DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	7/11/2022-8/18/2022* FEI NUMBER 3012053582

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sophia I. Flores, Director Manufcturing Operations

FIRM NAME	STREET ADDRESS
QuVa Pharma, Inc.	1075 W Park One Dr Ste 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sugar Land, TX 77478-2576	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

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

Specifically, on 7/27/2022, during visual observations of your firm's (b) (4) -Shift Compounding Technicians gowning within the ISO 8 Anteroom, cleaning methods of the ISO 5 LAFU and ISO 5 BSCs, aseptic processing, and environmental monitoring sample collection methods; I observed within Cleanroom (b) (4) ISO 8 Anteroom, EM Technician and Compounding Technician attempt to don a sterile gown in order to gain entry into your firm's ISO 7 Cleanroom where (b) (4) ISO 5 BSCs are located used to produce the hazardous drug product, Cefazolin PF. EM Technician was observed touching the outside of the gown and touching a cart while attempting to don the sterile gown. Compounding Technician was observed failing to put on an addition pair of shoe covers after entering from a different area within controlled non-classified area of your facility to begin sterile gown donning process. Your firm's Sterility Assurance Manager, who was also observing at the time these observations were made, interceded, stopping both technicians from completing and starting the gowning process for further entry into the ISO 7 Cleanroom.

OBSERVATION 2

Determinations of conformance to appropriate written specifications for acceptance are deficient for drug products.

Specifically, on 7/12/2022 during a walk-through of the firm's (b) (4) Laboratory where samples are received from production, I observed sterile finished drug products, Methohexital Sodium

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Camerson E Moore, Investigator X Camerson E Moore Investigator Signed By: Camerson E. Moore - S Date Signed: 08-18-2022 12: 5: 2	8/18/2022

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100mg/10 mL PF, Lot Numbers (b) (4) (Exp: 10/9/2022) and (b) (4) (Exp: 10/9/2022) sitting on a table at room temperature for an unspecified amount of time awaiting to be received by the (b) (4) laboratory. Methohexital Sodium 100mg/10 mL PF product label specifies it should be refrigerated. Your firm's Laboratory Supervisor stated due to limited space in the sample receiving area, finished drug samples are not refrigerated until after they have been checked into the lab. At that time, they are received and refrigerated. Samples undergo sterility testing using (b) (4).

OBSERVATION 3

The written stability testing program is not followed.

Specifically, during a review of your BUD stability report, Dexamethasone Phosphate 6mg in 25mL NS (0.24mg/mL) in 50mL IV Bag (API) 90 Days BUD Stability Study Report, which was produced as part of the (b) (4), I found the following deficiency within the provided report used to establish the 90 day BUD for the distributed lots of drug product.

A. Your firm failed to provide a documented justification for not performing a Container Closure Integrity test at the 90 day assigned BUD for the (b) (4) used as the primary packaging to ensure the bag was adequate for its intended use. Container Closure Integrity test was performed only at (b) (4) days. There was a total of (b) (4) CSP Lots ((b) (4)) produced between 11/2/2020 to 11/25/2020 in which were distributed to hospitals.

***DATES OF INSPECTION**

7/11/2022(Mon), 7/12/2022(Tue), 7/13/2022(Wed), 7/14/2022(Thu), 7/15/2022(Fri), 7/18/2022(Mon), 7/27/2022(Wed), 7/29/2022(Fri), 8/01/2022(Mon), 8/02/2022(Tue), 8/03/2022(Wed), 8/04/2022(Thu), 8/05/2022(Fri), 8/08/2022(Mon), 8/11/2022(Thu), 8/12/2022(Fri), 8/17/2022(Wed), 8/18/2022(Thu)

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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."