DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CDER/OPQ/OPMA/Division of Biotechnology Manufacturing 10903 New Hampshire Avenue; White Oak Building 51, Room 2269 Silver Spring, MD 20993 E-mail: OPFBLAInspection483Responses@fda.hhs.gov	06/02/2022-06/09/2022
	FEI NUMBER 3010479596

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sam MacHour, Executive Vice-President & Chief Quality Officer

FIRM NAME	STREET ADDRESS
Samsung Biologics Co., Ltd. (SBL)	300, Songdo bio-daero, Yeonsu-gu
CITY, STATE, ZIP CODE, COUNTRY Incheon, 21987, Korea	TYPE ESTABLISHMENT INSPECTED Drug Substance and Drug Product 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

The endotoxin detection method is not reliable to detect endotoxin consistently in all the in-process and release samples for (b) (4) During the investigation of endotoxin non-conformance results (NCR), the firm re-tested the samples with (b) (4) Endotoxin Specific (ES) buffer and the test results suggested (b) (4) interference. However, some samples tested for endotoxin with ES buffer resulted in invalid assays due to positive product control (PPC) spike recovery exceeding (b) (4) - (b) (4) % acceptance criteria. Therefore, ES buffer will be introduced as a retest remediation without initiation of NCR for routine (b) (4) in-process and release testing when initial testing with LAL Reagent (b) (4) results in NCR (proposed CAPA 006327). The proposed CAPA 006327 does not resolve assay variability due to (b) (4) interference.

OBSERVATION 2

Written procedures for cleaning and maintenance provide inadequate description of actions to be taken and/or not followed. Specifically, SOP MFP-00290 "Aseptic Operation and Sanitization for (b) (4) DP RABS & Grade A" Version 32 does not provide sequence of RABS cleaning steps. This RABS in plant (b) (4) is used for the aseptic filling of (b) (4) drug product.

a. Although the SOP states "When disinfecting/sanitizing, begin from the (b) (4) surfaces in the RABS and work (b) (4) ", RABS operators were seen spraying RABS (b) (4) first and then cleaning the HEPA filters during RABS cleaning.
b. The Grade A side of the RABS (b) (4) were seen brushing the operator gowning while both RABS (b) (4) were open during RABS cleaning.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Madushini N. Dharmasena -S Digitally signed by Madushini N. Dharmasena -S Date: 2022.06.09 01:16:55 -04'00'	Madushini Dharmasena, Ph.D.	06/09/2022

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OBSERVATION 3

Investigations conducted to resolve assay failures were inadequate. High invalid assay rates were reported for Capillary Gel Electrophoresis (CE-SDS) assay and Imaged Capillary Isoelectric Focusing (icIEF) assay for (b) (4). For example;

a. The 2021 4Q invalid rate for the (b) (4) CE-SDS assay was (b) (4) % (OOT-001269).
b. The 2021 4Q invalid rate for the (b) (4) icIEF assay was (b) (4) % (OOT-001270).

The root causes for the high invalid rates were not identified. No CAPAs were put in place to prevent future assay failures.