DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900	3/25/2025-4/4/2025* FEI NUMBER 3013931875

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Kevin W. White, Director of Manufacturing Operations, Interim General Manager

FIRM NAME	STREET ADDRESS
QuVa Pharma, Inc.	519 State Route 173
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bloomsbury, NJ 08804-4047	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

The accuracy, specificity and reproducibility of test methods have not been established.

Specifically,

Your firm did not appropriately qualify the performance qualification, RDIReport-0083, for (b) (4) sterility testing method for Cefazolin 3g in 100mL Normal Saline (NS). Your firm did not achieve the percent recovery (b) (4)) of all challenge microorganisms, specifically *P. aeruginosa.* There is a non-conformance associated with the performance qualification that states that low recovery was achieved for *P. aeruginosa* so retesting was performed and that all 3 replicates pass. The raw data sheets show that the method suitability testing was retested multiple times with only the results meeting criteria being reported. The initial test shows results of 33%, 0%, and 0% recovery. The first retest shows results of 54%, 31%, and 62%. The second retest shows results of 30%, 60%, and an unreported result. The firm has used this method to test for sterility on all lots of Cefazolin in Sodium Chloride compounded at the site.

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,

1)Sterility out of specification investigations do not include an identification of the microorganism

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	Logan T Williams, Investigator X Logan T Williams Investigator Signed By: 2002955055 Date Signed: 04-04-2025 14:58:16	4/4/2025

recovered due to destructive methods of the (b) (4) testing used. Your firm opened Dev-2383 and sterility OOS-0562 for Phenylephrine HCL 400mcg (50mcg/ml) 10ml in 0.9% Sodium Chloride solution 10ml syringe to investigate a non-sterile event on 2/5/2024. No root cause was identified for this non-sterile event and no remediation actions were taken. The lot was rejected.

2)Your firm failed to investigate Norepinephrine 1mg/mL EDTA 3L Bulk lot (b) (4) for particulate matter in the bulk solution. This bulk solution was located in your firm's hold cage without any additional hold tags or deviations opened. This lot was formulated on 12/10/2024 and was discovered in the hold cage during the inspection on 3/26/2025. Your quality department was unaware of the reason for the hold and had to inspect the bulk solution to determine why the lot was on hold.

3)Your firm's AQL failures for visual inspection do not include corrective actions to address defect rates found during the inspection process. In addition, your firm's procedure NJ-SOP-QA-0011 Rev. 20, "Performing Acceptable Quality Limit Inspections" states, in part, that "..Unless otherwise specified by Quality and Operations Management; operations will repeat 100% inspection on the units that were not rejected during the initial inspection and document the re-inspection…". For example:

IR-13200 was opened on 3/13/2025 for Amiodarone 900mg in 500mL D5W IV Bag lot (b) (4) failing an initial AQL for containing particulate matter. An additional AQL was performed at the normal inspection level and passed. Your firm stated in the incident report that the most probable root cause for the failure is defective material from the supplier and that there is no product impact because 100% reinspection was performed and the 2nd AQL passed. Your firm did not plan any corrective actions for the upstream defect root cause. Trend deviations into visual inspection defects have been opened to identify root causes, however, this batch was released for distribution without addressing any root cause.

IR-13233 was opened on 3/21/2025 for Phenylephrine HCL 40mg in 250mL 0.9% Sodium Chloride Solution IV Bag lot (b) (4) failing an initial AQL for a missing protect from

(b) (4) . This lot was (b) (4) reinspected and a second, passing, AQL was obtained. Your firm did not identify corrective actions to the cause for missing the (b) (4) even though a statement is made in the incident report that (b) (4) labels are not inspected after packaging operations. This batch was released without addressing a root cause. The historical review performed by the firm for "AQL" and "Failure" showed 33 similar events from 1/13/2025 – 3/13/2025.

IR-13235 was opened on 3/20/2025 for Cefazolin Sodium PF 2gm (100mg/ml) 20ml in SWFI BD Syringe failing AQL and exceeding a reject rate of (b) (4) for visual inspection. This root cause of this investigation stated that the likely cause was personnel as the underfilled units were not identified in the visual inspection process. The investigation did not address why the underfill and "liquid past the plunger" units were present throughout the lot or initiate any corrective actions other than rejecting the batch for exceeding the reject rate limit of (b) (4).

