

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417		DATE(S) OF INSPECTION 9/9/2019-9/19/2019*
		FEI NUMBER 3011152407
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Douglas F. Cammann, Vice President of Operations		
FIRM NAME AnazaoHealth Corporation	STREET ADDRESS 7465 W Sunset Rd Ste 1200	
CITY, STATE, ZIP CODE, COUNTRY Las Vegas, NV 89113-1944	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility	

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 OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

A) Following the cleaning of classified laminar flow hoods/biosafety cabinets and clean rooms, your firm does not require a visual inspection to check that the cleaning has been completed and that it was effective. With any type of cleaning there needs to be some type of verification process in place.

During inspection walk-through on September 9th, I noted the following:

- 1) An accumulation of cleaning residue from present and past cleanings, was found in LFH # (b)(4) Cleanroom (b)(4). The residue was located in the back, right hand corner of the LFH, (b)(4).
(b)(4) In addition, small cracks/fractures (less than the size of a Washington quarter) were observed in the (b)(4) side paneling (b)(4) LFHs # (b)(4) and # (b)(4).
- 2) A small piece of plastic (1/2-inch x 1/8 inch) was observed stuck in the (b)(4) front grill of BSC # (b)(4) Cleanroom (b)(4).
- 3) A thin 2-inch string of Teflon tape was observed dangling from a (b)(4) located inside BSC # (b)(4) Cleanroom (b)(4).

- Prior to entering both cleanrooms, I was informed rooms were in clean status.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Zachery L Miller, Investigator	Zachery L Miller Investigator Signed By: Zachery L Miller -S3 Date Signed: 09-19-2019 07:32:00 X	DATE ISSUED 9/19/2019

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FIRM NAME

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B) During the inspectional walk-through of your facility on 9/9/19, non-smooth cleaning surfaces (porous speakers) were observed in the ISO 7 certified cleanroom/buffer areas, to include a JBL Bluetooth Speaker and office phones.

OBSERVATION 2

The flow of components, drug product containers, closures and in-process materials ~~through~~ ^{through} the building is not designed to prevent contamination. *Final 9/19/19*

Specifically,

(b) (4) your sterile compounding clean rooms ((b) (4)), have (b) (4) (b) (4) the ISO 7 buffer rooms to unclassified work spaces. Equipment and components are (b) (4) prior to and during sterile production.

These (b) (4) are not designed with interlocking mechanisms to prevent cross-contamination of the adjoining spaces (b) (4) door at a time can open.

OBSERVATION 3

Bulk drug substances used by your outsourcing facility to compound drug products are not each manufactured by an establishment that is registered under section 510 of the FDCA as required by section 503(a)(2)(C).

Specifically,

Although you are receiving bulk drug substances from FDA-registered suppliers, you have neither verified these components are manufactured in an FDA-registered establishment nor established a supplier quality agreement that ensures the component's pedigree. An example of suppliers and components with insufficient quality agreements, include:

- (b) (4)

SEE REVERSE
OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Zachery L Miller, Investigator

DATE ISSUED

9/19/2019

Zachery L Miller
Investigator
Signed By: Zachery L Miller-53
Date Signed: 09-19-2019 07:32:00

X

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- (b) (4)

***DATES OF INSPECTION**

9/09/2019(Mon), 9/10/2019(Tue), 9/11/2019(Wed), 9/12/2019(Thu), 9/13/2019(Fri), 9/16/2019(Mon),
9/17/2019(Tue), 9/18/2019(Wed), 9/19/2019(Thu)

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OF THIS PAGE**

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Zachery L Miller, Investigator

Zachery L Miller
Investigator
Signed By: Zachery L Miller -53
Date Signed: 09-19-2019 07:32:00

X

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9/19/2019