DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CDER/OPQ/OPMA/DPMA 10903 New Hampshire Avenue; White Oak Building 51, Room 2269 Silver Spring, MD 20993 Email: OPMABLAInspection483Responses@fda.hhs.gov	12/08/2025-12/16/2025
	FEI NUMBER 3026506583

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Brendan McGrath, VP of Manufacturing and Ireland Site Lead

FIRM NAME	STREET ADDRESS
WuXi Biologics Ireland Limited	Dundalk Science and Technology Park
CITY, STATE, ZIP CODE, COUNTRY Mullagharlin, Dundalk, County Louth, A91 X56F, Ireland	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

(b) (4) equipment utilized in the (b) (4) drug substance manufacturing process is deficient. Specifically,

Multiple deviations of bag leaks have been identified in 2024 and 2025 involving various bag sizes (b) (4) (b) (4) *etc.*) of (b) (4) bags. The calculated bag defect rates range from 0.45% to 5.88% for 2025. These bags perform critical functions throughout the manufacturing process, including (b) (4) (b) (4) *etc.* Change control PR 218330 was initiated on Dec 1, 2025, proposing to implement (b) (4) (b) (4) bags as a corrective measure. However, this change control is currently under board review and pending approval. The effectiveness of this proposed change control in reducing the bag leakage rate is currently unclear.

OBSERVATION 2

Laboratory controls are inadequate to ensure reliable analytical testing of critical quality and safety attributes. Specifically,

Critical analytical methods showed high invalid assay rates from (b) (4) to current: (b) (4) for (b) (4) (b) (4) A Laboratory Investigation Report (LIR) has been initiated, and operator training was identified as the main root cause. While some methods have shown improvement following enhanced training programs (b) (4) invalid rates for the following critical analytical methods remain high in (b) (4) for (b) (4) (b) (4) In addition, invalid rates are also high for (b) (4) in (b) (4)

OBSERVATION 3

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	LIQUN ZHAO -S Digitally signed by LIQUN ZHAO -S Date: 2025.12.16 09:40:31 -05'00' Dilip D. Devineni -S Digitally signed by Dilip D. Devineni -S Date: 2025.12.16 09:37:17 -05'00'	Liqun Zhao, Ph.D., Pharmaceutical Scientist Dilip Devineni, Ph.D., Biologist	12/16/2025

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Written documents are inadequate to ensure proper documentation of manufacturing operations. Specifically,

During walk-through of the manufacturing area for (b) (4) step, it was observed that the logbook reflected a completed (b) (4) cycles while the SAP system showed (b) (4) cycles. This discrepancy between physical records and SAP system represents inadequate documentation practices.

OBSERVATION 4

Laboratory investigation procedures for Out of Specification (OOS) results are inadequate. Specifically,

In WX-SOP-10217: Laboratory Investigation Report Procedure, Section 5.5.9.1, states: "If no root cause is identified through phase 1 and 2 investigations, upon consultation with QA, the investigation may progress to retesting.". Section 5.5.9.5 specifies: "If all results meet specification, are within system suitability and sample acceptance criteria the re-testing can be reported and the original analysis invalidated.". This SOP allows retesting and subsequently invalidate the original results if no root cause has been identified, which is inappropriate. When no clear laboratory error has been identified, the initial results may constitute valid analytical findings that should be reported and considered in the batch release decisions.

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	LIQUN ZHAO -S Digitally signed by LIQUN ZHAO -S Date: 2025.12.16 09:41:09 -05'00' Dilip D. Devineni -S Digitally signed by Dilip D. Devineni -S Date: 2025.12.16 09:37:50 -05'00'	Liqun Zhao, Ph.D., Pharmaceutical Scientist Dilip Devineni, Ph.D., Biologist	12/16/2025