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	9/24/2024-10/28/2024* FEI NUMBER 3012053582

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sophia I. Flores, General Manager

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

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

Specifically, for example:

A. During a review of your firm's incident reports (IRs) since the previous FDA inspection, your firm failed to adequately investigate the following documented events:

1. Your firm documented 10 - 2024 IRs and 19 - 2023 IRs of (b)(4) for ISO 5 BSC/LAFU "Hood Cleaning contact time discrepancy" for use of your firm's disinfectant agent, (b)(4) less than (b)(4) per manufacturer specification to disinfect surfaces within your firm's ISO 5 BSC/LAFU used in the aseptic processing of sterile drug products. Your firm's documented root cause was "Personnel Error". Your firm's documented corrective action for the root cause to prevent recurrence was to conduct employee training.

   Your firm's investigation failed to conduct a detailed impact assessment supported by a scientific study and data for the potential deviation from your firm's written cleaning and disinfecting procedure, SUG-SOP-SA-0001, Cleaning Disinfection of Compounding

AMENDMENT 1

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Manufacturing Areas to ensure no microbial growth occurs within your firm's ISO 5 BSCs/LAFUs in the absence of adequately implementation of your firm's procedure. Your firm's Disinfectant Efficacy Study for (b)(4) was based on a contact time of (b)(4). For example, your firm initiated incident report (IR), IR-12156 dated 9/12/2024 reported, during review of your firm's (b)(4) Cleaning for ISO 7 Cleanroom (b)(4) ISO 5 LAFH (b)(4) contact time was reported as being only (b)(4) (Manufacturer specification (b)(4)), with a second verifier reviewing and approving the contact time deficiency. Your firm's corrective action to prevent recurrence, involved employee training only. Your firm's corrective action failed to adequately address the potential impact of deviation within the disinfectant agent contact time.

B. During a review of your firm's (b)(4) environmental monitoring reports, the following deficiencies were found:

1. During a review of your firm's 2023 - 2024 incident reports (IRs) for "Fingertips recovery/excursions" within your ISO 5 LAFHs/BSCs, I found your firm documented 45 - 2024 and 15 -2023 recovery/excursions. In a further review of your firm's ISO 5 BSCs/LAFUs (b)(4) environmental monitoring report, "QuVa Pharma - Sugar Land Environmental Monitoring (b)(4) Trend Report (b)(4)-2024", I found the following recoveries listed below, which your firm documented no specific root cause was identified, but gowning and sterile gloving disinfection technique as a potential root cause. Your firm failed to ensure compounding technicians performing gowning and sterile gloving disinfection techniques were being performed

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adequately in the control of microbiological contamination periodically. Your firm's preventive action documented employee training only. Batches were released and distributed. For example, your firm 2024 (b)(4) Report documented:

a) Sampled 1/26/2024, Dextrose PF 25 gm (500 mg/ml, 50%) 50 ml in Sterile Water for injection 50 ml syringe, Lot (b)(4) (Compound Date 1/25/2024), Cleanroom(b)(4) ISO 5 LAF/BSC(b)(4) right fingertip, Staphylococcus haemolyticus - 3 CFUs (DEV-02354)

b) Sampled 2/9/2024, Fentanyl Citrate PF 500 mcg (2 mcg/ml)/Bupivacaine HCL PF 0.125% in 250 ml NS IntraVia Bag, Lot (b)(4), Cleanroom(b)(4) ISO 5 LAF/BSC(b)(4) left fingertip, Bacillus Infantis - 1 CFU (DEV-02380)

c) Sampled 2/23/2024, Fentanyl Citrate PF 500 mcg (2 mcg/ml)/Bupivacaine HCL PF 0.125% in 250 ml NS IntraVia Bag, Lot (b)(4) (Compound Date 2/23/2024), Cleanroom(b)(4) ISO 5 LAF/BSC (b)(4)right fingertip, Staphylococcus cohnii ssp urealyticus - 4 CFUs (DEV-02354).

d) Sampled 2/28/2024, Fentanyl Citrate PF 200 mcg (2 mcg/ml)/Bupivacaine HCL PF 0.125% in 150 ml NS IntraVia Bag, Lot (b)(4) Cleanroom(b)(4) ISO 5 LAF/BSC (b)(4) left fingertip, Bacillus megaterium - 1 CFU (DEV-02431).

2. During a review of your firm's "QuVa Pharma - Sugar Land Environmental Monitoring (b)(4) Trend Report (b)(4)-2024", ISO 5 Microorganism ID Log (b)(4) - 2024) along with ISO 7 Microorganism ID Log (b)(4) - 2024), I found documented on 2/12/2024, Cleanroom(b)(4) Site(b) (4) Settling Plate,

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your firm recovered the organism, Bacillus circulans documented in deviation, DEV- 02386. Within your firm's ISO 7 Cleanroom Sample date 2/22/2024, location (b)(4), a surface sample was collected with a recovery of Bacillus cereus group. Your firm's investigation documented the ISO 5 microbial contamination potentially resulted from personnel error, due to inadequate sterile glove disinfectant. Your firm failed adequately investigate and identify the potential source of the microbial organism introduced into the ISO 5 LAFH.

OBSERVATION 2

Complaint records are deficient in that they do not include the findings of the investigation.

