DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Use this check box to generate the required 483 statement on page 1 for medical device observations. ☐

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139 Industry Information: www.fda.gov/oc/industry	5/6/2019-6/6/2019* FEI NUMBER 3011509553

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Edward J. Zatta, CEO and Founder

FIRM NAME	STREET ADDRESS
RXQ Compounding LLC	340 W State St Unit 9
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Athens, OH 45701-1564	503B Outsourcing Facility

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

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,

A. Since August 2017, your firm has conducted approximately eight (8) sterility failure investigations for the following:

Dated	Investigation	Product	Lot Number	Microbial Identification
04/22/2019	INV-2019-043	Ascorbic Acid 500 mg/mL	04012019:82	*Kocuria rihzophilla*
04/19/2019	INV-2019-040	Sodium Bicarbonate 8.4%	03272019:41	*Paenibacillus urinalis; Streptococcus oralis; Rothia aeria*
03/26/2019	INV-2019-034	Procaine HCl 20 mg/mL	03112019:27	Pending as of 5/30/2019
01/03/2019	INV-2019-002	Ascorbic Acid 500 mg/mL	12182018:90	*Penicillium citrinum*
11/19/2018	INV-2018-073	Ascorbic Acid 500 mg/mL	11132018:68, 11132018:43	*Bacillus cereus*
09/17/2018	INV-2018-059	Lidocaine HCl 1%	09122018:66	*Bacillus infantis; Microbacterium liquefaciens/oxydans/maritypicum*

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08/01/2018	INV-2018-043	Lidocaine HCl 1%	07162018:93	*Propionibacterium (Cutibacterium acnes*
06/06/2018	INV-2018-025	Phenylep 1.5% Lidocaine 1%	05212018:01	*Propionibacterium acnes; Staphylococcus aureus; Staphylococcus epidermis*

These investigations were incomplete in that they did not include other lots of product potentially impacted, did not include environmental monitoring results, were not opened or completed in a timely manner, and did not have adequate root cause assessments or CAPAs.

B. Complaint investigation RCA-2019-013 was opened on 03/19/2019 for reported crystallization of Ascorbic Acid 500 mg/mL lot #12122018:20. The investigation identified approximately 18 additional lots that exhibited crystallization in the retain samples or in released finished goods inventory. A root cause could not be determined, and no further action was taken regarding product that was identified as having crystallization.

C. Since August 2017, there have been approximately 107 out of specification investigations for potency, for example:
   a. INV-005-18 was opened on 03/05/2018 for the potency failure of Ascorbic Acid 500 mg/mL lot #02122018:52. This lot was retested after receiving an initial result of 86.2% (specification is (b) (4) %) and the quality assurance unit released the lot for distribution. No laboratory error was identified for the original result of 86.2% and no root cause was identified by the investigation.
   b. INV-2019-023 was opened on 02/19/2019 for the potency failure of Trypan Blue 0.06% lot #01232019:40. This lot was retested after receiving an initial result of 220% (specification is (b) (4) %). The retest results were 200% and the product was not released, however, the master formula was changed. Approximately (b) (4) lots of Trypan Blue 0.06% were produced prior to the formula change and released for sale. Your firm's quality assurance unit did not evaluate the effect of the formula change on previously released Trypan Blue lots.

D. Endotoxin failure investigations INV-2019-022 and INV-2019-041 were opened on 02/15/2019 and 04/19/2019, respectively, for approximately six lots of methylcobalamin. Your firm determined that the root cause for the endotoxin failures was the active pharmaceutical ingredient, methylcobalamin. (b) (4)

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(lot #(b) (4) and (b) (4)). Your quality assurance unit did not evaluate the released methylcobalamin lots produced from these lots of API. For example, methylcobalamin 10 mg/mL lot #01022019:53.

E. Since August 2017 there have been six (6) investigations for environmental monitoring limit excursions, for example:
   a. INV-2019-030 was opened on 03/11/2019 for three separate recoveries of bacillus species from ISO5 hood (b) (4) and (b) (4) The samples were collected on (b) (4) . There were approximately (b) (4) finished product lots made between (b) (4) using hood (b) (4) that were released, for example, PHEN 10% CYCLO 1% TROP 1% KETO 0.5% OPTH lot #03142019:95.
   b. INV-2018-076 was opened on 10/25/2018 for a personnel glove sample that exceeded the action limit of (b) (4) CFU. The lot associated with the recovery was rejected, however the investigation was incomplete as it did not include other drug product lots or environmental monitoring data and trends.

