DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION*
Cincinnati District Office 550 Main St. Suite 4-930 Cincinnati, OH 45202 513-322-0700 Industry Information: www.fda.gov/oc/industry	12/16/2025-12/23/2025 FEI NUMBER 1527761

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
Ronald P. Ipach, Senior Director

TO: FIRM NAME	STREET ADDRESS
Smithfield Biosciences, Inc.	12150 Best Place
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cincinnati, OH 45241	API 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/WE OBSERVED:

OBSERVATION 1

Process Validation performed does not demonstrate that critical process parameters produce consistent APIs meeting their specifications and quality.

Specifically,

Your firm's process validation for (b) (4) USP, (b) (4) product codes, does not include validation of processing times listed in the batch record and in procedure SOP# 149. For example, (b) (4) (b) (4) cycle minimum times in the batch record were not tested, (b) (4) function was not monitored or recorded, maximum and minimum loads are not defined for stress testing the process, and (b) (4) being held throughout the cycle is not monitored. In addition, your firm manually switches cycle (b) (4) and (b) (4) operation rather than using recipes for repeatability. Your firm processed (b) (4) product code batches and (b) (4) product code batches during process validation due to various significant deviations and OOS results, such as product Color, atypical Loss on Drying, Total Plate Count failures, and other issues. This caused your firm to make additional batches in order to achieve process validation criteria of three consecutive product batches meeting specification. Your firm has released approximately (b) (4) out of (b) (4) batches of (b) (4) product code produced in the past two years and (b) (4) out of (b) (4) batches of (b) (4) product code produced in the past two years.

In addition, your firm's procedure, SOP# 149, "Operating the (b) (4) " states to (b) (4)

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	Logan Williams Anna M. Spiros Martin Kimani	Logan Williams, Investigator Anna Spiros, Investigator LCDR Martin M. Kimani, PhD, Investigator	~~09/27/2024~~ 12/23/2025 LTW

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(b) (4) Your firm does not document or review (b) (4) (b) (4) to confirm it approaches maximum low. In addition, your firm halts (b) (4) cycles during (b) (4) to (b) (4) check for product appearance to be (b) (4). On 11/04/2025, during (b) (4) USP, lot (b) (4) your firm halted the (b) (4) cycle from approximately 11:00am to 01:59pm to check for product appearance to be (b) (4). Your firm resumed the cycle and continued (b) (4) until 11/6/2024 at 8:15am.

OBSERVATION 2

Supplier qualification do not include evaluations that provide adequate evidence that the manufacturer can consistently provide material meeting specifications.

Specifically,

A.) Your manufacturer of (b) (4) has stated that "This product is unsuitable for use in the production of APIs as (b) (4) do not follow required GMP practices and do not sell pharmaceutical grade products". You proceeded to qualify this manufacturer of (b) (4) without obtaining a COA listing the identification and quantitation of all impurities as per the USP requirements. Additionally, you did not conduct a risk assessment to determine if this product would affect the quality of the final product.

B.) Your firm has not completed additional testing of (b) (4) per USP standards at appropriate intervals since 2021 to assure that the manufacturer can consistently provide (b) (4) meeting specifications.

C.) Your supplier of (b) (4) has not provided comprehensive certificates of analysis per USP requirements for every shipment/lot of (b) (4) received since 2021 and your firm has not checked and verified the reliability of certificates of analysis at regular intervals.

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OBSERVATION 3

Batch records and laboratory records of critical steps are not reviewed and approved by the quality unit appropriately.

Specifically,

A.) Your analytical laboratory paper records do not include signature and date of the second person reviewing (b) (4) impurity data on HPLC-1 for batches (b) (4) (b) (4) These batches were later released by QA without investigating whether they were reviewed or not. In addition, your firm does not include an electronic signature of review for HPLC data.

B.) Your microbiology laboratory paper records do not include the signature of the second person reviewing the record for accuracy including for growth promotion studies and finished product testing.

C.) (b) (4) used in production of (b) (4) USP does not have user login and parameters on the (b) (4) can be changed by anyone with access to the room. Non-production personnel such as engineering, regulatory affairs, and quality assurance can access these controls. In addition, without user login there is no electronic traceability of operators performing manual cycle switches.

D.) (b) (4) contain a shared administrator password for all users. This causes there to be no electronic traceability of operators performing manual cycle switches.

OBSERVATION 4
*****REPEAT OBSERAVTION FROM FDA 2019 INSPECTION*****

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Failure to conduct thorough investigations into unexplained discrepancies and the failure of a batch to meet any of its specifications.

Specifically,

A.) Your complaint investigation #137 for an additional doublet peak in the NMR spectra around (b) (4) ppm has not been thoroughly investigated. The identity of this peak has not been identified to date and retrospective analysis of previous NMR results data was not conducted.

B.) Your firm failed to positively identify "black specks" that were found in (b) (4) lots (b) (4) Your firm performed FTIR testing on the substance and no peaks were obtained. Your quality unit failed to get a positive identification on the "black specks". (b) (4) batches were reprocessed into (b) (4) and released on 12/16/2025. (b) (4) was rejected.

C.) In October 2024, your firm recorded two out-of-specification (OOS) results for Limit of (b) (4) in (b) (4) in batches (b) (4) Batch (b) (4) was retested twice, and the OOS result was confirmed on both occasions. Batch (b) (4) was retested six times, with the OOS result confirmed in each retest. As the OOS results were confirmed for both batches, they were deemed unsuitable for release, and Quality Assurance determined that the batches required reprocessing. This decision included batch (b) (4) which was being reprocessed during the week of 12/15/2025 into (b) (4) Your firm did not identify a root cause for the OOS results associated with these batches.

OBSERVATION 5

There is an inadequate number of personnel to manufacture and test APIs adequately.

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Specifically,

Your firm is using equipment that does not have audit trail capabilities and unique logins:

A.) Your firm currently uses GC-8A by Shimadzu which utilizes printed chromatograms and has no unique logins for analysts. Your firm has purchased a new GC-8860 by Agilent approximately 5 years ago, qualified the GC in April 2023, but have not started utilizing the new equipment due to resources being limited with turnover of key quality personnel.

B.) Your firm is utilizing a UV-Vis that is not capable of audit trail review or unique logins for analysts. Your firm qualified a new UV-Vis in January 2025, however, you have not started testing with this equipment due to validation needing performed. Your firm's Regulatory Affairs and Laboratory Managers stated that this was also delayed do to turnover of key quality personnel.

OBSERVATION 6

The stability program to justify assigned expiration or retest dates is not followed.

Specifically,

Your firm has not placed any (b) (4) USP (b) (4) batches on stability in 2024 or 2025. In accordance with your approved stability procedure SOP 021 Stability Testing of Bulk Drug Substances, Rev. S, Effective Date 12/22/2020, at least one batch per year is required to be put on stability. In 2024, (b) (4) USP (b) (4) batches, were released and in 2025 (b) (4) batches of (b) (4) USP, (b) (4) were released.

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***DATES OF INSPECTION**

12/16/2025, 12/17/2025, 12/18/2025, 12/19/2025, 12/22/2025, 12/23/2025

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