DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Director, Division of Inspections and Surveillance FDA / CBER / Office of Compliance and Biologics Quality 10903 New Hampshire Avenue (W071-5128) TEL: 240-402-9159 Silver Spring, MD 20993-0002 CBER483responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	2/20-28/2023 FEI NUMBER 3010479596

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Sam MacHour, Executive Vice President/Chief Quality Officer, Quality Center

FIRM NAME	STREET ADDRESS
Samsung Biologics Co., Ltd.	300 Songdo bio-daero,
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Yeonsu-gu, Incheon, 21987, Republic of Korea	Licensed Biological 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:

1. The responsibilities and procedures applicable to the quality control unit were not always fully followed. The following deviations reported that the initial Quality Control Unit review of the referenced records did not identify data discrepancy, data handling, and calculation errors and follow-up investigations were not complete. Specifically,

a) Deviation Report, DEV-(b) (4) reported on February 3, 2023 during a (b) (4) data verification of (b) (4) data for Technical Report TR-(b) (4) dated July 18, 2022 (including (b) (4) and TR-(b) (4) Study Report, dated January, 2020, a data discrepancy was discovered. Per the Client method (b) (4) should be used for calculation. The (b) (4) analyst used (b) (4) (b) (4) for calculation. A follow up to ensure this calculation error did not occur with a similar (b) (4) test method (b) (4) (b) (4) released batches, was not documented.

b) Deviation Report, DEV-(b) (4) reported on January 18, 2023 during a (b) (4) data review for (b) (4), which was performed as part of TR-(b) (4) Study, dated January, 2020, a QA reviewer identified the following data integrity violation. Specifically, during a data and audit trail review it was found that a single analyst reported that (b) (4) was valid by intentionally deleting the specified (b) (4) after (b) (4) was completed. The initial date of analysis was conducted on 31Oct2018. The DEV-(b) (4) conclusion was silent on whether (b) (4) was used in other in-process or release methods for (b) (4)

c) Deviation Report, DEV-(b) (4) reported on 6/23/2021 that a CMC analyst discovered a calculation formula difference in the %deviation calculation formula between the old (b) (4) (b) (4) and the new (b) (4) The

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		Prabhu P. Raju, Investigator Laurel Beer, Investigator	02/28/2023

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new (b) (4) was configured to meet user requirements, but there were no standard procedures or detailed instructions for setting parameters that could affect data processing and reporting values. DEV- (b) (4) was silent on why this deviation was not classified as (b) (4) and Effective Checks initiated for CAPA activities. A (b) (4) Deviation is defined as (b) (4) (b) (4) A formal impact assessment was conducted for DEV- (b) (4)

d) Deviation Report, DEV- (b) (4) reported on 06Feb2022 during preparation of (b) (4) a document generation error was observed on step (b) (4) A (b) (4) from step (b) (4) should have been attached during preparation of previous Batch (b) (4) but (b) (4) for added was attached instead of the (b) (4) The disposition/status of the (b) (4) was not documented in DEV- (b) (4)

e) Deviation Report, DEV- (b) (4) dated 3Jun2020, Plant (b) (4) Suite (b) (4) and Deviation Report, DEV- (b) (4) dated 19Oct2022, Plant (b) (4) reported batteries being removed from (b) (4) equipment during sampling of (b) (4) Umbrella CAPA - (b) (4) opened in 8/28/2020, titled "Improvement to resolve limited function of (b) (4) Equipment" mentioned audit trail functions would be implemented with new (b) (4) but was silent on whether a review of audit trails after use of (b) (4) would be conducted.

2. Non-Conforming Results Report, NCR- (b) (4) closed on 02/23/2023, titled (b) (4) NCR of (b) (4) testing for (b) (4), reported the "requalification design" to determine (b) (4) of Reference Standard (b) (4) against itself caused "lower measurement" and caused the NCR for (b) (4) (i.e. (b) (4). Result: (b) (4) Spec: (b) (4) Through the hypothesis test under (b) (4) dated 12/23/2022, it was proven that the actual (b) (4) of the (b) (4) Reference Standard (b) (4) measured with the WHO International Standard (b) (4) (b) (4) was higher than the assigned value tested against itself (b) (4). The root-cause was determined to be in the Re-qualification of (b) (4) Reference Standard (b) (4) (b) (4), dated 12/16/2021, for the (b) (4) requalification of Reference Standard against itself rather than against the external standard (primary reference standard which is the WHO International Standard). Accumulation of (b) (4) requalifications of the (b) (4) standard caused by requalification against itself has accumulated into an underestimated value of the (b) (4) reference standard vs. the true value when calibrated

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against the WHO standard. This resulted in reporting an underestimation of (b) (4) which resulted in the NCR for (b) (4) The original NCR (b) (4) test was invalidated when the Reference Standard (b) (4) (b) (4) was retested against the WHO (b) (4) assigned reference standard. The root cause investigation/ impact assessment did not include an assessment of the following. Specifically,

a) The Re-qualification of the (b) (4) Reference Standard (b) (4) dated 2/3/2023, continues to be deficient as it instructs for (b) (4) requalification of the reference standard with (b) (4) replicates (b) (4) which is not supported by the observed high variability of the (b) (4) (i.e., (b) (4) requalifications are performed based on (b) (4) measurements which can be variable, and a higher number of test replicates has not been evaluated).

b) There was a failure to identify/assess the variability of the test method, (b) (4) (b) (4) " (b) (4) , dated 10/25/2022, and the process for (b) (4) " (b) (4) " value requalification, which is based on (b) (4) measurements.

c) There was a failure to identify the root-causes for the negative trend in (b) (4) during (b) (4) requalifications (2017-2022) of reference standard (b) (4) and confirm the suitability of the reference standard for its intended purpose.

3. Certificates of Quality (COQ or COA) for incoming lots of final containers for (b) (4) (b) (4) are accepted and lots are released without a visual identification being conducted on the containers and without appropriate validation of the supplier's test results at appropriate intervals. Specifically, (b) (4) (b) (4) (b) (4) have been accepted and released for use in manufacturing based on reliance of the supplier's COQ without at least a visual identification of the containers. Additionally, the firm has not validated the supplier's test results at appropriate intervals. These containers have been used in the final (b) (4) of the (b) (4) batches of (b) (4) manufactured since the license was approved. (b) (4) of these batches have been released.

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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."