DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Lead Insp.: Erin Hill, Consumer Safety Officer Telephone: 240-402-9706 Industry Information: www.fda.gov/oc/industry	11/08/2023-11/20/2023
	FEI NUMBER 3020270660

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Luca Alberici, General Manager, Site Head

FIRM NAME	STREET ADDRESS
AGC Biologics S.p.A.	Via Antonio Meucci 3, Openzone
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Bresso, Milan, Italy 20091	Cell and Gene Therapy Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation 1

There is a failure to identify a root cause and implement corrective actions to address repeated incidents of alarms, in addition to not following procedures regarding alarms, specifically,

a. According to MLN-RPT-000381: "Summary report for GMP environmental monitoring: (b) (4) (b) (4)", effective 07/13/2023, there were a total of 19 non-viable particulate alarms during batch production in the presence of personnel in Grade (b) (4) space from (b) (4), and 40 alarms for non-viable particulate in the absence of personnel from (b) (4). The source of these particulates has not been investigated.

b. According to MLN-SOP-000188: "Monitoring of particles classified area (Bresso)", effective 04/14/2023, in the event of an out of action non-viable particulate result during operation in Grade (b) (4) space, any unprotected exposed material in direct contact with the product must be removed, the hood air velocity must be verified, and the hood must be sanitized. It is not clear if the procedure regarding out of action result for non-viable particles was followed since these actions were not verified during the investigation nor documented in the batch record.

Observation 2

Failure to follow procedures, specifically,

a. According to MLN-SOP-000065: "Behavior and Hygiene for Aseptic Areas of AGC Biologics", 05/31/2023, operator movement in a Grade (b) (4) space should be slow and deliberate and GMP manufacturing operators have to sample gloves before replacement. During the sterile filtration and filling of lot (b) (4) batch (b) (4), the Grade (b) (4) operator working in the BSC was observed executing rapid movements. Additionally, an operator was observed

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		Erin Hill, CSO Viviana Ramirez, CSO CHRISTELLE MBONDJI WONTEMO Tiffany Lucas, CMC Analyst Jacob Bittinger, CMC	11/20/2023

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replacing gloves without first performing environmental monitoring.

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		Erin Hill, CSO Vivienne Ramirez, CSO Christelle Mbondji Wonje, CMC Tiffany Lucas, CMC Project Jacob Hoffman, CMC	11/20/2023