DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71-5128 Silver Spring, MD 20993-0002 240-402-8906 orabioinspectionalcorrespondence@fda.hhs.gov	3/7/2024-3/15/2024* FEI NUMBER 3004066112

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mark Proctor, Senior Director of Site Operations

FIRM NAME	STREET ADDRESS
MedImmune U.K. Limited	Plot 6, Renaissance Way, Boulevard Industry Park
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Liverpool, L24 9JW United Kingdom	Biologic Vaccine Drug Substance 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:

1. Inadequate information and impact assessment were included in deviation QE-048460:

   a. In the deviation report, the event was briefly described as (b) (4) found (b) (4) not in contact with (b) (4). However, no details were provided with the types of (b) (4) and the dilution of (b) (4) where the (b) (4) were observed.

   b (b) (4) batches of (b) (4) were affected by this deviation, but no details were provided regarding how many batches were associated with the commercial batches and how many were associated with the (b) (4) manufacture.

   c. The report did not provide explanation why this (b) (4) finding was not identified in the (b) (4), but only identified in the (b) (4). However, the SOP for (b) (4) testing states that "The (b) (4) should be in full contact with the (b) (4)."

   d. The presence of colonies found between (b) (4) and (b) (4) areas is inadequate to support the (b) (4) have no inhibitory effect on microbial growth on the (b) (4) nor supporting lack of impact on the (b) (4) results for these (b) (4) batches of (b) (4).

   e. The approximate % plate coverage from reported (b) (4) were only provided for (b) (4) batches out of (b) (4) batches in the deviation report.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Brentley S Collins, Investigator Gene D Arcy, Investigator - Team Biologics Anissa M Cheung, FDA Center Employee X Brentley S Collins Investigator Signed By: Brentley S. Collins -S Date Signed: 03-15-2024 07:24:42	3/15/2024

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2. Inadequate data for the qualification of the (b) (4) positive control used for the (b) (4) assay to monitor the (b) (4) level of the (b) (4) fluid in the (b) (4):

   a. Lack of stability data to support the shelf-life of the (b) (4) positive control ((b) (4) from the date of preparation) stored at (b) (4).

   b. No data to support that the (b) (4) of the (b) (4) positive control has no interference effect on the assay.

3. Inadequate investigation was performed on the (b) (4) action level excursions on % (b) (4) of the (b) (4) from the (b) (4) during Jan 25 – Mar 8, 2023 recorded in the qualification report of the (b) (4) from (b) (4):

   a. No deviation was initiated for these consecutive action level excursions on % (b) (4) of the (b) (4) as per SOP-0067565.

   b. The rejected (b) (4) were not manually inspected to verify that the (b) (4) were in poor quality prior to concluding that the root cause was due to the malfunction of the light and camera.

4. Your firm's batch record is not designed to capture critical information in support of (b) (4) which are used in the production of flu vaccine monovalent (b) (4).

   Specifically, Master Batch Record, MABR-0009649, entitled "(b) (4)", v10.0, was used to document step (b) (4), monovalent bulk (b) (4), strain serotype H1N1, strain A/Norway/31694/2022 V1, is not designed to capture all verification steps performed during

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Mark Proctor, Senior Director of Site Operations	
FIRM NAME MedImmune U.K. Limited	STREET ADDRESS Plot 6, Renaissance Way, Boulevard Industry Park
CITY, STATE, ZIP CODE, COUNTRY Liverpool, L24 9JW United Kingdom	TYPE ESTABLISHMENT INSPECTED Biologic Vaccine Drug Substance Manufacturer

(b) (4) of (b) (4). Such steps pertain to visual verifying that (b) (4) is dosed into (b) (4). In a full batch ((b) (4)) this verification step is performed (b) (4). However, in batch record MBR-0009649, it only allows for this step to be documented twice.

***DATES OF INSPECTION**

3/07/2024(Thu), 3/08/2024(Fri), 3/11/2024(Mon), 3/12/2024(Tue), 3/13/2024(Wed), 3/14/2024(Thu), 3/15/2024(Fri)

X Gene D Arcy
Investigator - Team Biologics
Signed By: 1300159963
Date Signed: 03-15-2024 07:25:15

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EMPLOYEE(S) SIGNATURE

Brentley S Collins, Investigator
Gene D Arcy, Investigator - Team Biologics
Anissa M Cheung, FDA Center Employee

X Brentley S Collins
Investigator
Signed By: Brentley S. Collins -S
Date Signed: 03-15-2024
07:24:42

DATE ISSUED
3/15/2024

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."