DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	4/14/2025-4/18/2025
	FEI NUMBER 3000209996

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jose M. Gonzalez, SVP General Manager

FIRM NAME	STREET ADDRESS
AGC Biologics, Inc.	21511 23rd Dr Se
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bothell, WA 98021-3900	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

Review of laboratory data for drug substance in-process and release testing is not adequate:

a) We observed raw data from (b)(4) does not match the analytical packet (b)(4), for lot # (b)(4) used to document the final results. This data is generated as part of Final Bulk Drug Substance release testing for residual (b)(4). The analysis packet was reviewed by a QC reviewer on 19 NOV 2024 and did not catch the error.

b) On 15 APR 2025, your quality control associate (analyst) who performs the (b)(4) testing method for - final bulk drug substance, demonstrated (with typical system access rights) the ability to delete original electronic data from the (b)(4) which saves data files from the (b)(4) used for (b)(4) test method (b)(4), among others). There is no routine system-level review to ensure the veracity of electronic data files submitted.

c) On 8 Jun 2016, (b)(4) instrument for in-process monitoring of (b)(4) and (b)(4) bio-reactors in Building - were qualified by testing reference (b)(4) at various concentrations. Along with deviations noted in the protocol, the final report was reviewed and approved in April 2024. One (b)(4) used in the qualification is the (b)(4) which was evaluated by (b)(4) to show average results of (b)(4) The qualification of the instrument has no acceptance criteria for accuracy. These instruments (b)(4) are still in use today for monitoring bio-reactor cell viability including for - production.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Christian Lynch, Investigator Scott T Ballard, National Expert X Christian Lynch Investigator Signed by: Christian D. Lynch -S Date Signed: 04-18-2025 20:38:12	4/18/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	4/14/2025-4/18/2025
	FEI NUMBER 3000209996

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jose M. Gonzalez, SVP General Manager

FIRM NAME	STREET ADDRESS
AGC Biologics, Inc.	21511 23rd Dr Se
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bothell, WA 98021-3900	Drug Substance Manufacturer

OBSERVATION 2

Documentation of critical material inventory is not accurate.

On 14 APR 2025, we observed the inventory system "[-]" indicating [-] vials of working cell bank (WCB [(b)(4)], lot # [(b)(4)]) located within liquid nitrogen storage vessel # [-] at Building # [(b)(4)] records of the same lot show conflicting inventory of [-] vials. Upon observation of the storage location, only [-] vials were found in cryo-storage. This working cell bank is the starting material for upstream culture that will produce the drug substance [-] under BLA [(b)(4)].

As stated by your Senior Director, Quality Systems and Compliance, no established procedures exist for conducting inventory/cycle counts of WCB stored in the release and quarantine liquid storage vessels (# [-] and # [-], respectively) in Building [-].

X Scott T Ballard
National Expert
Signed By: Scott T. Ballard -S
Date Signed: 04-18-2025 20:39:00

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Christian Lynch, Investigator Scott T Ballard, National Expert	X Christian Lynch Investigator Signed By: Christian D. Lynch -S Date Signed: 04-18-2025 20:38:12	4/18/2025

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."