OBSERVATION 3

Written procedures for sanitation are not followed.

Specifically,

Your firm did not perform (b) (4) cleaning in controlled non-classified formulation areas as required by procedure NJ-SOP-SA-0003, "Cleaning/Disinfection of Compounding Manufacturing Areas". Your firm's cleaning log for Building 2, Room 1408 used for formulation of bulk drug product for further processing does not include (b) (4) cleaning documentation until the week of 3/24/2025. Your firm only documented a (b) (4) clean of this room. In addition, conditions of the room were found to be in disrepair including build up of debris in the floor scale, apparent residue splashes on the ceiling and discoloration from potential dust build up on the air return grate that is located above where weighing and mixing occurs. This room is constructed with a drop tile ceiling that does not lend itself to be easily

cleaned.

Your firm's controlled non-classified formulation room in Building 1, Room 175, also did not have documented (b) (4) cleaning performed. Bulk drug product is also prepared in this room.

OBSERVATION 4

The statistical quality control criteria fail to include appropriate rejection levels.

Specifically,

Your firm has a (b) (4) overall reject limit for defects found in the visual inspection process that is not scientifically or statistically justified. Individual defect categories do not have reject limits. Your firm does not open deviations or events until the (b) (4) reject rate is reached. During production of Cefazolin Sodium PF 2mg, 20mL in SWFI syringe, lot (b) (4) your visual inspection process rejected 9.6% of (b) (4) syringes including (b) (4) rejects for liquid past the plunger. These liquid past the plunger units are major defects, as defined by procedure NJ-SOP-QA-0011, "Performing Acceptable Quality Limit Inspections". The defect rate was not investigated or corrected to prevent these defects from occurring during compounding. Your firm has opened thirteen deviations for reject rates exceeding limits (b) (4) % of the batch) since 10/14/2022.

Since 11/7/2024, your firm has not investigated approximately (b) (4) batches of drug product that have total reject rates exceeding your (b) (4) % alert limit for total rejects. These batches include:

- Morphine PF 1mg/ml in 30ml syringe lot (b) (4) with a total reject rate of 13.9% including 13.6% (b) (4) syringes) overfilled units.
- Dextrose PF 500mg/ml 50ml SWFI syringe lot (b) (4) with a total reject rate of 12.8% including 10.5% (b) (4) syringes) overfilled units.
- Dextrose PF 500mg/ml 50 ml SWFI syringe lot (b) (4) with a total reject rate of 16.1% including 14.5% (b) (4) syringes) underfilled units.

- Morphine PF 1 mg/ml 50ml NS syringe lot (b) (4) with a total reject rate of 22.2% including 20.6% (b) (4) syringes) overfilled units.
- Ephedrine PF 10mg/ml in 5ml NS syringe lot (b) (4) with a total reject rate of 12.5% including 9.5% (b) (4) syringes) leaking units.

In addition, your firm's "CSP Defect Evaluation" used for initial defect classification does not include scientific justification for how each defect was categorized.

OBSERVATION 5

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

Specifically,

A) Your firm's syringe visual inspection qualification kit used during visual inspection qualification testing is not representative of the visual inspection process. The qualification kits used contain a mix of syringe sizes ranging from (b) (4) to (b) (4) L. The (b) (4) unit kits contain a mix of (b) (4) selected critical (b) (4) b) (4) selected major defects, and (b) (4) defects. This results in a test kit reject rate of approximately (b) (4). In addition, (b) (4) of the (b) (4) minor defects in the kit contain the same defect for (b) (4) .

B) Your firm's qualification testing for visual inspection does not adequately simulate fatigue. The (b) (4) unit kit must be completed within (b) (4) and is repeated in (b) (4) for initial qualification. The operators routinely inspect for (b) (4) during production prior to taking an eye break.

***DATES OF INSPECTION**

3/25/2025(Tue), 3/26/2025(Wed), 3/27/2025(Thu), 3/28/2025(Fri), 3/31/2025(Mon), 4/01/2025(Tue), 4/02/2025(Wed), 4/03/2025(Thu), 4/04/2025(Fri)

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EMPLOYEE(S) SIGNATURE

Logan T Williams, Investigator

X Logan T Williams
Investigator
Signed By: 2002955055
Date Signed: 04-04-2025
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DATE ISSUED
4/4/2025

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."