DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Main Place 1201 Main St., Suite 7200 Dallas, TX 75202 214-253-5200 Industry Information: www.fda.gov/oc/industry	06/8-12 & 16-17/2026
	FEI NUMBER 3006341547

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Eric A. Bell, Sr. Director of Quality

FIRM NAME	STREET ADDRESS
Cytovance Biologics Inc.	800 Research Parkway, Ste 200
CITY, STATE AND ZIP CODE Oklahoma City, OK 73104	TYPE OF ESTABLISHMENT INSPECTED Active Pharmaceutical Ingredient (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:

The following observations pertain to the manufacture of commercial bulk drug substance (b) (4) and/or other bulk drug substances that may be used in clinical research studies in humans. From July 2023 to present, approximately (b) (4) lots of (b) (4) bulk drug substance were manufactured.

FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 1

Failure to properly maintain buildings, facilities and equipment used in the manufacture of active pharmaceutical ingredients (API).

Specifically,

On June 12, 2026, the following deficiencies were identified in manufacturing areas located in Building (b) (4) where manufacturing of bulk drug substances occurs, including (b) (4). These observations are illustrative and not exhaustive.

A. I observed ~~dirty~~ the appearance of rust and residue in the return air vents in the Inoculum Preparation Room (b) (4) (ISO 7) and Solvent Preparation Room (b) (4) (ISO 8). Cell thaw activities are performed in Room (b) (4). Room (b) (4) is dedicated to the preparation of media and buffer solutions for all products other than (b) (4).

MMA 6/17/26

B. I observed the appearance of moisture ingress on the drywall adjacent to the return air vent located to the left of

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	MARGARET M. ANNES -S Digitally signed by MARGARET M. ANNES -S Date: 2026.06.17 13:31:21 -05'00' Margaret M. Annes	Margaret M. Annes, Sr. CSO Hung H. Do, M.Sc., Investigator	06/17/2026

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your Biosafety Cabinet (b) (4) in Room (b) (4) (ISO 7). This room is used for inoculum preparation of (b) (4) . Additionally, the appearance of moisture ingress was also observed on the (b) (4) flooring used as baseboard material in the same area. Moisture infiltration of this nature may compromise the structural integrity of the room and present a risk of microbial contamination in a critical manufacturing environment.

C. I observed live insects in Solvent Preparation Room (b) (4) (ISO 8).

mmA 6/17/26

This is a REPEAT OBSERVATION from the inspection conducted 07/11-20/2017.

OBSERVATION 2

Equipment used in the manufacture of active pharmaceutical ingredients is not fully qualified.

Specifically,

A. Smoke studies performed during the performance qualification of the ISO 5 biological safety cabinets (BSC) and laminar flow hoods (LFH) in Building (b) (4) are inadequate to evaluate unidirectional airflow and contamination risk. To manufacture the drug substance (b) (4) , your firm uses the following equipment for cell thaw ((b) (4); Room (b) (4)), (b) (4) ~~inoculation~~ Sample (b) (4) ((b) (4); Room (b) (4)), and bulk fill (b) (4) ; Room (b) (4)).

6/17/26 mmA

This is a REPEAT OBSERVATION from the inspection conducted 05/01-9/2019.

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i. Absence of Study Protocols
Your firm failed to establish and approve protocols for the smoke studies conducted by your third-party vendor. For example, there is no documentation detailing the type of fogger or the fluid used to generate the smoke. Without this information, your firm cannot verify that the generated smoke was neutrally buoyant. The inability to confirm neutral buoyancy compromises the validity of the study, as it may mask true airflow patterns and preclude the identification of critical vulnerabilities such as recirculating air or dead zones.

ii. Inadequate Visualization
The angle of video recording during dynamic conditions of (b) (4), and (b) (4) does not capture the full range of airflow, preventing a complete evaluation of air sweeps over the critical areas.

iii. Insufficient Simulations
Your firm failed to evaluate dynamic conditions that accurately represent the drug substance commercial process for (b) (4). Routine activities, including the cell thaw of (b) (4) in (b) (4) (Room (b) (4)) and (b) (4) inoculation in (b) (4) (Room (b) (4)), were excluded from the studies. Additionally, your Quality Unit selected a worst-case dynamic condition (the (b) (4) process of a (b) (4) to collect samples inside (b) (4) and (b) (4)) that is not established in your commercial process and failed to provide a risk assessment or scientific rationale to justify this selection.

