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 Fax:(973)331-4969	5/7/2019-5/31/2019*
	FEI NUMBER 3013931875

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Michael Rutkowski, Vice President and General Manager

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

The quality control unit lacks responsibility to approve and reject all procedures or specifications impacting on the identity, strength, quality and purity of drug products.

Specifically,

A) (b) (4) missing media fill 60 mL syringe units of (b) (4) total units processed during aseptic process simulation conducted on 09/20/2018 for Lot #092018LR were not incubated and tested for microbial growth as part of the performance qualification for Building (b) (4) Manufacturing Suite/Cleanroom (b) (4) In addition, the (b) (4) syringes used to prime and calibrate equipment were not incubated and tested for microbial growth. No explanation was documented for the missing media fill units.

B) (b) (4) missing media fill 60 mL syringe units of (b) (4) total units processed during aseptic process simulation conducted on 09/19/2018 for Lot #091918KS were not incubated and tested for microbial growth as part of the performance qualification for Building (b) (4) Manufacturing Suite/Cleanroom (b) (4) In addition, the (b) (4) syringes used to prime and calibrate equipment were not incubated and tested for microbial growth. No explanation was documented for the missing media fill units.

OBSERVATION 2

Written records of investigation of a drug complaint do not include the findings of the investigation and the follow-up.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Guerlain Ulysse, Investigator	DATE ISSUED 5/31/2019

X Guerlain Ulysse
Investigator
Signed By: Guerlain E. Ulysse -S
Date Signed: 05-31-2019 11:43:45

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Specifically,

Complaint 0115, Event Date: 02/04/2019 was received due to particulates being observed for multiple lots ((b)(4) syringes) of Sodium Bicarbonate 1meq/1mL, 50 mL syringes, including for the following only lot information provided: Lot #30001883, Exp: 04/03/2019. The complaint investigation report determined that sodium biocarbonate likely crystallized in transit under extreme conditions and is not associated with production error. However, the investigation did not include review of drug product stability and formulation, retain samples, or identification of the particulate matter. In addition, shipping studies have not been performed to determine the effects of shipment and transit conditions on the compounded drug product.

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include validation of the aseptic process.

Specifically,

There is no standard operating procedure or batch record instructions for the number of IV bag units allowed within the ISO 5 hood at a time. For example:

(b) (4) units were compounded as part of Oxytocin (b) (4) Units added to (b) (4) ml 0.9% Sodium Chloride solution bag, Lot# 30003332, Exp. Date: 07/23/2019. However, there is no documentation or batch record instructions for the number of units allowed within the ISO 5 hood during each dosing set of the total (b) (4) units processed.

OBSERVATION 4

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

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A) Hard-to-reach areas within the ceilings of ISO 7 Cleanroom suites are not evaluated and sampled as part of the environmental monitoring (EM) program. This includes the lack evaluation for crevices of the wireless router box mounted on the ceiling of ISO 7 Manufacturing Suite/Cleanroom (b)(4)

B) EM sampling locations within the ISO 5 hood area are not defined within standard operating procedures, batch record instructions or EM sampling worksheets.

OBSERVATION 5

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that conform to appropriate standards of identity, strength, quality and purity.

Specifically,

A) Reach-in incubator NJ-INC-0006, with Operating Range: (b) (4) degrees Celsius, is used to incubate environmental monitoring (EM) and personnel monitoring (PM) samples. However, it has not been evaluated to determine whether the loaded chamber works within-the-specified limits of temperature through-out the chamber. The effect of opening doors at different lengths of time, and the effect of a power failure on the incubator's ability to get back into the temperature profile have not been evaluated either. Temperature mapping studies were conducted using empty incubator conditions.

B) Walk-in refrigerator NJ-REF-0006, with Operating Range: (b) (4) degrees Celsius, is used to store finished product lots requiring refrigerated conditions prior to shipment, including that of: Lidocaine 1% Bicarbonate 10 mL syringes and Vancomycin 1.25g - 250 mL bags. However, it has not been evaluated to determine whether the loaded refrigerator works within-the-specified limits of temperature through-out the chamber. The effect of

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opening doors at different lengths of time, and the effect of a power failure on the refrigerator's ability to get back into the temperature profile have not been evaluated either. Temperature mapping studies were conducted using empty refrigerator conditions.

OBSERVATION 6

Establishment of the reliability of the component supplier's report of analyses is deficient in that the test results are not appropriately validated at appropriate intervals.

Specifically,

Test results of Active Pharmaceutical Ingredients (APIs) suppliers used for compounding bulk drug products have not been appropriately validated at appropriate intervals. This includes the lack of qualification for related substances, organic impurities and/or residual solvents test results received for:

A) Norepinephrine Bitartate API, Expiry Date: five (5) years

B) Phenylephrine HCL API, Retest Date: five (5) years

C) Epinephrine API, Retest Date: two (2) years

*DATES OF INSPECTION

5/07/2019(Tue), 5/08/2019(Wed), 5/09/2019(Thu), 5/10/2019(Fri), 5/14/2019(Tue), 5/15/2019(Wed), 5/16/2019(Thu), 5/31/2019(Fri)