DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
New England District Office 1 Montvale Avenue Stoneham, MA 02180 Tel. 781-587-7500 Industry Information: www.fda.gov/oc/industry	8/23 - 9/1/2022
	FEI NUMBER 3003058218

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mireli Fino, Executive Vice Chancellor

FIRM NAME	STREET ADDRESS
MassBiologics	460 Walk Hill Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Boston, MA 02126-3120	Vaccine 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:

OBSERVATION 1

Manufacturing procedures designed to prevent microbiological contamination of drug products and medial purporting to be sterile during aseptic filling operations are deficient.

Specifically,

Deficiencies were noted in the media aseptic filling operations of (b) (4) process simulation lot (b) (4).

a. The microbiology quality control analyst was observed to wipe the outer Grade-B floor and an outside glass window with (b) (4) wipes and then bring those dirty wipes into the (b) (4) that is used for (b) (4) and line manipulations. The microbiology analyst then sprayed these dirty wipes with (b) (4) and reused them to wipe in a (b) (4) manner the inside glass door of the Grade-(b) (4).

b. A production operator was observed to enter the (b) (4) twice and perform interventions by taking a filled vial off the filling line. The production operator exited and touched the bottom of the (b) (4) glass door, then he touched other equipment in the filling room prior to spraying his gloved hands with (b) (4). Immediately after spraying his gloves he touched the instrument control panel. Production operators were observed to step on a foot pedal to open trash containers and touch the trash container, then enter the (b) (4) without decontamination.

c. Operators were observed moving swiftly in the Grade-B filling room of (b) (4). Operators were observed to be rubbing up against others' gowns, potentially transferring contamination from one person to another. The environmental non-viable and viable measurements were performed while all staff were standing still. This may not be indicative of the worst-case dynamic conditions.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Roger F. Zabinski -S Digitally signed by Roger F. Zabinski -S Date: 2022.09.01 15:39:59 -04'00' Roger F. Zabinski	Roger F. Zabinski, Investigator - Team Biologics	09/01/2022

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OBSERVATION 2

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to the storage of in-process, finished product, stability, and research samples pending testing or examination by the quality control unit.

Specifically,

a. Controlled in-process and finished product Tetanus and Diphtheria vaccine samples are maintained in the same walk-in (b) (4) °C Cold Room 1038 of (b) (4) building, along with samples for research and development and waste disposal. Td vaccine samples include (b) (4) This cold room includes samples for other antibody research and development projects; microbiology media both quarantined and released for use; (b) (4) . Some of the locked cages and samples were organized in plastic bins. Samples were stacked on carts and on shelves, in boxes and other containers, stacked in a disorderly manner with a potential to fall over or spill. Samples in plastic tube and glass vials were laying horizontally and could spill or leak.

b. Td tetanus and diphtheria in-process and finished product samples were observed to be maintained scattered, laying loosely and horizontally, in a drawer in a (b) (4) °C refrigerator in the (b) (4) lab, (b) (4) Room 1042, that is used for (b) (4) testing.

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OBSERVATION 3

Buildings, facilities, and equipment used in the manufacturing, processing, and holding of drug products and samples are not always maintained in a clean and sanitary condition.

Specifically,

a. Apparent chemical spill brown spots were observed on the floor of the (b) (4) lab near the (b) (4) and the biosafety cabinet in the area where (b) (4), and (b) (4) are produced.

b. Large dust balls and debris were observed behind the (b) (4) and biosafety cabinet in the (b) (4) room where Tetanus and Diphtheria toxoids are (b) (4). Apparent chemical residue was observed on the return air grills in the (b) (4) room.

c. Debris, dirt, and cobwebs were observed in the controlled locked warehouse in (b) (4) building for storing raw materials and components.

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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."