEPATIDE 5MG, B12 0.5/ML, Lot 0006-121125-1 m. SEMAGLUTIDE 1MG, B12 0.5MG/ML, Lot 0001-121125-1 n. SEMAGLUTIDE 10MG, GLYCINE 0.5MG/ML, Lot 0065-121125-1, BUD 3/21/2026 Your firm failed to document any action or initiate an investigation into identifying the root cause and or microbial type. B. During a review of your firm's 2025 - 2026 ISO 5 LAFC EM contact surface sampling for each batch, the following deficiencies were found: I found a total of nine (9) different occurrences, where contact surface samples were reported as 1 CFU or greater within ISO Classified Cleanroom Suite ^{(b) (4)} with all batches released and dispensed with no investigations included (surface sampling Acceptance Limits (ISO Class 5 ^{(b) (4)}):			
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1. 11/12/25 12:26pm: Sema 10mg, Lot 0005-111225-2 (1 CFU)
2. 11/12/25 12:54pm: Sema 6mg, Lot 0004-111225-1 (2 CFUs)
3. 11/14/25 12:09pm: Sema 1mg, Lot 0001-111425-1 (1 CFU)
4. 11/24/25 6:11pm: Tirzep 15, Lot 0008-112425-1 (1CFU)
5. 11/25/25 10:50am, Tirzep 20, Lot 0009-112525-1 (1CFU)
6. 11/25/25 11:59am, Tirzep 15, Lot 0011-112525-1 (1CFU)
7. 12/02/25 10:07am. Trizep 15mg, Lot 0008-120225-1 (1 CFU)
8. 12/04/25 9:56am: Sema 10mg, Lot 0065-120425-1 (2 CFUs)
9. 12/26/25 1:12pm: GHKCU/Epi/cjc, Lot 0042-122625-1; your firm failed to report laboratory sample results.

I found your firm failed to consistently report sample results in support of reporting passing/fail for the acceptance of designated batches compounded from December 2025 to August 2026. No investigation was carried out for any of the batches where CFUs were reported.

- C. Your firm defined ISO 5 laminar air flow cabinet (L AFC) action limits at less than (b)(4) CFU instead of 1 CFU.
- D. I found during my review of your firm's Cleanroom (b)(4) Recertification Report Collection date 3/18/2026 that 2 different contact EM surface sample locations within the ISO 5 L AFC within ISO Classified Cleanroom Suite (b)(4) were collected per unit. I found your firm's certifier results reported for CR (b)(4) LAF (b)(4) Work surface reported 3 CFUs/plate. The organism was identified as being Coag-negative Staphylococcus species. The second sample collected within the same but different sample location work surface reported a 1 CFU/plate, with the same organism being identified. Your firm documented no action or investigation to identify a potential root cause into this event.
- E. During my site walk-through on 8/17/2026, I found compounding technicians and pharmacist shoes worn from outside your facility, being stored in front of open vents for (b)(4) ISO Classified Cleanroom Suites (b)(4) that potentially contain microbials from the outside

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environment and having the potential of introducing contamination into the ISO classified areas.

OBSERVATION 4

Personnel were observed conducting aseptic manipulations where the movement of "first air" in the ISO 5 area is blocked or disrupted.

Specifically, during compounding observations of your firm's technicians, I observed your firm's technicians reaching over open vials while filling and stoppering filled sterile vials using their sterile gloved hands in the processing of sterile finished drug products, Tirzepatide 30mg/B12 0.5mg/mL (2.4mL) 30mg/0.5mg mg/mL, Lot number 0011081726-1 BUD 2026-11-25; and Semaglutide 10mg/B12 0.5mg/mL (1.3mL) 10mg/0.5mg, Lot number 0005081726-1, BUD 2026-11-25 having the potential of blocking first air within the ISO 5 LAFC. The rubber stoppers were removed from a non-sterile (b) (4) bag that were originally stored in the approved supplier's sterile packaging.

OBSERVATION 5

A pattern of frequent or acute pressure reversals was observed from areas of less clean air to areas of higher air cleanliness.

Specifically, during a review of your firm's 2026 (b)(4) ISO Classified Cleanroom differential pressure monitoring logs approved by the firm's pharmacist for Cleanrooms Suites (b)(4), I found differential pressure reversals that occurred in the following months for Cleanroom (b)(4)

- February 2026 (18 out of 22 Differential pressures equal; 1 missing data for Garbing Rooms; 1 pressure reversals)
- March 2026 (17 out of 24 Differential pressures equal; 6 pressure reversals)
- April 2026 (20 out of 25 Differential pressures equal; 1 missing data for (b)(4) & Garbing Rooms; 1 pressure reversals)
- May 2026 (22 out of 27 Differential pressures equal; 1 missing data for Clean Room; (b)(4) pressure

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- reversals)
- e. June 2026 (16 out of 19 Differential pressures equal; 1 missing data for (b)(4) & Garbing Rooms; 2 pressure reversals)
 - f. July 2026 (4 out of 19 Differential pressures equal; 2 missing data for Clean Rooms; & 7 pressure reversals)

Your firm's PIC reported no investigations or hold activities were performed on any drug products compounded on the days the reversal occurred. Cleanroom (b)(4) ISO 7 Buffer Room contains 2 ISO 5 LAFCs used in the compounding of sterile drug products. Cleanroom Suite (b)(4) has been operational since February 2026.

OBSERVATION 6

The facility design was observed to allow the influx of lesser quality air into a classified area containing higher quality air.

