DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900	5/11/2026-5/19/2026* FEI NUMBER 2246315

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Leticia Fabiano, Sr. Director/General Manager

FIRM NAME	STREET ADDRESS
Patheon Manufacturing Services LLC	1125 Pleasantview Ter
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ridgefield, NJ 07657-2310	Vaccine 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

Actual yield and percentages of theoretical yield are not determined at the conclusion of each appropriate phase of manufacturing of the drug product.

Specifically, there are no specifications established for percent (%) filling yield and percent (%) fill volume rejects. (b) (4) batches of (b) (4) vaccine have been manufactured and released since June 2024.

OBSERVATION 2

Failure to maintain a backup file of data entered into the computer or related system.

Specifically, you utilize a (b) (4) (b) (4) on manufacturing Line (b) (4) to control and execute the filling process for (b) (4) Vaccine. The (b) (4) contains critical fill parameters, including, but not limited to, fill volume, that directly govern the filling operation and are critical quality attributes for this injectable biological product. During the inspection, it was observed that the (b) (4) version format (b) (4), is not always electronically maintained as part of the batch record.

OBSERVATION 3

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

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EMPLOYEE(S) SIGNATURE
Shafiq Ahadi, Investigator
Laurel A Beer, Investigator

X Shafiq Ahadi
Investigator
Signed By: 2000594974
Date Signed: 05-19-2026
10:45:08

DATE ISSUED
5/19/2026

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Specifically, written procedure, TFS-QU-SOP-0035039, *Aseptic Gowning*, version 13.0, effective 21Jul2025, is deficient as it allows personnel to perform aseptic manufacturing processes before they are fully qualified by permitting operators to continue in aseptic manufacturing despite being disqualified for, among other things, failing aseptic gowning requalification.

***DATES OF INSPECTION**

5/11/2026(Mon), 5/12/2026(Tue), 5/13/2026(Wed), 5/14/2026(Thu), 5/15/2026(Fri), 5/18/2026(Mon), 5/19/2026(Tue)

X Laurel A Beer
Investigator
Signed By: 0014345915
Date Signed: 05-19-2026 10:45:50

SEE REVERSE OF THIS PAGE

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Shafiq Ahadi, Investigator
Laurel A Beer, Investigator

X Shafiq Ahadi
Investigator
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Date Signed: 05-19-2026 10:45:08

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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."