DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240)402-9160	1/13/2025-1/21/2025* FEI NUMBER 3013416813

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Peter Coleman, CEO

FIRM NAME	STREET ADDRESS
ROSLIN CELL THERAPIES LIMITED	9 Little France Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Edinburgh, EH16 4UX United Kingdom	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

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

Specifically,

Inadequate aseptic operator gown was observed during the production of the following (b)(4)

(b)(4)

A total of (b)(4) operators were observed on (b)(4) in the Grade - manufacturing area wearing goggles that had (b)(4), exposing the operators' skin. The goggles are part of the sterile gown worn by the operators in the Grade (b)(4) operators include the Operator whose main duties are to perform process steps on the drug product in the Grade (b)(4) Biosafety Cabinet (b)(4) and the Assistant Operator who provides assistance to the Grade - Operator in the (b)(4).

OBSERVATION 2

Appropriate controls are not exercised over (b)(4) or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Peng Zhou, Investigator Susan M Jackson, Investigator	X Peng Zhou Investigator Signed By: 2002104595 Date Signed: 01-21-2025 18:20:21	1/21/2025

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There are [redacted] used to isolate [redacted] cells during manufacturing of [redacted] drug product do not access control, audit trails or any features that safeguard GMP electronic production data.

A. On January 15th, 2025, [redacted] batch lot [redacted] was observed being loaded onto [redacted] during the [redacted] of the manufacturing operation. The Operator input only [redacted] into the system after completing the [redacted].

B. The risk assessment performed for data integrity of [redacted] has identified deficiencies for access control and audit trails. However, your firm has used the [redacted] to manufacture [redacted] lots of [redacted], including [redacted] lots for the [redacted] market.

OBSERVATION 3

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

A. Deviations are not always closed within the target dates defined by SOP[redacted]/32 Version 15 "Deviation Management Section 10.3.16. Out of a total of 1144 deviations without extension:

- Three out of four Critical deviations since CBER licensure were closed beyond the target of 45 days. The Critical deviations were open from [redacted] days.
- A total of 119 Major deviations were closed beyond the target date of 30 or 45 days. The Major deviations were open from [redacted] days.
- A total of 105 Minor deviations closed beyond the target date of 30 days. The Minor deviations were open from [redacted] days.

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B. Your firm's training program is deficient in that it does not require the contemporaneous documentation of training attendance. Receipt of training is only captured in [redacted], which is not validated for attendance recording and verification. Examples include:

- [redacted] GMP Refresher 2024 training was delivered on [redacted]. The record of participation was captured in [redacted]. The QC analyst signed for the receipt of training in [redacted].
- [redacted] GMP Refresher 2024 training was delivered on [redacted]. The record of participation was captured in [redacted]. The Production Operator signed for the receipt of training in [redacted].
- [redacted] GMP Refresher 2023 training was delivered on [redacted]. The record for participation was captured in [redacted]. The QC analyst signed for the receipt of training in [redacted].

***DATES OF INSPECTION**

1/13/2025(Mon), 1/14/2025(Tue), 1/15/2025(Wed), 1/16/2025(Thu), 1/17/2025(Fri), 1/20/2025(Mon), 1/21/2025(Tue)

X Susan M Jackson
Investigator
Signed By: Susan M. Jackson -S
Date Signed: 01-21-2025 18:20:55

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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 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."