DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Mahesh Ramanadham, PhD Director (Actg), Division of Inspectional Assessment, OPF/OPQ/CDER WO 51 RM 4238, 10903 New Hampshire Ave, Silver Spring, MD 20993 Phone: (+1) 301-796-3272 Industry Information: www.fda.gov/oc/industry	7/17-7/21/2017, 7/24-7/25/2017
	FEI NUMBER 3010479596

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Ronald Marchesani, Sr. Vice President, Quality Assurance Center

FIRM NAME	STREET ADDRESS
Samsung BioLogics	300 Songdo Bio Way (Daero)
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Yeonsu-gu, Incheon, Korea	Drug Substance Manufacturing Facility

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. Laboratory controls used to release (b) (4) drug substance do not include scientifically sound and appropriate test procedures that assure conformance to appropriate standards of quality and purity.

Specifically,

a. The (b) (4) method to test for (b) (4) is not adequately verified or validated for its intended use. You reported that between January 22, 2016 and December 19, 2016, nine (45%) out of twenty (b) (4) assays were deemed invalid due to failed system suitability criteria. Seven (b) (4) assays failed system suitability due to unexpected spike peaks in reference material samples or system suitability samples. The root cause(s) for recurring system suitability failures is unclear and there is no assurance that the method is capable of consistently meeting system suitability acceptance criteria.

b. The competition (b) (4) method to test for (b) (4) is not adequately verified or validated for its intended use. You reported that between December 12, 2016 and December 26, 2016, six (40%) out of fifteen competition (b) (4) assays consecutively failed system suitability criteria due to high absorbance at the upper asymptote of the reference standard. The root cause(s) for recurring system suitability failures is unclear and there is no assurance that the method is capable of consistently meeting system suitability acceptance criteria.

c. Reading and reporting of microbial results as per SOP-QC-4020 v.6.0 does not provide adequate instructions on how to report confluent microbial growth in the bioburden (b) (4) test. According to this procedure, confluent growth (referred to as "spreader") on the surface of the (b) (4) is reported as (b) (4) CFU regardless of the (b) (4) surface area covered by the spreader. No assessment has been performed to evaluate the impact of extensive spreader growth on the recovery of other organisms.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
		Maria J. Lopez-Barragan, Microbiologist (Lead); Zhong Li, Chemist; Patrick Lynch, Biologist; Sarah Arden, Staff Fellow.	07/25/2017

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2. Deviation investigations are inadequate.

Specifically,

Bioburden recoveries exceeding the action limit of (b) (4) CFU/(b) (4) mL (Stenotrophomonas maltophilia) for the (b) (4) in-process (b) (4) were observed in (b) (4) batches (b) (4) ((b) (4) CFU/(b) (4) mL) and (b) (4) ((b) (4) CFU/(b) (4) mL). Batch (b) (4) was placed on accelerated stability as a worst-case to evaluate impact to product quality on both affected batches. However, batch (b) (4) was released prior to completion of the stability study.

3. Procedures to ensure microbial control of (b) (4) drug substance are inadequate.

Specifically,

The microbial swabbing test method used for GMP investigations impacting critical product-contact equipment is not adequately verified for its intended use.

4. Your laboratory controls for the critical raw material (b) (4) [material code (b) (4)] used in the manufacture and processing of drug substances and drug products do not conform to the current USP-NF standards for (b) (4)

Specifically,

Neither the assay nor the (b) (4) tests specified in USP-NF were performed for the release of received shipments and routine monitoring at the points of use in the (b) (4) storage and distribution system in your pharmaceutical manufacturing facility.

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