DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	5/28/2025-6/5/2025* FEI NUMBER 3007867647

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jonathan Kegerise, Site Head and Vice President of Manufacturing

FIRM NAME	STREET ADDRESS
Seqirus Inc	475 Green Oaks Pkwy
CITY, STATE, ZIP CODE, COUNTRY Holly Springs, NC 27540-7976	TYPE ESTABLISHMENT INSPECTED Manufacturing

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

The responsibilities and procedures applicable to the quality control unit are not in writing.

Specifically, your firm's procedure for deviation management does not ensure timely documentation and assessment of quality events to determine potential impact on product quality. The current procedure does not require quality events to be recorded in the quality system at the time of the occurrence or upon initial discovery. Instead, a quality event record is (b) (4) the Quality Unit (b) (4). Additionally, the procedure lacks defined timeframe requirements for the Quality Unit to evaluate and determine whether a quality event should be classified as a deviation once it is reported.

For example:

- A quality event occurred on August 20, 2020, but the associated deviation QE-081374 was not initiated until March 27, 2025, more than four years later.
- A quality event occurred on January 12, 2022, but the associated deviation QE-077007 was not initiated until February 21, 2025, more than three years later.
- A quality event occurred on June 6, 2024, but the associated deviation QE-084962 was not initiated until April 25, 2025, more than eight months later.
- A quality event occurred on September 22, 2022, but the associated deviation QE-073262 was not initiated until November 6, 2024, more than two years later.
- A quality event occurred on August 1, 2022, but the associated deviation QE-003385 was not initiated until May 5, 2023, more than eight months later.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Laurel A Beer, Investigator Thai D Truong, Investigator	X Laurel A Beer Investigator Signed By: 0014345915 Date Signed: 06-05-2025 13:50:29	6/5/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	5/28/2025-6/5/2025*
	FEI NUMBER 3007867647

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jonathan Kegerise, Site Head and Vice President of Manufacturing

FIRM NAME	STREET ADDRESS
Seqirus Inc	475 Green Oaks Pkwy
CITY, STATE, ZIP CODE, COUNTRY Holly Springs, NC 27540-7976	TYPE ESTABLISHMENT INSPECTED Manufacturing

- A quality event occurred on June 21, 2021, but the associated deviation QE-004279 was not initiated until May 19, 2023, almost two years later.
- A quality event occurred on November 22, 2021, but the associated deviation QE-004594 was not initiated until May 24, 2023, more than one year later.

OBSERVATION 2

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically, your firm utilizes the (b) (4) electronic system to (b) (4) . While current practice permits production personnel to request materials (b) (4) for drug manufacturing during (b) (4) outages, your firm has not established written procedures governing how these requests are (b) (4) during unplanned system outages.

*DATES OF INSPECTION

5/28/2025(Wed), 5/29/2025(Thu), 5/30/2025(Fri), 6/02/2025(Mon), 6/03/2025(Tue), 6/04/2025(Wed), 6/05/2025(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Laurel A Beer, Investigator Thai D Truong, Investigator X Laurel A Beer Investigator Signed By: 0014345915 Date Signed: 06-05-2025 13:50:29	6/5/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	5/28/2025-6/5/2025*
	FEI NUMBER 3007867647

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Jonathan Kegerise, Site Head and Vice President of Manufacturing

FIRM NAME	STREET ADDRESS
Seqirus Inc	475 Green Oaks Pkwy
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Holly Springs, NC 27540-7976	Manufacturing

X Thai D Truong
Investigator
Signed By: 0014274389
Date Signed: 06-05-2025 13:51:19

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Laurel A Beer, Investigator
Thai D Truong, Investigator

X Laurel A Beer
Investigator
Signed By: 0014345915
Date Signed: 06-05-2025 13:50:29

DATE ISSUED
6/5/2025

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."