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	4/20/2026-5/4/2026*
	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 Sugar Land, TX 77478-2576	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

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

Specifically, your firm failed to adequately establish procedures to prevent microbiological contamination of drug products purporting to be sterile. For example,

A. Your firm failed to adequately define and document the frequency of disinfection of a device used by technicians to pick items off the floor and place items into the trash in the ISO 7 cleanrooms. The device storage location has not been defined and documented. Currently, your technicians hang the device on the side of the (b) (4) used to hold drug components, utensils, drug product containers, and finished drug products.

B. On 4/20/2026, during a site walk-through of your firm's ISO 7 classified aseptic processing cleanroom, I observed a "black residue" near the (b) (4) of each (b) (4) used to hold drug components, utensils, drug product containers, and finished drug products (b) (4) within all ISO 7 cleanrooms. Your firm's technicians failed to adequately clean and disinfect the entire (b) (4) located within the ISO 7 cleanroom.

C. Your firm's dynamic ISO 5 LAFH/BSC smoke studies were found to be inadequate. Your firm's smoke studies within the ISO 5 LAFH/BSCs fail to adequately assess laminar air flow patterns for actual production setup, aseptic processing components placement within the hood, and maximum drug filled syringes and IV bags within the area used for aseptic processing. Your firm's general manager stated new smoke studies will be performed to assess aseptic activities within ISO 5 LAFHs/BSCs.

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: 05-04-2026 11:56:11	5/4/2026

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This is a repeat Observation.

OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, during a review of nonconformance number, IR-12512 (DEV-02984) documented on 14 Nov 2024, prior to compounding Fentanyl Citrate PF 50 mcg/mL Syringe, PC 700092168448, Lot 10138352, Expiry 02/12/2025 compounding in ISO 7 Cleanroom Suite 7, ISO 5 LAFH number (b) (4) your compounding technician found on the ISO 5 LAFH grate in front of the installed HEPA filter, a brown to black foreign residue contaminate, later within an investigation identified as a "Heat Resistant Sealant (b) (4)". The sealant is applied during the HEPA filter production as an exterior coating. Potential particulates from the degradation may become an airborne contaminate affecting first air quality used during aseptic processing of sterile drug product. The ISO 5 LAFH was removed from service, HEPA filter replaced by your firm's contract cleanroom re-certifier, re-certified, clean/disinfected, before returning to service in aseptically processing the product, Fentanyl Citrate PF 50 mcg/mL Syringe, PC 700092168448, Lot 10138352. Your firm was unable to provide sufficient documented evidence in support of the HEPA filter degradation start and if other potential ISO 5 LAFHs/BSCs in other ISO 7 Cleanrooms may have been impacted. Your quality unit failed to adequately investigate and document the potential HEPA filter degradation issues within other operational ISO 7 Cleanroom ISO 5 LAFHs and potentially released lots compounded in these units.

OBSERVATION 3

Buildings used in the manufacturing, processing, packing and holding of a drug product are not maintained in a good state of repair.

Specifically, on 4/20/2026, during a site walk-through of your firm's ISO classified cleanroom, I observed paint peeling off Suite 3 ISO 8 Degowning Room wall corners and around the door frame

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exiting the ISO 7 Cleanroom.

***DATES OF INSPECTION**

4/20/2026(Mon), 4/21/2026(Tue), 4/22/2026(Wed), 4/27/2026(Mon), 4/28/2026(Tue), 4/30/2026(Thu), 5/01/2026(Fri), 5/04/2026(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."