DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 orabioinspectionalcorrespondence@fda.hhs.gov	8/23/2021-8/31/2021* FEI NUMBER 3011948449

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Gerry J. Farrell, Chief Operating Officer

FIRM NAME	STREET ADDRESS
FUJIFILM Diosynth Biotechnologies Texas, LLC	100 Discovery Dr Ste 200
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
College Station, TX 77845-6314	Biologic 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

There are not adequate controls to prevent cross-contamination of other products in your multiproduct facility. Specifically, there are no written policies/procedures regarding showering or the time that must elapse before personnel who work in the virus positive production environment of one product can enter a virus negative area for that product or the virus positive or negative production environment for another product.

OBSERVATION 2

Your firm has not adequately investigated a batch contamination under PR#236900. (b) (4) batch (b) (4) indicates that technicians took microbiological (b) (4) samples of (b) (4) at (b) (4) The technicians observed suspected microbial contamination in (b) of the (b) (4) by (b) (4). Although operations management was notified, no request was recorded/identified for QA authorization for collection of non-routine samples from the suspect (b) (4) (Per SOP Use of Non-Routine Sample Request Form, MF-SOP-138).

The process continued to the (b) (4) of the (b) (4) of the (b) (4) suspect (b) (4) non-suspect(b) (4)), and later aliquoted to the (b) (4) step (step (b) (4), Lot (b) (4)). Non-routine samples were collected at the (b) (4) and (b) (4) steps. The process was terminated at the (b) (4) step post confirmation of contamination.

Collection of samples from suspect contaminated (b) (4) was not done and so contamination investigation PR236900 relied on other samples that were collected from subsequent steps.

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	Gene D Arcy, Investigator - Team Biologics Scott T Ballard, National Expert X Gene D Arcy Investigator - Team Biologics Signed By: 1300159983 Date Signed: 08-31-2021 16:23:53	8/31/2021

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OBSERVATION 3

There are no quantitative or specific measurements taken to qualify (b) (4) equipment used in (b) (4) bulk drug substance manufacturing. On 26 AUGUST 2021, I observed a demonstration of qualification (b) (4) testing of (b) (4) applicable for addition of reagents to bio-reactors or collecting fluid samples from bio-reactors. This testing is referenced by report ENT-OQ-21-215 (dated 28 APRIL 2021). For example:

a) The testing relies on (b) (4).
b) The testing relies on (b) (4).
c)The testing utilizes a (b) (4) which precludes the use of (b) (4) measurements to detect leaks.

In 2021, your firm has opened four deviations related to performance of (b) (4). Additionally, (b) (4) have no data to qualify this process, either quantitative or qualitative.

OBSERVATION 4

Your firm is not following your contamination control strategy for product (b) (4). Report, Microbial control of the (b) (4) Process in High Throughput Processing Area (b) (HTP(b)), FDBT-PPQ-0024, and your firm's Risk Assessment (FBF-RA-20-103), indicate that all formulated buffers or medias undergo (b) (4) along with (b) (4) testing. Of the (b) (4) media or buffer formulations reported to be (b) (4), only the (b) (4) that is used for the Final Formulation Buffer was reported to be (b) (4) tested (b) (4) (but not (b) (4)).

OBSERVATION 5

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Data integrity (D.I.) corrective measures are inadequate because you have not assessed all analytical instrumentation for possible corrections. (b) (4) CAPAs were opened to address your firm's data integrity measures for in-process (b) (4) analyzers (CAPA (b) (4)), which are used to determine in-process (b) (4) . (b) (4) are used in, but not limited to, the process monitoring of product (b) (4) (asset ID (b) (4)). Although the CAPAs address all (b) (4) across your firm's various production areas, no CAPAs have been created for chemistry analyzers known as (b) (4) (e.g., testing for (b) (4)), and, for example, your firm's software driven analyzers in the QC laboratory, even though D.I. vulnerabilities were reported to be identified by your firm's risk assessments.

OBSERVATION 6

Your firm does not have a procedure/policy that requires (b) (4) testing of cell banks that have been received from outside sources. For example, Working Cell Bank (WCB) lot (b) (4) and Working Virus Bank (WVB) lot (b) (4) were received by your firm for use in the production of a Bulk Drug Substance ((b) (4)). The WCB's were received as early as 6 OCT 2020 and WVB received as early as 13 OCT 2020 with no (b) (4) testing conducted.

OBSERVATION 7

On 23 and 24 August 2021, I observed warehouse locations inadequately labeled and inventory software (b) (4) showed inaccurate locations of materials. For example:

a) In the (b) (4) building, I observed (b) (4) cold storage rooms used for reagents and consumables for (b) (4) drug substance manufacturing. The cold storage rooms physically labeled (b) (4) are reversed as compared to facility drawings (e.g. (b) (4) is labeled as (b) (4))

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b) The cold storage room physically labeled as (b) (4) was empty and down for maintenance as stated by warehouse employees. However, (b) (4) software showed over (b) (4) items stored in cold storage (b) (4).
c) I observed material (b) (4) stored at ambient temperature in the general warehouse as indicated by (b) (4) inventory software, but the physical location had no label to correlate to software inventory data.
d) In the (b) (4) building, I observed materials such as (b) (4), located on pallets in the staging area, but when checking (b) (4), the software shows these materials in the manufacturing cage (b) (4)-Cage" location.

In the (b) (4) warehouse, I observed material (b) (4), batch (b) (4), but the (b) (4) software showed the material as located in (b) (4) warehouse approximately (b) (4) miles away.

OBSERVATION 8

Your firm does not perform reviews or trending of Work Orders (e.g., routine or corrective maintenance) to assess whether PM plans need to be changed or determining the need for re-qualification of equipment, utilities or facilities. The relevant SOP, (b) (4) Work Orders Process, FDBT-SOP-0521, was identified as lacking this requirement.

OBSERVATION 9

During review of training records on 25 AUGUST 2021, I observed that records were missing and required training was not assigned for employees that manufacture (b) (4) bulk substance. For example: The SOP#0323 version 5 was updated and made effective to include instructions with respect to dispensing (b) (4). The new instructions include improved labeling of (b) (4) and documenting work in a

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logbook. Your Director of Manufacturing support stated employees were not trained until 24 AUGUST 2021 due to my request to review training records. Your director stated the training software (b) (4) was supposed to push training out to the appropriate manufacturing employees, but it did not perform as expected and did not deliver the training.

***DATES OF INSPECTION**

8/23/2021(Mon), 8/24/2021(Tue), 8/25/2021(Wed), 8/26/2021(Thu), 8/27/2021(Fri), 8/29/2021(Sun), 8/30/2021(Mon), 8/31/2021(Tue)

X Scott T Ballard
National Expert
Signed By: Scott T. Ballard -S
Date Signed: 08-31-2021 16:24:35

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