DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Atlanta District Office 60 Eight Street, NE Atlanta, GA 30309; (404)253-1169	June 01 - 09, 2022 FEI NUMBER **3007857647**

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dave Sehgal, Ph D., Vice President, Manufacturing and Site Head

FIRM NAME	STREET ADDRESS
Seqirus, Inc.	475 Green Oaks Parkway
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Holly Springs, North Carolina 27540	Influenza 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, WE OBSERVED:

Observation 1

Adverse experience information was not reported to FDA as required. Specifically,

a. From 01-January-2020 through 01-June-2022, six serious unexpected adverse experiences were not reported to FDA no later than 15 calendar days of initial receipt of the information. These adverse experiences were reported to FDA from 16 to 323 calendar days of initial receipt of the information.

b. From 01-January-2020 through 01-June-2022, four follow-up reports containing new information regarding serious unexpected adverse experiences were not reported to FDA within 15 calendar days of receipt of new information. These follow-up reports were reported to FDA from 19 to 32 calendar days of receipt of new information.

Observation 2

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed. Specifically,

There was a failure to thoroughly investigate a power outage which affected the HVAC System shutting down (b)(4) Air Handling Units and causing a disruption to classified areas and utilities in Building 4, such as (b) (4) Filling Line (b) (4) Suite (b) (Room 1028) and other classified (b) (4) and (b)(4) rooms. Deviation 1089805 was initiated on 21-October -2021. This investigation failed to document critical information required to evaluate the impact of the disruption, such as the disruption duration, the start time, end time of the disruption, the alarms in the Building Automation System and any product information in the (b) (4) and (b) (4) A second deviation (1089923) was initiated for an ongoing Media Fill which was aborted due to the power disruption; however, the details of the classified rooms were not documented in either investigation. Based on these investigations, the Quality Unit determined that no material batches were impacted by the disruption.

Observation 3

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Susan Jackson Priscilla Pastrana	**Susan Jackson, CSO** **Priscilla Pastrana, CSO** **Jeremy Wally, Senior Advisor**	**6/9/2022**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Atlanta District Office 60 Eight Street, NE Atlanta, GA 30309; (404)253-1169	June 01 - 09, 2022
	FEI NUMBER **3007867647**

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dave Sehgal, Ph.D., Vice President, Manufacturing and Site Head

FIRM NAME	STREET ADDRESS
Seqirus, Inc	475 Green Oaks Parkway
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Holly Springs, North Carolina 27540	Influenza Vaccine Manufacturer

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

a. Deviation 1051569, initiated on 11-December-2019, assessed as having SQuIPP (Safety, Quality, Identity, Potency, Purity) impact to (b)(4) batches of sterile MF59 adjuvant used to manufacture distributed Fluad product, was classified at a lower classification category (Major) than the category (Critical) required per the applicable procedure. SOP GSOP-000093474, Deviation and CAPA Management, version 6.0, states in section 5.3.6 that a risk classification for a deviation must be selected based on Impact from one of the categories listed in Table 2 of the SOP. Table 2 states that deviations for which there is potential impact to SQuIPP to released or distributed product are to be classified as Critical.

b. From 01-Jan-2020 through 01-June-2022, there were 22 deviations initiated more than (b) (4) of the issue being initially identified which is greater than the timeframe required per the applicable procedure. SOP GSOP-000093474, Deviation and CAPA Management, version 6.0, states in section 5.2.3 that once it is determined that a deviation has occurred, the deviation must be initiated in the Quality Management System as soon as practical and within (b) (4) of the issue being initially identified.

6/9/2022

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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."