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	2/19/2026-2/27/2026* FEI NUMBER 3001314775

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Carsten Schneider, Site Director

FIRM NAME	STREET ADDRESS
GSK Vaccines GmbH	Emil-Von-Behring-Str. 76
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Marburg, Hassia, 35041 Germany	Licensed 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

Your firm has not validated the cleaning procedures for dedicated equipment used in the manufacture of Aluminum Hydroxide adjuvant to prevent contamination or carry-over. This adjuvant is a component of your licensed U.S. products including (b) (4) Infanrix, Boostrix, Kinrix, and Pediarix.

Specifically, your cleaning validation and monitoring program for the aluminum hydroxide adjuvant production suite ((b) (4) and (b) (4)) is inadequate. You have introduced unvalidated (b) (4) cleaning steps into routine production, failed to maintain a state of control for your validated (b) (4) cleaning process, and failed to adequately investigate recurring cleaning failures.

a) You introduced an unvalidated (b) (4) workaround into your routine cleaning and manufacturing process.

Since May 2023, you have used an unvalidated (b) (4) cleaning procedure with (b) (4) (b) (4) for all batches of Aluminum Hydroxide adjuvant. This procedure was implemented to mitigate a known design flaw where aluminum hydroxide (b) (4) (implemented January 2026) and (b) (4) (implemented May 2023) and is (b) (4) This (b) (4) cleaning step was not validated to demonstrate its effectiveness. Furthermore, this change to your cleaning process was not managed through your firm's change control system.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Burnell M Henry, Investigator Travis S Bradley, Investigator X Burnell M Henry Investigator Signed By: Burnell M. Henry -S Date Signed: 02-27-2026 06:35:41	2/27/2026

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Carsten Schneider, Site Director	
FIRM NAME GSK Vaccines GmbH	STREET ADDRESS Emil-Von-Behring-Str. 76
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b) Your cleaning verification monitoring program is inadequate in that you failed to complete required (b) (4) verification for extended periods while continuing to manufacture and release commercial batches.

Your firm's monitoring program (b) (4) -118805-07) requires (b) (4) cleaning verification. These (b) (4) occurred because of (b) (4) invalid cleaning verification runs. The primary cause of these invalidated runs were (b) (4) Clean-In-Place (CIP) (b) (4) during the (b) (4) (also observed during routine production), an issue that stemmed directly from corrective actions your firm implemented to address the equipment design flaw referenced in observation 1a. You experienced (b) (4) where the process was not in a verified and controlled state:

- (b) (4) Following a valid verification run in (b) (4) the next successful (b) (4) verification was not completed until (b) (4) During this period, when the cleaning process was not in a verified state, at least (b) (4) batches of Aluminum Hydroxide adjuvant (b) (4) (b) (4) and (b) (4) were manufactured and subsequently used in final drug products released for distribution in the U.S.

- (b) (4) Following a valid verification run in (b) (4) the next successful (b) (4) verification was not completed until (b) (4) During this period, at least (b) (4) batches of Aluminum Hydroxide adjuvant (b) (4) and (b) (4) were manufactured and subsequently used in final drug products released for distribution in (b) (4)

c) Your firm failed to adequately investigate cleaning verification failures and implement timely and effective corrective actions.

Of the eleven invalid cleaning verification runs between January 2024 and October 2025, eight were not documented as deviations to investigate failures, as required by your procedure (b) (4) SOP 014 "Deviation Handling" ((b) (4) -SOP-082366). These undocumented failures include at least six instances of recurring CIP system malfunctions during the (b) (4) step related to (b) (4) (b) (4) in (b) (4) which prevented the achievement of required (b) (4) These failures occurred in:

Run (b) (4) (April 2024)

Run (b) (4) (May 2024)

Run (b) (4) (June 2024)

Run (b) (4) (September 2024)

Run (b) (4) (March-April 2025)

Run (b) (4) (July 2025)

OBSERVATION 2

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

Specifically, the firm failed to conduct formal investigations, in accordance with SOP-082366, "Deviation Handling," for failed (b) (4) test results associated with the Aluminum Hydroxide Adjuvant filling equipment. SOP 9000087625, "Requirements for (b) (4)

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(b) (4) states that a quality deviation is not required to be initiated unless (b) (4) (b) (4) test failures occur. Although each (b) (4) test failure is reviewed by Quality Assurance and documented in the Aluminum Hydroxide Adjuvant batch record, a formal investigation is not required for (b) (4) failures of this validated (b) (4) test performed using the (b) (4) A retrospective review identified a pattern of (b) (4) failures across (b) (4) consecutive batches manufactured in 2024 and periodic failures afterwards. The lack of documented investigations for the (b) (4) test failure(s) results in insufficient data for effectiveness verification, or trending of recurring (b) (4) test failures.

Deviation 201088144 was generated on 09/18/2024 after two (b) (4) test failures. The (b) (4) tests for the aluminum hydroxide (b) (4) was (b) (4) by the (b) (4) with the result (b) (4) which is classified as invalid. After using (b) (4) of the other (b) (4) possible (b) (4) according to defined procedure, the (b) (4) test passed (b) (4) prior to filling for batch # (b) (4) However, there was no justification for the aborted tests. CAPA 201097467 was initiated on 03/05/2026 and the effectiveness check is currently in progress.

***DATES OF INSPECTION**
2/19/2026(Thu), 2/20/2026(Fri), 2/23/2026(Mon), 2/24/2026(Tue), 2/25/2026(Wed), 2/26/2026(Thu), 2/27/2026(Fri)

X Travis S Bradley
Investigator
Signed By: TRAVIS S. BRADLEY -S
Date Signed: 02-27-2026 06:36:19

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Burnell M Henry, Investigator Travis S Bradley, Investigator X Burnell M Henry Investigator Date Signed: 02-27-2026 06:35:41	2/27/2026

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."