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 orabioinspectionalcorrespondence@fda.hhs.gov	8/31/2023-9/8/2023* FEI NUMBER 3005001757

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Dr. Jürgen Betzing, Chief Executive Officer	
FIRM NAME IDT Biologika GmbH	STREET ADDRESS Dessau-Rosslau, Am Pharmapark
CITY, STATE, ZIP CODE, COUNTRY Dessau-Rosslau, Saxony-Anhalt, 06861 Germany	TYPE ESTABLISHMENT INSPECTED Vaccine 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

Lots of licensed products were released by the manufacturer prior to completion of tests for conformity with standards applicable to such product.

Specifically,

The firm implemented a (b) (4) assay of (b) (4). The following (b) (4) batches (b) (4) and (b) (4) were released for (b) (4) distribution to the (b) (4) market, but the firm lacked evidence of whether an application supplement was submitted for review and approval pursuant to the drug product application.

OBSERVATION 2

(b) (4) processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, the following locations of environmental monitoring (b) (4) within (b) (4) line (b) (4), located in room (b) (4) of building (b) (4), are not adequate to monitor (b) (4) environmental (b) (4) during production:

a. (b) (4); and (b) (4), located at (b) (4) used to monitor the environment during filling operations are, (b) (4),

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Roger F Zabinski, Investigator - Team Biologics Laurel A Beer, Investigator	X Roger F Zabinski Investigator - Team Biologics Signed By: Roger F. Zabinski -S Date Signed: 09-08-2023 14:59:31	9/8/2023

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(b) (4) from and (b) (4) the filling activity.

b. (b) (4), and (b) (4), used to monitor the environment during loading of (b) (4) are (b) (4) from the (b) (4) to lyophilizer FD2.

c. (b) (4), and (b) (4), used to monitor the environment during (b) (4) are (b) (4) from the (b) (4) to (b) (4).

OBSERVATION 3

The suitability of all testing methods is not verified under actual conditions of use.

Specifically,

The QC microbiology review of environmental monitoring (b) (4) is deficient including room design and equipment. During inspection of the lab, it was observed that the room used for (b) (4) environmental monitoring (b) (4)) is small (about (b) (4)) with (b) (4) operators and a supervisor to review as many as (b) (4) .

A system to prevent mix-ups is lacking. (b) (4) are (b) (4) and (b) (4) throughout the room.

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The firm does not use a (b) (4) for operators to see the colonies. Operators use (b) (4) to view colonies. During inspection of the lab, it was observed that the (b) (4) and (b) (4) cause (b) (4) that could cause one to see (b) (4) and this may inhibit accurate reading of colonies. The area supervisor reported that different results may be obtained from (b) (4) that receive a (b) (4) review, but the frequency and extend of colony count differences is not tracked.

The operators that review environmental monitoring (b) (4) are not required to have (b) (4). (b) (4) operator re-qualification does not represent a worst case of full day of an operator reading (b) (4) under these room and (b) (4) conditions.

OBSERVATION 4

GMP training is not conducted on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.

Specifically,

The training effectiveness is not systematically monitored, with respect to deviations and CAPA effectiveness. The firm had 25 deviations for training deficiencies in the past 3 years, in (b) (4) classified areas. Corrections and CAPAs to individual training deficiencies are not well described in the deviation reports and training on deficiencies are not extended to all relevant operators or production areas. The firm has only recently started to trend and categorize deviations based on root cause and has only recently begun to implement a continuous improvement training but has not taken action to ensure that critical manufacturing steps are carried out effectively.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
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OBSERVATION 5

Backup data is not assured as exact, complete and secure from alteration, erasure or loss through keeping (b) (4) systems.

Specifically,

The firm's Quality Unit including Quality Control Molecular Biology lab manager and IT staff do not perform (b) (4) audits of all GMP lab data including all (b) (4) to ensure adequate controls are in place for all lab systems including the (b) (4) systems.

***DATES OF INSPECTION**

8/31/2023(Thu), 9/01/2023(Fri), 9/04/2023(Mon), 9/05/2023(Tue), 9/06/2023(Wed), 9/07/2023(Thu), 9/08/2023(Fri)

X Laurel A Beer
Investigator
Signed By: 0014345915
Date Signed: 09-08-2023 15:00:15

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Roger F Zabinski, Investigator - Team Biologics Laurel A Beer, Investigator X Roger F Zabinski Investigator - Team Biologics Signed By: Roger F. Zabinski -S Date Signed: 09-08-2023 14:59:31	9/8/2023

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."