DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA Atlanta District Office Atlanta, GA 30310 1777 Hardee Ave SW FDA Atlanta District Office (214) 293-4940	03/23/2026 – 03/27/2026
	FEI NUMBER 3000718852

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mark J. Kuenzi, Site Head-Morrisville and Vice President

FIRM NAME	STREET ADDRESS
Fujifilm Diosynth Biotechnologies USA Inc.	101 J Morris Commons Ln
CITY, STATE, ZIP CODE, COUNTRY Research Triangle Park, NC 27709	TYPE ESTABLISHMENT INSPECTED 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:

OBSERVATION 1

Facility design and procedural controls for manufacturing drug substance intended for commercial distribution do not provide adequate assurance against microbial contamination and cross-contamination risks in the manufacturing suite at your Fujifilm Diosynth Biotechnologies USA Durham facility.

Specifically,

A. Your firm has failed to establish a facility cleaning and sanitization program that effectively prevents microbial contamination in drug substance manufacturing areas and products. Despite the repeated isolation of spore-forming organisms including approximately 80 bacterial isolates and approximately 6 mold isolates from classified air spaces between January 2025 and the present and the rejection of at least (b)(4) batches due to contamination with these organisms since 2024, your firm continues drug substance manufacturing intended for sterile injectable production without determining root cause or implementing corrective and preventive actions. In several investigations launched for these recoveries, your firm's documented position that "there is no impact to process performance or product quality" is unacceptable and demonstrates a fundamental failure to recognize the serious contamination risks posed to sterile drug products.

B. You do not perform routine monitoring of your ISO-5 conditions. Currently, environmental monitoring (EM) of these conditions is limited to major activities such as (b) (4) , passaging of (b) (4) , and bulk fill operations. You do not have EM data do support “at rest” conditions. Furthermore, you have not performed a risk assessment or study to verify that your EM locations used for current sampling of these environments are suitable for collecting data representative of the actual conditions. Additionally, you do not have scientific rationale to demonstrate that settle plates used for passive air monitoring of these areas can recover micro-organisms for your established maximum exposure time of (b) (4) .

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Veronica Fuentes, Drug Investigator Saundrea A Munroe, Drug Investigator Kayla V Sprague, Drug Investigator	VERONICA FUENTES -S Digitally signed by VERONICA FUENTES -S Date: 2026.03.27 13:56:09 -04'00'	3/27/2026

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C. Your firm lacks scientific justification for failing to ensure that all cleaning agents used in controlled environments are purchased sterile. For example, you have not ensured that (b) (4) [(b) (4)], which is used as (b) (4) disinfectant for [(b) (4)] application in these areas to include ISO-5 environments is sterile. Drug substances produced in your facility are intended for the manufacture of parenteral drug products.

OBSERVATION 2

Your unexplained discrepancies associated with your processes are not thoroughly investigated.

Specifically,

A. You opened several investigations after recovering mold in your processing rooms, supporting rooms, raw materials, and product in various stages of your process. From our review, we concluded the following were not thoroughly investigated:

Event Number	Reason for Investigation	Mold Recovered	Reason for Inadequate Investigation
PR 386943	Filamentous mold recovery in (b) (4) Viral (b) (4) pool of [(b) (4)] lot (b) (4) .	*Talaromyces rugulosus*	The root cause was not identified. Batch was released.
PR 327905	Mold in (b) (4) viable air sites.	*Cladosporium allicinum/ cladosporioides/ cucumerinum/ herbarum/ macrocarpum/ phaenocomae/ ramotenellum*	No root cause was identified, and no remediation was performed.
PR 380876	Mold recovery in batch (b) (4) during (b) (4) Post Hold.	*Aureobasidium melanogenum*	No root cause identified, inadequate corrective actions. Batch was ultimately rejected.
PR 353881	Mold recovery in batch (b) (4) during (b) (4) (b) (4) .	*Paenibacillus glucanolyticus/ Purpureocillium lilacinum.*	No root cause identified, no identified impact to product or process, and inadequate corrective actions. Batch was ultimately rejected.

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B. Your firm does not investigate all instances of spore-forming bacteria recovered in your drug substance samples. Since January 2025, there have been at least 26 bacterial spore-forming recoveries found in your drug substance samples at different stages of the manufacturing process. Your Senior Director of Microbiology stated that these recoveries are not investigated because the firm's written procedure, SOP-01732 version 33 'Investigation of Invalid, Out of Specification and Atypical Test Results,' does not require investigation of these findings. Your firm has not determined the source or route of entry for these spore-forming organisms into the manufacturing process.

C. On 10/14/2025, your firm recovered *Ralstonia pickettii,* a gram-negative biofilm forming organism in the (b) (4) system ((b) (4)). For remediation, you replaced (b) (4) on (b) (4) sample ports and (b) (4) the system. Your quality unit failed to evaluate whether this system continues to operate in a validated state following these modifications. Furthermore, you have not conducted a risk assessment to support that your bioburden sampling for (b) (4) (b) (4) post these corrective actions is adequate to verify complete biofilm removal. Per your Associate Director of Facilities, this (b) (4) is used as starting material for the (b) (4) (b) (4) system, cleaning of equipment/utensils, upstream processing, and as starting material for the (b) (4) .

D. On 03/09/2024, your firm recovered *Ralstonia pickettii,* a gram-negative biofilm forming organism in your (b) (4) system. You determined there was no impact to your (b) (4) system since the (b) (4) was resampled on 03/11/2024 and had passing results. No additional actions were taken other than trending your (b) (4) testing for (b) (4) . You do not have evidence that your sanitization process is eliminating biofilm or biofilm forming organism. Per your Associate Director of Facilities, this (b) (4) is used for downstream processing and equipment cleaning.

E. On 12/20/2023, you recovered *Burkholderia lata (B. cepacia complex*), a gram-negative biofilm forming organism in your (b) (4) system. You determined there was no impact to your (b) (4) system since all other samples collected that day obtained passing results. You trended these samples collected (b) (4) for (b) (4) , and trended other similar investigations. However, no additional actions were taken, and you do not have evidence that your sanitization process is eliminating biofilm or biofilm forming organism. Per your Associate

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Director of Facilities, this (b) (4) is used for downstream processing and equipment cleaning.

OBSERVATION 3

Your procedure for testing (b) (4) after use in your drug substance processing is inadequate in that in does not limit of times it could be tested.

Specifically, your written procedure for testing process (b) (4), SOP-01444, Use and (b) (4) Testing of Solution and (b) (4) Assemblies in the Manufacturing and Facilities, Version 22, has a limit of (b) (4) (b) (4) tests before contacting the area manager. Per this procedure, the area manager can approve additional (non-defined) (b) (4) testing. This procedure is inadequate to detect (b) (4) failures.

OBSERVATION 4

You have not ensured your microbiological methods are suitable for your operations.

You have not performed a risk assessment or evaluation to determine if your current bioburden methods of testing for both total aerobic microbial counts (TAMC) and total yeast microbial counts (TYMC) using both (b) (4) and (b) (4) media is suitable for recovering organisms that could potentially pose a risk to patients in light of the spore forming isolates (bacteria and mold) routinely recovered in your facility. Per your Sr. Quality Director, your organization "does not have a tolerance for spore-formers" and further stated "mold is bad." Your current process does not screen for specific organisms. Per your Sr. Scientist of Microbiology, there is no trigger to evaluate the capability of the methods once its approved for use.

Saundrea A. Munroe -S
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Date: 2026.03.27 13:53:05 -04'00'

KAYLA V. SPRAGUE -S
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Date: 2026.03.27 13:57:23 -04'00'

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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."