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.: Prajakta Varadkar Telephone: 240-402-7439 Industry Information: www.fda.gov/oc/industry	08/06/2024-08/12/2024
	FEI NUMBER 3011802152

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Adriana Vives Rodriguez

FIRM NAME	STREET ADDRESS
MassBiologics South Coast	1240 Innovation Way
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Fall River, MA, 02720	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:
Environmental monitoring of the Grade (b)(4) areas is deficient.
Specifically,

a. Biosafety Cabinet (BSC # (b)(4)) and Biosafety Cabinet (BSC# (b)(4)) in the (b)(4) is used for the (b)(4) of Eladocagene exuparvovec drug product (DP) before (b)(4) operated in series. According to SOP 09QA001" Environmental Monitoring: Alert/Action Levels Attained" passive air monitoring (Settle plates) and personnel monitoring is performed only (b)(4) basis when in operation.

b. Attachment# 12 (SOP 09QA001) for (b)(4) in operation sampling locations do not include the sampling points for BSC # (b)(4) and BSC # (b)(4)

OBSERVATION 2:
Deviations and investigations are not being closed in a timely manner
Specifically,

According to SOP 01GN014, deviations must be closed within (b)(4) business days for incident, within (b)(4) business days for Level [illegible] deviations, and within (b)(4) days for Level [illegible] deviations. Over the last 12 months, there were 81 deviations opened, of which more than 50% were not closed within the specified timeframe, with 22% remained open for up to (b)(4) days, 32% remained open for over (b)(4) days. There are no established procedures for managing deviation and investigation extensions.

OBSERVATION 3:
Buildings used for the production and storage are not maintained in a good state of repair.
Specifically,

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a. During inspection of the facility, multiple cracks in floor were observed in the corridor (b)(4) that were poorly repaired by Epoxy fillings.

b. The air vents in the ceiling of the (b)(4) room (b)(4) were observed to be visibly dirty.

c. Dust balls, debris (including bottle caps and plastic bits) were found behind the (b)(4) in Grade (b)(4) (b)(4) where the final filtration of Eladocagene exuparvovec DP is conducted.

d. Standing open water was observed in the trays beneath the (b)(4) in the Grade (b)(4)

e. For facility and HVAC system, Incident reports, Corrective maintenance, Calibration and Work orders are not completed in timely manner [e.g., work order records are open from 2021 (b)(4) wall is cracking from ceiling to middle of wall) and 2022 (b)(4) window resealing causing water leakage)].

OBSERVATION 4:
Lack of sufficient details in the written standard operating procedures.
Specifically,

a. (b)(4) gloves are used in (b)(4) filling line specifically for the Eladocagene exuparvovec product filling operation whereas the gloves are reused for the filling of other products. SOP 20FL077" Cleaning and Assembly of the (b)(4) Filling, Sealing and Capping Machine" does not specify that the gloves used for Eladocagene exuparvovec product are (b)(4), nor there is any other accompanying document that specifies this practice.

b. SOP 25QC008 for manual AQL directs the operator to select the AQL vials (b)(4) from the vial tray, but there are no specific instructions on how sample vials should be selected from the vial tray for the AQL process.

c. Manual AQL form 25QC014 for color specification requires the operator to perform the AQL either by (b)(4) (b)(4) process. The manual AQL form 25QC014 does not describe the conditions when a (b)(4) (b)(4) AQL process should be performed.

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d. SOP 01WM038 for shipping of Eladocagene exuparvovec drug product (DP) requires personnel to perform a weather check prior of shipping (print out a weather forecast from the internet on the day of shipping and file it with order packing slip) to ensure that DP vials are shipped during appropriate weather conditions. Form 1PWM-031 does not have the check box to verify if this requirement is fulfilled as instructed by SOP 01WM038.

e. The SOP 20MA181 for (b)(4) is deficient in providing check for cleaning verification prior to use of (b)(4) in a downstream manufacturing process. The check to verify cleaning verification is also not provided in the batch record (b)(4)

f. SOP 09QA001 does not include in operation EM for Biosafety Cabinet (BSC# (b)(4)

OBSERVATION 5:
Failure to follow established procedures or protocols.
Specifically,

a. Vial Volume check is performed for Eladocagene exuparvovec DP vials during manual visual inspection. During visual inspection process observation on August 7, 2024, an operator was observed to perform the volume check by comparing standard vials with multiple DP vials deviating from SOP 25QC001 for visual inspection which requires the operator to perform the volume check with (b)(4) DP vial at a time.

b. During shipping process observation on August 7, 2024, it was observed that the operator failed to place bulk in-process material in the (b)(4) container while transporting the product out of the classified manufacturing area as per the SOP 10QA009.

c. According to SOP 09QA001" Environmental Monitoring: Alert/Action Levels Attained", it is required to open a deviation report and conduct a full EM investigation when EM action limit is reached. Several EM action level incidents were noted in the Q4 2023 and Q1 2024 reports for Environmental Monitoring Trends in the South Coast Facility, but they were not investigated as required by the SOP.

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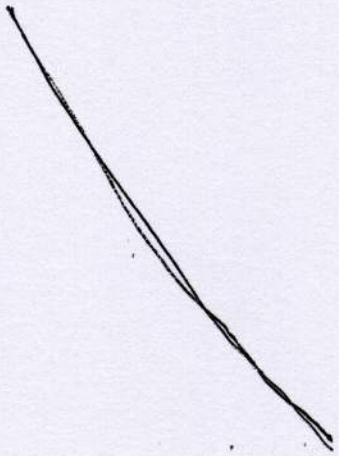
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OBSERVATION 6:
Document management process is not properly controlled
Specifically,

a. Executed Paper Batch Records are stored at (b)(4) with their scanned copies stored online that is updated as new information. The physical copy batch records can be accessed by MassBiologics approved (b)(4) personnel. A (b)(4) logbook in the room is used when the physical batch records are removed and/or updated, but in IR-23-0160, the Executed Batch Records for (b)(4) went missing for a period of (b)(4). The Batch Records were returned to their proper place with the location of the records during this duration unknown, and this incident was closed in (b)(4) with a report as an Operator Error, not following procedure to sign out the document in the logbook.

b. From interview with SME for Document Control, it was found that routine checks are not done of the document room for physical copies and individuals are responsible for telling document control when images need to be added to the online copies of the executed batch records which can allow for the online records to fall behind the physical record. There is no effective document tracking system to track the current location of the documents when signed out and when information needs to be added to online copy.



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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."