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	5/11/2026-5/19/2026* FEI NUMBER 3002653483

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Nicole Futterer, Site Head Stein DP Aseptics & CGT

FIRM NAME	STREET ADDRESS
Novartis Pharma Stein AG	Schaffhauserstrasse 101
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Stein Ag, Aargau, 4332 Switzerland	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 I OBSERVED:

OBSERVATION 1

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

Specifically, Active viable air sampling is not performed during KYMRIAH (b) (4) filling steps on (b) (4), which involve (b) (4). This practice was observed on May 12, 2026 in Suite (b) (4) across BSC (b) (4) (ROW (b) (4), BSC (b) (4) (ROW Batch (b) (4), and BSC (b) (4) (ROW Batch (b) (4). Your risk assessment provides no rationale for excluding active air sampling during this critical step, while other steps, with equivalent or lower (b) (4), are sampled. This practice has been in place since commencing commercial KYMRIAH manufacturing operations in May 2020. Since 2024, there have been (b) (4) Grade (b) (4) EM (including Personnel Monitoring (PM)) excursions reported during KYMRIAH manufacturing operations (across (b) (4) manufacturing suites (b) (4) and (b) (4)) while active air monitoring during the most critical operation (filling) was never conducted.

OBSERVATION 2

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically, your quality unit has failed to correct a recurring, systemic failure in your environmental monitoring (EM) program and did not ensure that errors were fully investigated and resolved before release of KYMRIAH (b) (4) product (ROW Batch (b) (4). The following was observed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Travis S Bradley, Investigator X Travis S Bradley Investigator Signed By: TRAVIS S. BRADLEY -S Date Signed: 05-19-2026 03:55:29	5/19/2026

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a) Your firm has a recurring trend of failing to analyze EM samples taken from your Grade (b)(4) and (b)(4) aseptic processing areas. Since 2025, there have been approximately 19 deviations (all initially classified as Major) reported for this issue (16 Grade (b)(4) and 3 Grade (b)(4)). Examples include, but are not limited to:

i. DEV-805600 (April 2026): Initiated on 05/05/2026, a Grade (b)(4) surface sample (Physical Sample ID: 11080136734; Location: (b) (4) BSC(b)(4): (b) (4)) was not sampled after (b) (4) step filling/ (b) (4) activities for KYMRIAH ROW Batch (b) (4). Investigation concluded no batch impact and batch released.

ii. DEV-804078 (April 2026): Initiated on 04/21/2026, a Grade (b)(4) passive air sample taken at the beginning of the (b) (4) step (Physical Sample ID: 11080122103; Location: (b) (4) BSC(b)(4): (b) (4) BSC) for KYMRIAH ROW Batch (b) (4) was not submitted for testing. This batch was released prior to the deviation being opened (see Observation 2 part b).

iii. DEV-791341 (December 2025): Initiated on 01/04/2026, a Grade (b)(4) passive air sample (Physical Sample ID: 11070463218; Location: (b) (4) BSC(b): (b) (4) BSC) taken during (b) (4) step filling/ (b) (4) activities for KYMRIAH ROW Batch (b) (4) was not submitted for testing. Investigation concluded no batch impact and batch released.

iv. DEV-788323 (November 2025): Initiated on 12/01/2025, a Grade (b)(4) personnel sample (Physical Sample ID: (b) (4); Location: (b) (4)) taken after end of day (b)(for KYMRIAH ROW Batch (b) (4) was not submitted for testing. Investigation concluded no batch impact and batch released.

v. DEV-785020 (October 2025): Initiated on 11/03/2025, a Grade (b)(4) active air sample (Physical Sample ID: 11070384916; Location: (b) (4) BSC(b): Active air, (b) (4) (b) (4) taken (b) (4) step filling/ (b) (4) activities for KYMRIAH ROW Batch (b) (4) was not submitted for testing. Investigation concluded no batch impact and batch released.

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Investigator
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vi. DEV-781067 (September 2025): Initiated on 09/30/2025, a Grade (b)(4) active air sample (Physical Sample ID: 11070344526; Location: (b) (4) BSC(b): Active air, (b) (4) (b) (4) taken (b) (4) Day (b) for KYMRIAH ROW Batch (b) (4) was not submitted for testing. Investigation concluded no batch impact and batch released.

Your quality unit failed to thoroughly review production records to assure that any deviations/discrepancies that could impact the batch had been resolved, addressed, and/or investigated prior to release. This failure resulted in the release of (b) (4), Kymriah ROW batch (b) (4), on April 20, 2026, despite never submitting a release-relevant Grade (b)(4) EM passive air sample. The deviation for this missing sample (DEV-804078 – as referenced in part ii above) was not initiated until April 21, 2026, after the batch had already been released.

b) As documented in deviation DEV-804209, initiated 04/21/2026, your quality unit's batch disposition procedure SOP-7045257 (ver. 19.0 effective 03/16/2026) titled "Release Process" is inadequate because it does not include a verification of the completeness of the EM data set against the sampling plan; to date the SOP has not been updated to include this step.

c) Your quality unit has failed to ensure that deviations are fully investigated, and that appropriate and effective corrective actions are implemented. Despite identifying the root cause of recurring failures to take and/or test Grade (b)(4) and Grade (b)(4) EM samples as a process failure prone to human error during (b) (4) and packing steps, your firm failed to implement an adequate verification step to ensure all required EM samples are (b) (4) packed for transport to the laboratory after being (b) (4) into your (b) (4) system.

***DATES OF INSPECTION**
5/11/2026(Mon), 5/12/2026(Tue), 5/13/2026(Wed), 5/18/2026(Mon), 5/19/2026(Tue)

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5/19/2026

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."