Specifically,

- A. Your firm was found to be using 2 separate modular ISO classified cleanrooms designed with open vents existing into non-controlled/non-classified areas of the facility. I found ISO 8 Anteroom for Suite (b)(4) vent appeared to contain white foreign particulates in the flow path. The vent was being held open using a yellow/black handle screwdriver, which was on the opposite side of the ISO 8 Anteroom Cleanroom for Cleanroom Suite (b)(4). Your firm's Compounding Manager reported that the contract cleanroom certifier had used the screwdriver to hold open the vent during an issue with balancing the ISO 8 Anteroom differential pressure.
- B. I found what appeared to be white foreign particulates on the floor within your firm's ISO 8 gowning room of Cleanroom Suite (b)(4) along with the vent remaining in the open position directly in front of the outside shoe storage rack.

OBSERVATION 7

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Personnel were observed moving quickly in a critical area or in an area immediately adjacent to a critical area likely causing disruption of unidirectional airflow.

Specifically, I found during aseptic processing involving stoppering and capping using sterile gloves, your firm's technicians were using a (b)(4) disrupting unidirectional airflow within (b)(4) ISO 5 LAFC units within Cleanroom Suites (b)(4) during the processing of sterile drug products, Tirzepatide 30mg/B12 0.5mg/mL (2.4mL) 30mg/0.5mg mg/mL, Lot number 0011081726-1 BUD 2026-11-25; and Semaglutide 10mg/B12 0.5mg/mL (1.3mL) 10mg/0.5mg, Lot number 0005081726-1, BUD 2026-11-25.

OBSERVATION 8

Personnel infrequently changed and sanitized gloves to prevent contamination.

Specifically, your firm's technician was observed pushing trash into trashcan using their sterile gloves without performing a sterile glove change afterward. The technician disinfected their gloves and returned to the ISO 5 LAFC within ISO 7 Buffer Room (b)(4) to continue aseptic processing activities.

OBSERVATION 9

Lack of disinfection of supplies at each transition from areas of lower quality air to areas of higher quality air.

Specifically,

- A. Your firm's technician was observed failing to disinfect components located within the ISO 7 Buffer Rooms (b)(4) prior to placing them into the ISO 5 LAFC unit.
- B. Your firm's technicians in both ISO 7 Buffer Rooms suites during the aseptic processing of the sterile drug products, Tirzepatide 30mg/B12 0.5mg/mL (2.4mL) 30mg/0.5mg mg/mL, Lot number 0011081726-1 BUD 2026-11-25; and Semaglutide 10mg/B12 0.5mg/mL (1.3mL) 10mg/0.5mg, Lot number 0005081726-1, BUD 2026-11-25, was observed transferring stoppered

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trays of vials from LAFC (b)(4) (ISO 5 filling LAFC) through the ISO 7 Buffer Room, and into ISO 5 LAFC (b)(4) (ISO 5 LAFC capping and crimping) without disinfecting the trays.

- C. I observed your firm's technicians transferring sterile stoppers and metal caps from their original sterile packaging and into a non-sterile plastic (b)(4) storage bag within the same ISO 5 LAFC units used for aseptic processing, disrupting unidirectional airflow. The non-sterile (b)(4) bags remained in the ISO 5 LAFC for use during the aseptic stoppering and capping process step.

OBSERVATION 10

Inadequate (b)(4) testing on (b)(4) used to sterilize drug products.

Specifically, during a review of your firm's (b)(4) test of (b)(4) used in the compounding of finished drug sterile products, your firm failed to use calibrated gauge(s) and equipment to ensure adequate testing and (b)(4) were capable of meeting their intended use.

OBSERVATION 11

Compounding with components, containers or other materials that have not been verified to assure that they do not contribute endotoxin contamination that may be objectionable given the product's intended use.

Specifically, your firm fail to (b)(4) glass beakers used in the formulation of bulk non-sterile drug products that undergo sterile (b)(4) to render bulk product sterile. Your firm's management reported that glassware is (b)(4), rinsed with (b)(4), and wiped with sterile (b)(4) prior to use. Your firm's cleanroom manager reported a (b)(4) has been purchased for the processing of glassware. I found your firm's washed glassware used in the formulation and compounding of bulk non-sterile drug products are stored on a wire shelf in a non-controlled non-classified area directly in from of the entry door of the facility. The glassware is positioned (b)(4) on the rack with no covering over the opening of the glassware.

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OBSERVATION 12

Failure to conduct media fills that closely simulate aseptic production operations under the worst-case, most-challenging, and stressful conditions.

Specifically, your firm failed to provide adequate rational evidence in support that media fills that closely simulate aseptic production operations under the worst-case, most-challenging, and stressful conditions.

OBSERVATION 13

Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically, on 8/19/2026, two (2) technicians were observed donning their sterile gowns to enter the ISO 7 Cleanroom to start aseptic processing. Sterile gowns worn by both technicians contacted the floor while donning rendering the gowns non-sterile. Additionally, poor sterile gloving techniques were found inadequate by the technicians contacting the non-sterile side of the glove using the sterile fingers of the opposite sterile glove.

OBSERVATION 14

Smoke studies were not performed under dynamic conditions.

Specifically,

- A. Your firm's PIC and cleanroom manager, reported that they neither received, reviewed, nor approved any static or dynamic smoke studies for either Cleanroom Suites (b)(4) following original certifications or recertifications since the firm began operating in June 2025 for the (b)(4) cleanrooms.
- B. Your firm's compounding manager reported that no smoke studies during media fills were

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performed to assess laminar air flow conditions within any of the ISO 5 LAFCs, during aseptic manipulations and interventions to determine impact on finished sterile drug products.

***DATES OF INSPECTION**

8/17/2026(Mon), 8/18/2026(Tue), 8/19/2026(Wed), 8/20/2026(Thu), 8/24/2026(Mon), 8/25/2026(Tue), 8/26/2026(Wed), 8/28/2026(Fri), 8/31/2026(Mon), 9/08/2026(Tue), 9/09/2026(Wed)

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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."