DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1777 Hardee Ave SW Atlanta, GA 30310 (404)253-1284 Fax:(404)669-4443	5/12/2026-5/20/2026* FEI NUMBER 3006525584

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Amanda M. Taylor, Vice President Operations, Plant Manager

FIRM NAME	STREET ADDRESS
Merck Sharp & Dohme LLC	5325 Old Oxford Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Durham, NC 27712-8730	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

The firm's equipment maintenance program is not always effective in ensuring that equipment functions as intended.

Prior to using the lyophilizer, the firm performs validated (b) (4) and static (b) (4) per SOP 7451, *"Lyophilization Cabinet Operation"*; however, these tests do not always identify all potential equipment failures. The (b) (4) is classified as a critical process parameter within the (b) (4) lyophilization cabinets during production operations. Despite equipment functional tests yielding acceptable results prior to use, the following Quality Notifications (QNs) were initiated due to lyophilization (b) (4) excursions.

a. QN201320331 - On 10/25/2025, at (b) (4), during lyophilization of VARIVAX (b) (4) (Material (b) (4) batches 0001954495, 0001954499, and 0001954501 in lyophilizer (b) (4), the maximum allowable (b) (4) during the (b) (4) was exceeded, with an actual recorded value of (b) (4) (Criterion: (b) (4) (b) (4) and (b) (4)).

b. QN 201323227 - On 11/11/ 2025, at (b) (4), the (b) (4) (b) (4) of the lyophilization process for VARIVAX (b) (4) VIAL ((b) (4); Material: (b) (4)), batch (b) (4), in lyophilizer (b) (4) resulted in an exceedance of the maximum allowable (b) (4) (b) (4). The recorded (b) (4) was (b) (4) (Criterion: (b) (4) (b) (4) and (b) (4) (b) (4)).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Lizaida Perez, Investigator Burnell M Henry, Investigator X Lizaida Perez Investigator Signed By: 2004213019 Date Signed: 05-20-2026 11:30:20	5/20/2026

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c. QN 201349388- On 2/23/2026, during lyophilization operations of VARIVAX (b) (4) VIAL ((b) (4); Material: (b) (4)), batch (b) (4), the maximum allowable (b) (4) was exceeded in lyophilizer (b) (4). The excursion occurred during the (b) (4) to (b) (4) (b) (4). The recorded chamber pressure of (b) (4) (Criterion: (b) (4) (b) (4) to (b) (4)(b) (4)).

OBSERVATION 2

There is a failure to thoroughly investigate any unexplained discrepancy or malfunction of equipment, whether or not the batch has been already distributed.

Specifically, the firm identified lyophilization equipment failures and initiated quality notifications (QN) per SOP 7541, titled, "Lyophilization Cabinet Operation"; however, the investigations remained open while the same lyophilizer continued to be used in bulk drug product manufacturing. The following quality notifications were outstanding during continued equipment use:

a. QN 201189265 - On 6/5/2024, an Out-of-Range (OOR) (b) (4) excursion occurred during the lyophilization of MMR II 0.5ML RHA 1DOSE VIAL (b) (4) (Material (b) (4)), batch (b) (4), in the (b) (4) lyophilizer (b) (4) cycle at Bldg. (b) (4) in room (b) (4). (b) (4) reached (b) (4) (Criterion: (b) (4)).

While the investigation into this excursion remained open, lyophilizer (b) (4) continued to be used in production for eight additional bulk drug batches. On 7/72024 a second (b) (4) excursion was documented under QN 201197180 during the lyophilization of MMR batch (b) (4). This event prompted the replacement of the (b) (4), which was identified as the root cause of the original June 5th pressure excursion.

b. QN 201300672 - On 8/11, 8/24, and 8/28/2025, the maximum allowable (b) (4) was

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exceeded during the (b) (4) phase of lyophilization for VARICELLA (b) (4) VIAL (b) (4) (b) (4) (batches 0001931827, 0001931829, 0001931831), VARIVAX (b) (4) (batches 0001934613, 0001934649, 0001934654), and VARIVAX (b) (4) VIAL (batch (b) (4)), all processed in lyophilizer (b) (4) . The recorded OOR (b) (4) values were (b) (4) , (b) (4) , and (b) (4) (criterion: (b) (4) (b) (4) Three additional batches of VARIVAX (b) (4) (b) (4) / Material (b) (4) (batches 0001934613, 0001934649,0001934654) and one VARIVAX (b) (4) VIAL/Material (b) (4))(batch (b) (4)) were manufactured in (b) (4) while the investigation remained open. The root cause was identified as a slow response from the (b) (4) , the (b) (4) responsible for regulating (b) (4) flow during lyophilization.

c. QN 201314013 - On 10/6, 10/15, 10/20/2025, the maximum (b) (4) was exceeded during the (b) (4) phase of the lyophilization cycle for VARIVAX (b) (4) batches (b) (4) , (b) (4) , and (b) (4) , processed in lyophilizer (b) (4) . The recorded (b) (4) (b) (4) values were (b) (4) , and (b) (4) (Criterion: (b) (4) (b) (4) (b) (4) During the period in which the investigation remained open, three additional batches of VARIVAX (b) (4) VIALS were manufactured using the same lyophilizer, (b) (4) . The root cause of the exceedances was identified as a malfunction of (b) (4) a component primarily responsible for (b) (4) (b) (4) during the lyophilization cycle.

***DATES OF INSPECTION**
5/12/2026(Tue), 5/13/2026(Wed), 5/14/2026(Thu), 5/15/2026(Fri), 5/18/2026(Mon), 5/19/2026(Tue), 5/20/2026(Wed)

Burnell M Henry
Investigator
Signed By: Burnell M. Henry -S
X Date Signed: 05-20-2026 11:31:40

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	Lizaida Perez, Investigator Burnell M Henry, Investigator Lizaida Perez Investigator Signed By: 2004213019 X Date Signed: 05-20-2026 11:30:20	5/20/2026

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."