DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA 4040 North Central Expressway #300 Dallas, TX 75204 (214) 253-5310 Industry Information: www.fda.gov/oc/industry	1/20, 21, 25, 26, 27, & 2/1, 5, & 8/2016
	FEI NUMBER 3012053582

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. David C. Short, Vice-President, Quality

FIRM NAME	STREET ADDRESS
QuVa Pharma, Inc.	1075 West Park One Drive Suite #100
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sugar Land, TX 77478	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) (WE) OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review 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, Vancomycin, lot #13350 (Date prepared: 10/13/2015, Expiration date: 11/12/2015) was determined to be Out of Specification (OOS) for endotoxin. The lot was not distributed.

Your investigation failed to include a determination of the root cause for the endotoxin failure.

In addition, the following two sterility OOS investigations and fourteen potency OOS investigations have been open for more than thirty days, indicating the lack of an efficient and robust CAPA system:

Sterility OOS:
Nicardipine, Lot #13384, produced:10/19/2015, BUD:12/03/2015, investigation initiated 11/13/2015
Morphine, Lot #13170, produced: 09/17/2015, BUD: 11/01/2015, investigation initiated 09/28/2015

Potency OOS:
Lidocaine, Lot #13514, produced: 11/09/2015, BUD: 12/09/2015, investigation initiated 11/18/2015
Norepinephrine, Lot #13484, produced: 11/03/2015, BUD: 12/18/2015, investigation initiated 11/18/2015
Oxytocin, Lot #13466, produced: 11/03/2015, BUD: 12/03/2015, investigation initiated 11/22/2015
Amiodarone, Lot #13488, produced: 11/04/2015, BUD: 12/19/2015, investigation initiated 11/24/20

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Darla J. Christopher	Stephen D. Brown, Investigator Darla J. Christopher, Investigator	02/08/2016

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Amiodarone, Lot #1513515, produced 11/09/2015, BUD: 12/24/2015, investigation initiated 11/18/2015
Amiodarone, Lot #13553, produced: 11/13/2015, BUD: 12/28/2015, investigation initiated 11/18/2015
Epinephrine, Lot #13621, produced: 11/23/2015, BUD: 12/23/2015, investigation initiated 12/01/2015

Oxytocin, Lot #13607, produced: 11/23/2015, BUD: 12/23/2015, investigation initiated 12/04/2015
Norepinephrine, Lot #13208, produced: 09/22/2015, BUD: 11/06/2015, investigation initiated 09/28/2015
Ondansetron, Lot #13642, produced: 12/01/2015, BUD: 01/15/2016, investigation initiated 12/08/2015
Lidocaine, Lot #13730, produced: 12/14/2015, BUD: 01/13/2016, investigation initiated 12/28/2015
Lidocaine, Lot #13795, produced: 12/28/2015, BUD: 01/27/2016, investigation initiated 12/28/2015
Calcium Gluconate, Lot #13698, produced: 12/08/2015, BUD: 01/22/2016, investigation initiated 12/28/2015
Phenylephrine, Lot #13708, produced: 12/10/2015, BUD: 01/24/2016, investigation initiated 12/29/2015

None of these lots were distributed.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically,

Your media fill process simulations are not performed under the most stressful or challenging conditions. For example, protocol #(b) (4) entitled, "(b) (4) Operator Media Fill Qualification" dated 11/16/15 describes, in part, that (b) (4) . However, your firm has produced lots of Oxytocin (b) (4) (i.e. (b) (4) , lot #13472-0, Quantity: (b) (4)).

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OBSERVATION 3

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

Specifically,

SOP #103-06.02 entitled, "Surface Sampling Procedure" (Effective date: 5/22/14) documents, in part, that surface sampling will be performed (b) (4). Review of monitoring records revealed that sampling was routinely performed (b) (4) and not (b) (4). Surface sampling is not done during production.

OBSERVATION 4

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room to produce aseptic conditions.

Specifically, your SOP Document No.: SUG-SOP-SA-0001, entitled, "Sterile Compounding Area Cleaning and Disinfecting", dated 12/15/2015, states that (b) (4) cleaning of the (b) (4) shall be performed with a sporicidal disinfectant, (b) (4) or equivalent; however, the cleaning records for (b) (4) do not document that cleaning was performed. For example:

(b) (4) (b) (4) No documentation that a sporicidal cleaning agent was used (b) (4)

(b) (4) No documentation that a sporicidal cleaning agent was used (b) (4) (b) (4)

(b) (4) No documentation that a sporicidal cleaning agent was used (b) (4)

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The cleaning records for (b) (4) including the (b) (4) do not indicate the sporicidal was used (b) (4)

OBSERVATION 5

Procedures for the preparation of master production and control records are not described in a written procedure.

Specifically, SOP #104-05.02 entitled, "Variance Investigation Policy" (Effective date: 7/15/15) does not include time limitations for the closure of investigations. Currently, your firm has at least 16 open investigations which were opened over 30 days ago.

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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 judgement, 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."