

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 109 Holton Street Winchester, MA 01890 (781) 587-7500 Fax: (781) 587-7556		DATE(S) OF INSPECTION 4/8/2026-4/16/2026* FEI NUMBER 3001451441			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Kevin Kerls, Site Head, Portsmouth					
FIRM NAME Lonza Biologics, Inc.		STREET ADDRESS 101 International Dr			
CITY, STATE, ZIP CODE, COUNTRY Portsmouth, NH 03801-2846		TYPE ESTABLISHMENT INSPECTED Drug Manufacturer			
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 Your firm failed to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess. Specifically, your firm has not demonstrated a state of control over the CASGEVY manufacturing process: a) (b) (4) Aseptic Process Simulation (APS) runs were executed from (b) (4) in Grade (b) (4) suites (b) (4). APS runs (b) (4) were executed in Suite (b) (4) with results that met specifications, however, these runs were repeated due to a trend of aseptic lapses and inconsistent aseptic practices that were not considered representative of your firm's process quality standards. Additionally, a total of (b) (4) deviations (including (b) (4) major) were initiated during execution of the (b) (4) APS runs. b) (b) (4) healthy donor (HD) (b) (4) runs were executed in (b) (4) to support (b) (4) CASGEVY production capacity. HD Batch Nos. (b) (4) were (b) (4) rejected for failure to meet production control specifications in the HD protocol. The (b) (4) disposition for Batch No. (b) (4) was also rejected due to an out of specification (OOS) result for (b) (4). c) Commercial production of CASGEVY was initiated in November 2025 with manufacture of (b) (4) batches. Batch No. (b) (4) was rejected for (b) (4) observed in the BSC (b) (4).					
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filling activities, while Batch No. (b) (4) was rejected due to a confirmed sterility failure.

d) On (b) (4), your firm implemented an update to the CASGEVY manufacturing process (per (b) (4)) to include (b) (4) of an (b) (4) (b) (4) for production of a (b) (4) drug product batch. On (b) (4) HD batches were initiated with the updated CASGEVY manufacturing process to support the (b) (4) production capacity (b) (4) of CASGEVY. Results showed that the (b) (4) maximum capacity HD batches failed to meet protocol specifications for number of non-environmental monitoring (EM) deviations per batch, number of EM deviations per batch, exceeding a process acceptable range (PAR) for (b) (4), and an out-of-specification (OOS) result for (b) (4) testing.

e) Beginning on 1/23/2026, (b) (4) commercial batches were manufactured with the updated process (b) (4). Batch No. (b) (4) was aborted for (b) (4) and (b) (4) below acceptance criteria, while Batch No. (b) (4) was aborted for multiple (b) (4) processing. Of the (b) (4) remaining batches, all are pending disposition. A risk assessment (dated 1/14/2026) was performed to assess the impact of the updated process on the current process and the validated state of the APS performed in (b) (4). The assessment concluded that the updated process introduced a (b) (4) (b) (4) processing time. Despite the assessed impacts, your firm failed to evaluate the updated process with an APS campaign prior to use in the manufacture of commercial batches.

OBSERVATION 2

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Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed. Specifically, a)DEV-1358321 was initiated on 5/30/2025 for an identified trend of particulates (b) (4) for the CASGEVY manufacturing process. In response to this event, CAPA-1420656 was opened on 10/2/2025 for initiation of a (b) (4) for (b) (4) (b) (4) was created on (b) (4) to update (b) (4), the software for (b) (4) in-process monitoring of particulates and develop an SOP for governing (b) (4). However, in-process monitoring of particulates is still being implemented, and updates to (b) (4) and creation of a (b) (4) SOP have yet to be completed. Additionally, (b) (4) other deviations have been initiated (subsequent to the trend investigation) for investigation of particulates identified in APS runs and commercial batches. b)DEV-1435080 was initiated on 10/29/2025 after a trend was identified for EM good documentation practices (GDP) assay errors and incorrect performance of critical in operation (CIO) EM. CAPA-1447250 was opened on 11/18/2025 to include an action plan for initiation of a (b) (4) for establishment of a (b) (4) SOP for (b) (4) and training guidelines. However, a (b) (4) has yet to be initiated for development and implementation of a (b) (4) SOP and training guidelines. Additionally, since 8/7/2025, your firm has initiated approximately (b) (4) EM deviations and approximately (b) (4) EM excursion investigations for (b) (4) activities. c)DEV-1431374 was opened on 10/22/2025 after a trend was identified for repeated alert and action level (b) (4) excursions in the (b) (4) Grade (b) (4) suite (Room (b) (4)) during APS activities conducted from (b) (4). CAPA-1447254 was initiated on 11/18/2025 to evaluate (b) (4) materials for cleanroom suitability and cleaning					
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disinfection compatibility. The Phase (b) (4) assessment for this trend (b) (4) as the most probable root cause of this trend. However, revision of (b) (4) into Biosafety Cabinets in (b) (4) (b) (4), to (b) (4) is still pending. Evaluation of the need for new (b) (4) materials is also pending.

OBSERVATION 3

Procedures describing the warehousing of drug products are not followed.

Specifically, a review of the use log form ((b) (4)) for (b) (4) of CASGEVY final drug product vials in (b) (4) revealed that your firm failed to capture the number of vials transferred to this unit for Batch Nos. (b) (4). Additionally, the (b) (4) inventory list for CASGEVY final drug product vials (b) (4) units only reports the final product batch number and not the actual number of vials placed in the (b) (4) units.

***DATES OF INSPECTION**

4/08/2026(Wed), 4/09/2026(Thu), 4/10/2026(Fri), 4/13/2026(Mon), 4/14/2026(Tue), 4/15/2026(Wed), 4/16/2026(Thu)

Christian Lynch
Investigator
Signed By: Christian D. Lynch -S
Date Signed: 04-16-2026 21:21:22
X _____

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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."