DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240)402-9160	3/24/2025-4/1/2025* FEI NUMBER 3008694906

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Eva Gallagher, Associate Vice President, Plant Manager

FIRM NAME	STREET ADDRESS
MSD Ireland (Carlow)	Dublin Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Carlow, Co. CARLOW, R93 KF74 Ireland	Biological 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

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

a) While observing filling operations for Gardasil 9 drug product batch (0.5mL/Dose) (b)(4) manufactured for Rest of World (ROW) market within building (b)(4) on (b)(4), it was observed that a (b)(4) is not located near the (b)(4) worksite where (b)(4) of the drug product occur. It was identified that the closest (b)(4) (b)(4) worksite ((b)(4)). Since the first commercial batch was manufactured on (b)(4) total batches of Gardasil 9 have been filled within this (b)(4) and released to both US and ROW Markets.

b) While observing filling operations for Gardasil 9 drug product batch (0.5mL/Dose) (b)(4) manufactured for ROW market within building (b)(4), it was observed that a (b)(4) is not located near the (b)(4) worksite where (b)(4) of the drug product occur. It was identified that the closest (b)(4) is located (b)(4) worksite (from (b)(4)). Since conclusion of the previous inspection, - total batches of biological drug products to include Gardasil 9, Pnuemovax 23, Vaxneuvance, and Capvaxive, have been filled within this (b)(4) and released to both US and ROW Markets.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Travis S Bradley, Investigator Laurel A Beer, Investigator X Travis S Bradley Investigator Signed By: TRAVIS S. BRADLEY -S Date Signed: 04-01-2025 05:28:21	4/1/2025

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Eva Gallagher, Associate Vice President, Plant Manager	
FIRM NAME MSD Ireland (Carlow)	STREET ADDRESS Dublin Road
CITY, STATE, ZIP CODE, COUNTRY Carlow, Co. CARLOW, R93 KF74 Ireland	TYPE ESTABLISHMENT INSPECTED Biological Drug Manufacturer

OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Deviation investigation QN 201078686 initiated on 14MAR2023, documents a Grade [redacted] environmental monitoring (EM) action limit excursion ([redacted]) identified for [redacted] within building [redacted] during the production of Capvaxive drug product Process Performance Qualification (PPQ) batch [redacted] (0.5mL/Dose) on [redacted].

The probable root cause for the deviation was identified as sample exposure and contamination outside the Grade [redacted] environment during transfer and submission for [redacted]. This conclusion was made without evidence supporting the sample was contaminated during sample transfer. Your investigation concluded that no sample handling errors occurred during transfer of the [redacted] sample. However, additional evidence received during the investigation identified that sample contamination may have occurred during an intervention within the [redacted], and this was not referenced as the probable root cause within the investigation.

Capvaxive PPQ batch [redacted] was utilized to qualify the Capvaxive commercial manufacturing process within [redacted].

OBSERVATION 3

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

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Firm procedure SOP-17871(ver. 47.0) titled "(b)(4)" allows for two retests to be conducted by the (b)(4) when there is a failure before being sent to (b)(4) for additional testing. There is no description within the procedure identifying how many additional - tests (b)(4) can conduct on --- or the justification for each retest conducted by Technical Engineering. The following was observed:

a) Deviation QN 201185998 initiated on 23MAY2024 documents a post use (b)(4) (b)(4) failure investigation for the (b)(4) (b)(4) Lot no. (b)(4) Serial No. ---) utilized to - Capvaxive drug product (0.5mL/Dose) batch 0001790454 distributed to the US Market. Within the investigation, it is identified that the (b)(4) was retested -- times; (b)(4) as per procedure, and --- (b)(4) - failing each time. After - total failures, the -- was sent to the manufacturer for investigation. As part of the manufacturer investigation, an additional - test was conducted with passing results. Batch 0001790454 (exp. (b)(4).

b) Deviation QN 201163420 initiated on 16FEB2024 documents post use -- failure investigation for (b)(4), Lot no. (b)(4)) utilized to (b)(4) batch (b)(4) distributed to ROW Markets. Within the investigation, it is identified that the (b)(4) test was retested - times; (b)(4) as per procedure (both failing), and (b)(4) (both failing). After -- total retests, the filter was sent to the manufacturer for investigation. As part of the manufacturer investigation, an additional - test was conducted with passing results. Batch (b)(4) (exp. (b)(4).

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*DATES OF INSPECTION

3/24/2025(Mon), 3/25/2025(Tue), 3/26/2025(Wed), 3/27/2025(Thu), 3/28/2025(Fri), 3/31/2025(Mon), 4/01/2025(Tue)

X Laurel A Beer
Investigator
Signed By: 0014345915
Date Signed: 04-01-2025 05:29:23

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Travis S Bradley, Investigator Laurel A Beer, Investigator X Travis S Bradley Investigator Signed By: TRAVIS S. BRADLEY Date Signed: 04-01-2025 05:28:31	4/1/2025

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."