DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	4/16/2018-4/20/2018
	FEI NUMBER 3002468086

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ms. Donna Kohut, Vice President of Operations

FIRM NAME	STREET ADDRESS
QuVa Pharma, Inc.	5920 S General Bruce Dr
CITY, STATE, ZIP CODE, COUNTRY Temple, TX 76502-5804	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 authority to fully investigate errors that have occurred.

A. Negative controls run with (b) (4) testing intended to determine sterility of human drug products shows anomalous/unexpected data that has not been investigated or trended per SOP #QS-0012 rev 3 (effective May 2017). For example:
   - 16 November 2017, negative control showed (b) (4) "events" while Oxytocin, Cefazolin, and Sodium Bicarb product tested concurrently that day were dispositioned as sterile
   - 2 November 2017, product Oxytocin in Lactated Ringers showed (b) (4) "events" in Lot #10006280 and product was dispositioned as sterile

   (b) (4) test methodology requires a human review of (b) (4) "events" to determine if each instance represents a microorganism in the tested sample.

B. On 16 April 2018, I observed electronic records of differential pressure gauges for ISO 7 room "(b) (4)" showing persistent negative room pressure excursions down to -0.2 inches of water over the past twelve months.
   No quality unit investigation or corrective action was opened as of this date to address the system indicating reverse flow of air from the ante-room used for gowning into the ISO 7 room used for processing.

OBSERVATION 2

Written records of investigation of a drug complaint do not include the findings of the investigation.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Scott T Ballard, Investigator	X Scott T Ballard Investigator Signed By: Scott T. Ballard -S Date Signed: 04-20-2018 16:01:10	4/20/2018

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Complaint records do not include the applicable formulation records or identify the location of bulk product formulation. For example:

Complaint #1700040 for possible sub-potent product dated 9 August 2017 was documented without investigating the formulation batch or documenting the Quva location where formulation occurred. The complaint product was injectable Neostigmine 1mg/mL syringes.

Complaint #1700034 for possible sub-potent product dated 13 July 2017 was documented without investigating the formulation batch or documenting the Quva location where formulation occurred. The complaint product was injectable Rocuronium PF 10mg/mL syringes.

OBSERVATION 3

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically, there is no supporting data to show that (b) (4) (b) (4) (Model "(b) (4) ") is appropriate for sterilizing up to (b) (4) of bulk in-process drug product.

To date, the closest relevant data is non-sterile (b) (4) media simulation (lot#TTX641) (b) (4) sterilized sterilized to show maximum process of (b) (4) .

Ephedrine Sulfate bulk lot #TTX224 ((b) (4)) was (b) (4) sterilized using (b) (4) (b) (4) A portion of this bulk was filled into (b) (4) finished product syringes on 26 February 2018 as part of lot #20002610. The syringes were released by the quality unit and shipped on 16 March 2018.

OBSERVATION 4

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

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Specifically, your firm utilized pass-through boxes for each of the clean rooms (b) (4) and (b) (4) where bulk sterile injectable products such as Morphine Sulfate and Ketamine 10mg/mL are produced. This creates a route of communication between unclassified areas and ISO 7 clean rooms.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Scott T Ballard, Investigator X Scott T Ballard Investigator Signed By: Scott T. Ballard -S Date Signed: 04-20-2018 16:01:10	4/20/2018