Specifically, during a review of your firm's complaint, QuVa Complaint-0839 dated 12/28/2023, concerning the sterile finished drug product, Hydromorphone HCL PF 30 mg (1 mg/ml) 30 ml in 0.9% Sodium Chloride Solution PCA vial, NDC 70092111779, Lot (b)(4) Expiry 12/20/2023 (Preparation Date 9/21/2023); and Lot (b)(4) Expiry 11/13/2023 (Preparation 8/15/2023). Your firm's customer reported the product failed internal testing and 6 total partially filled and 2 total fully filled unopened (3 partial and 1 fully filled samples from each lot) samples were returned to your QuVa Bloomsbury, NJ location to undergo sample receiving inspection, laboratory testing using mass spectroscopy, and investigation by QuVa Sugar Land, TX. Your testing laboratory reported Lot (b)(4) & Lot (b)(4) all samples tested positive for Sodium Chloride and only one of the fully intact samples (Lot (b)(4) reported a Hydromorphone potency of 101.3%. No Hydromorphone potency was documented for Lot (b)(4) fully intact sample. Your firm's laboratory reported reviewing the chromatograms at higher magnification found trace amounts of Hydromorphone at below detectable limits at the expected retention time. Your firm reported laboratory testing of the retain from Lot (b)(4) and found it to be within specification 103.1 % (Specification (b)(4) Your firm reported there was no retain available for Lot (b)(4) due to being out of expiry. Your firm's quality unit investigation failed to ensure an adequate justification and supporting data for the reported issue. For example:

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A. Your firm failed to provide quantifiable laboratory results in support of traceable Hydromorphone amounts found in support of higher chromatograms magnifications for Lot (b)(4) and partially filled Lot (b)(4)

B. Your firm's quality unit failed to adequately investigate and document other potential root cause(s) that may have contributed to the potency reported issue as part of your firm's initial investigation.

OBSERVATION 3

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

Specifically, your firm's quality unit failed to adequately implement the procedure, COR-SOP-QS-0012 Incident Reporting and Escalation Failure to adequately investigate. For example:

A. During a review of reported deviation, your firm failed to adequately investigate and implement corrections to prevent the recurrence of the following:

   1. Your firm documented the following DEV-~~0222~~ **02222** dated 9/18/2023, your firm reported OOS-00527 concerning a potency failure for Phenylephrine 20mg add to 250mL NS Bag, NDC/Product Code 70092904205, Lot (b)(4) concerning laboratory results for the (b)(4) sample of 204.1% (Specification (b)(4) Your firm's investigation reported the root cause as being compounding error. It was further reported the operator, "... did not realize the bag was already dosed, and consequently, dosed the bag twice". Your firm's corrective action addressed technician training; however, your firm failed to adequately investigate and assign preventive actions for the following:

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i. Failure to investigate root cause of double dosage by compounding technician.
ii. Failure to expand investigation into documented dosing methods used during aseptic batch processing and identify potential corrective actions to prevent recurrence.

Your firm management reported initiation, Change Control, CCR-2197, SUG Introduce QC Totes for dedicated QC samples dated 4/23/2024 to address designated sample placement.

B. During a review of your firm's DEV-02329 dated 1/8/2024 linked to QuVa Complaint-0839, concerning distributed finished drug product, Hydromorphone HCL PF 30 mg (1 mg/ml) 30 ml in 0.9% Sodium Chloride Solution PCA vial, NDC 70092111779, Lot (b)(4) Expiry 12/20/2023 (Preparation Date 9/21/2023); and Lot (b)(4) Expiry 11/13/2023 (Preparation 8/15/2023) reported potency issues. Your firm's quality unit failed to include supporting laboratory documentation in support of quantifiable trace amounts below detectable measurable limits.

OBSERVATION 4

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, during a review of your firm's customer complaints, your firm received 15 complaints for leaking syringes, 10 ml in SWFI (b)(4) and 50 ml NS syringes for cracks along the syringe barrel. For example, a review of received customer complaints, QuVa Complaints-0561, 0642, 0656, 0691, 0698,

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0716, and 0871 reported cracks potentially occurred during shipping/distribution your firm's customer. Your firm's investigation failed to include internal packing process validation(s). During a review of your firm's pack-out validation reports: Winter Pack Out Shipping Validation Report, Report # COR-ENG-R-00028 dated 22 March 2022; and Summer Pack Out Shipping Validation Report, Report # COR-ENG-R-00022 dated 02 October 2021, was found to assess only the 3 ml syringe packaging configuration in the control of drug product temperature while shipping. It failed to assess and or provide a scientific rational for not evaluating shipping packaging configurations for larger syringe sizes and customer order quantities for larger syringe sizes: 5 ml, 10 ml, 20 ml, 30 ml, and 50 ml. Additionally, your firm failed to assess packing components and packaging method(s) to adequately ensure drug product integrity, while shipping to the customer for all primary packaging types.

***DATES OF INSPECTION**

9/24/2024(Tue), 9/25/2024(Wed), 9/26/2024(Thu), 9/27/2024(Fri), 9/30/2024(Mon), 10/03/2024(Thu), 10/07/2024(Mon), 10/08/2024(Tue), 10/28/2024(Mon)

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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."