B. Your firm's (b) (4) validation (b) (4) for the (b) (4) Sterilizer, Equipment ID: (b) (4), located in Building (b) (4) is inadequate, in that:

Your Quality Unit failed to adequately justify and document the placement of biological indicators (BIs) during the sterilization qualification of the (b) (4) used in the manufacture of (b) (4). First, no risk assessment was conducted to identify the worst-case, hardest-to-sterilize locations within the (b) (4), including the (b) (4) of the (b) (4) Second, performance qualification records (Working Copy No.: WC-25-0037, including the photographic record in Attachment 11.5.2) fail to specify the exact locations where BIs were placed.

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Critical manufacturing components used in production (b) (4) lot (b) (4) (via (b) (4) Batch Medium Lot (b) (4)) and lot (b) (4) (via (b) (4) Batch Medium Lot (b) (4)) were sterilized using an inadequately validated (b) (4) .

OBSERVATION 3

Failure to establish appropriate cleaning procedures for all manufacturing equipment.

Specifically, your firm failed to adequately validate the cleaning method for the (b) (4) (Working Copy No.: WC-18-0287) used in the manufacture of (b) (4) . Your cleaning validation did not include a risk assessment to identify worst-case cleaning locations, nor did it specify sampling locations or provide a scientific rationale for their selection. Your firm uses the (b) (4) .

QUALITY SYSTEM

OBSERVATION 4

Failure to adequately investigate deviations and implement appropriate corrective actions.

Specifically, your firm has not conducted a thorough investigation to find and remediate the source/root cause of the microbiological contamination in the (b) (4) system in Building (b) (4). DEV-2026-0012 initiated April 23, 2026, noted a trend in Total Aerobic Microbial Count (TAMC) testing of several (b) (4) drops located in Building (b) (4). Organisms recovered include Burkholderia cepacia and Ralstonia insidiosa. Your investigation determined that the elevated levels of TAMC counts "were caused by microbial contamination/biofilm within the distribution loop". Final approval by QA and closure of the deviation was on May 13, 2026 with no corrective action identified. These same two organisms have been recovered from the (b) (4) system in Building (b) (4) in July 2025 (DEV-2025-0037). (b) (4) is used to feed the (b) (4) system in Building (b) (4) that in turn is used

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to manufacture buffers for several products including (b) (4), as well as to make cleaning solutions for use in cleaning/sanitizing the facility to include floors, walls, ceilings, benches, tables and chairs.

MATERIALS SYSTEM

OBSERVATION 5

There is a failure to justify defined intervals for conducting periodic full testing (verifying supplier's Certificate of Analysis).

Specifically, per OKC-SOP-1379 Raw Material Test Strategy, revision 03 effective 18 Feb 2026, periodic full testing of raw materials is performed (b) (4) (or the next receipt(b) (4) after the last full testing) for common stock products and at every (b) (4) receipt for project specific raw materials. Your firm does not have documented justification/rationale for the frequency of performing full testing of raw materials.

For example, for (b) (4) and (b) (4) are considered excipients in the final drug substance. The last full testing for (b) (4) was performed on receiving lot #(b) (4) received 02/20/2023. Since the last time full testing was performed, your firm has received in (b) (4) project specific lots of this raw material.

(b) (4) is considered a common stock and a project specific product depending on how the purchase order is coded. The product can be used in several products as common stock, including as an excipient in the (b) (4). The last full testing was performed on lot #(b) (4) received on 12/09/2022. Since the last full testing, your firm has received in(b) (4) lots of common stock and(b) (4) lots of project specific (Project (b) (4)) lots.

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OBSERVATION 6

Failure to obtain a representative sample of each batch of each raw material for release testing.

Specifically, your firm has no documented rationale/justification for sampling only (b) (4) of a raw material regardless of the number of containers received. For example, (b) (4) containers were included in receiving #(b) (4) (vendor lot #(b) (4)) of (b) (4) . Only (b) (4) sampled for identity testing. This lot has been used to manufacture several lots of (b) (4) , including lot #(b) (4) released on March 19, 2026.

PACKAGING AND LABELING SYSTEM

OBSERVATION 7

Failure to have written procedures for the printing, issuance, review/approval and reconciliation of all labeling applied to bulk drug substances and failure to maintain a representative copy of all labeling used.

Specifically, your firm at times will collect a "(b) (4) sample" that is to be sent with the finished product to your customer, including for (b) (4) . Your firm has no written procedures for the printing, review and approval of the label that is placed on the container containing the (b) (4) sample nor do you maintain a copy of the actual label placed on the container. The label(s) are printed by Manufacturing and are not reviewed and approved by QA/QC prior to labeling operations.

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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 judgement, 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."