DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	2/3/2025-2/7/2025
	FEI NUMBER 3006500433

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Ahmad S. Hussin, Site Director	
FIRM NAME Charles River Laboratories Inc	STREET ADDRESS 4600 E Shelby Dr Ste 108
CITY, STATE, ZIP CODE, COUNTRY Memphis, TN 38118-7427	TYPE ESTABLISHMENT INSPECTED Cell Therapy 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

Employees engaged in the manufacture and processing of a drug product lack the training required to perform their assigned functions.

Specifically, training of employees who work in cell therapy manufacturing is not adequate

a. On 16 DEC 2024 video recording shows employee dropping paper batch record pages on the floor of a Grade (b) (4) room and subsequently returning the paper records to a table work surface and continuing with assisting to place materials into a Grade (b) (4)

b. On 1 and 16 DEC 2024 video recording shows employees working with their hands in a Grade (b) (4) wiped their hands and work surfaces with a sterile (b) (4) wipe immediately prior to collecting (b) (4) monitoring samples.

c. On 1 DEC 2024 video recording shows an employee working in a Grade (b) (4) class processing suite place (b) (4) on top of paper batch records prior to placing the units in a cell culture (b) (4).

d. As of 7 FEB 2025, your Senior QC Manager of Microbiology had not completed job specific training on revised SOPs such as:

i. CGM-SOP-00042, Investigation of Environmental Alert Level Excursions, Action Level Excursions, Contamination Recovery Rate Excursions and Adverse Trends (Revision 03)

ii. CGM-SOP-00027, Plate (b) (4), Enumeration and Microbial Identification (Revision 02)

iii. CGM-SOP-00241, Operation of the (b) (4) (Revision 01)

e. Training status is not adequately monitored to ensure employees are up to date on current training requirements. Specifically, in 2024, only 30% of training tasks were completed

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	Scott T Ballard, Investigator Christian Lynch, Investigator	X Scott T Ballard Investigator Signed By: Scott T. Ballard -S Date Signed: 02-07-2025 17:56:23	2/7/2025

on time.

OBSERVATION 2

Master production and control records lack complete manufacturing and control instructions.

Specifically, as stated by your Senior Manager of Quality Control Analytical, no established procedures exist regarding specific handling or loading patterns (and subsequent removal) of up to 50 (b) (4) (b) (4) from (b) (4) during manufacturing operations occurring in 2024. (b) (4) have a (b) (4) on the (b) (4) of the unit and are used in the manufacturing of cellular therapy products.

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

Specifically, batch records for aseptic process simulation (b) (4) do not adequately describe steps to fully simulate manufacturing processes for cell therapy products. APS protocol #QA-00214 rev 6 executed in January 2024 (b) (4) does not include a specific step for placing units (b) (4) as is done for commercial production.

OBSERVATION 4

Buildings used in the of a drug product are not maintained in a good state of repair.

Specifically, we observed facility deficiencies related to the manufacturing of cell therapies in cryostorage (b) (4) rooms and locker/change rooms for personnel, as follows:

a. On 3 FEB 2025, we observed visibly dirty and rough floor surfaces in the (b) (4) finished product and intermediate product storage room # (b) (4)

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b. On 3 FEB 2025, we observed hair and other residue in (b) (4) where these (b) (4) are used for personnel entering classified aseptic area for (b) (4) production area

c. On 3 FEB 2025, we observed a hand washing sink that lacked soap for employees entering classified aseptic areas for the (b) (4) production area

d. On 3 FEB 2025, we observed a loose ceiling access panel in personnel air lock leading to classified aseptic areas of the (b) (4) production area

e. On 3 FEB 2025, we observed rooms intended to segregate environmental aseptic conditions such as (b) (4) (rooms (b) (4)) that did not have a demarcation line between grades (b) (4) and (b) (4) not identified for location/grade

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OBSERVATION 5

Records fail to include an individual inventory record of each component and drug product container with sufficient information to allow determination of any associated batch or lot of drug product.

Specifically, raw material and finished product inventory is not adequately controlled and/or withheld from use until appropriate in relation to cell therapy manufacturing as follows:

a. On 3 FEB 2025, we observed missing (b) (4) (labeled (b) (4)) inside (b) (4) as compared to electronic inventory of finished product in (b) (4) software. Additionally, the software indicated the (b) (4) holding 19 (b) (4) of cryostorage (b) (4) where the (b) (4) is only capable of holding ~8 (b) (4)

b. On 3 FEB 2025, we observed missing (b) (4) (labelled (b) (4) among others) inside (b) (4) where (b) (4) inventory list indicated QC retain sample storage.

c. On 3 FEB 2025, we observed (b) (4) Log book documented a (b) (4) (b) (4) (QC retain storage) (b) (4) (finished product storage). The log did not note how many (b) (4) or the name/identification of those (b) (4). In (b) (4) only

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Scott T Ballard, Investigator Christian Lynch, Investigator	X Scott T Ballard Investigator Signed By: Scott T. Ballard -S Date Signed: 02-07-2025 17:56:23	DATE ISSUED 2/7/2025

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two of seven (b) (4) were labeled.

d. On 4 FEB 2025, we observed sterile water for (b) (4) units) stored at location (b) (4) where electronic (b) (4) inventory indicated the storage location as C04A1.

e. On 4 FEB 2025, we observed 372 units of (b) (4) cell culture containers in location (b) (4), where (b) (4) software indicated the storage location as (b) (4).

The change control (b) (4), dated 13 JUN 2024) intended to incorporate (b) (4) finished drug product into the (b) (4) program for improved inventory control did not include an effectiveness check (or justification for not including an effectiveness check) for evaluation of this change.

X Christian Lynch
Investigator
Signed By: Christian D. Lynch -S
Date Signed: 02-07-2025 17:56:13

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	Scott T Ballard, Investigator Christian Lynch, Investigator	X Scott T Ballard Investigator Signed By: Scott T. Ballard -S Date Signed: 02-07-2025 17:56:23	2/7/2025

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 judgment, 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."