F. Since August 2017, there have been eleven (11) (b) (4) testing failures, for example:
   a. INV-2018-021 opened on 05/31/2018 discussed one failed (b) (4) test for a (b) (4) (b) (4) used for SOD-PHOS INJ lot #11022017:73. (b) (4) (b) (4) were used for this lot, and the failure was recorded for the (b) (4) Your quality assurance unit released the lot for sale based on passing sterility test results.
   b. INV-2018-011 opened on 05/16/2018 discussed one failed (b) (4) test for a (b) (4) (b) (4) used for Ascorbic Acid 500 mg/mL lot #04202018:71. This was the only (b) (4) used for this lot. Your quality assurance unit released this lot for sale based on passing results of (b) (4) as many units than required for sterility testing per USP.

THIS IS A REPEAT OBSERVATION

OBSERVATION 2

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

Specifically,

A. Proper aseptic technique was not practiced by personnel engaged in manufacturing sterile drug products.

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For example, on 05/07/2019, during the production of Bupivacaine 0.125% / Ropivicaine 0.5%, lots 05072019:88 and 05072019:67, we observed the following:

a. Operators working in a (b) (4) laminar flow ISO5 hood were observed reaching over and blocking first pass air around open containers, either before or after it was filled with sterile product. The filled product containers were not discarded. Additionally, these movements were occurring at a rapid pace.

b. The sterile gowned operator was observed entering the ISO 8 anteroom, ISO 7 clean room, and the non-classified (b) (4) using sterile gloves to obtain materials for production such as product containers and environmental monitoring plates. This activity can occur more than 40 times. After such activities, the technician did not change their gloves before resuming (b) (4) operations of Bupivacaine 0.125%/ Ropivacaine 0.5% lot # 05072019:88 in the ISO 5 hood.

c. On multiple occasions, the sterile gowned operator was observed removing the sterile (b) (4) wipes in and out of the ISO 5 hood. The sterile wipes were used to clean materials coming into the ISO7 from non-classified space (b) (4) (b) (4) and then moved into the ISO5 hood. The wipes were then used in the ISO5 hood after being exposed to ISO7 quality air.

B. According to your firm's technicians, bulk drug product is routinely (b) (4) in the ISO 5 hood into (b) (4) . For example, a (b) (4) batch of Ascorbic Acid lot 04012019:11 was (b) (4) Approximately (b) (4) . These steps are not recorded as part of the batch record.

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OBSERVATION 3

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

Specifically,

A. The media fill program is deficient in scope and process, for example:
   a. Operator qualification media fills are performed in batch sizes of (b) (4) however, products are routinely compounded in (b) (4), for example, Ascorbic Acid 500 mg/mL Lot # 12122018:20. Filling of batch sizes greater than (b) (4) has not been validated.
   b. Operator qualification media fills are performed with (b) (4) vials; however, your firm produces compounded drug products in 10 mL, 30 mL, 50 mL and 100 mL vial sizes. Filling of vial sizes other than (b) (4) has not been validated.
   c. Media fills do not capture the worst-case processing conditions such as the number of operators dispensing product in one hood simultaneously and the number of aseptic manipulations in the hood. For example, bulk drug product is routinely (b) (4) This process typically involves (b) (4) technicians in the cleanroom.
   d. Media fill batch records and associated forms do not record the number of vials reviewed after incubation and the number of vials that were considered failing, if any.
   e. Media fill batch records and associated forms do not consistently record when vials are placed into incubation and when they are removed from incubation. In addition, the incubator used is not documented.

B. Our review of the smoke study videos from 03/27/2019 identified the following deficiencies:
   a. There is not enough smoke produced to visualize the air flow at critical production areas. Smoke studies do not simulate operations under dynamic conditions. For example, during the production of Bupivacaine 0.125% / Ropivacaine 0.5% lot #05072019:88 we observed bulk product being (b) (4) into the ISO5 hood, the use of equipment in the ISO5 hood, and the movement of materials in and out of the ISO5 hood. These activities were not conducted during the smoke study.

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C. (b) (4) qualifications are deficient in that:

a. On 10/19/2018 your firm produced tacrolimus 0.003% lot #10192018:21 exp 03/31/2019 with the use of (b) (4) to sterilize the (b) (4) This (b) (4) is not qualified to perform sterilization of (b) (4) drug product components. This product was released and distributed until its expiry, 03/31/2019. According to your firm, the use of the (b) (4) to sterilize components of a drug product formulation had ceased in (b) (4).

b. All (b) (4) for (b) (4), routinely used by lab technicians were not validated during qualification. For example, no (b) (4) exist that included (b) (4) that are used to clean ISO 8 and ISO 7 clean room areas, however, these are consistently documented on Form 005, (b) (4) Sterilization Log Sheet.

c. The qualification for (b) (4) used biological indicators that were not incubated using qualified equipment or for the duration indicated in the manufacturer's directions for use. For example, instructions state to (b) (4) however 9 out of (b) (4) biological indicators were incubated for less than 24 hours.

OBSERVATION 4

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

Specifically,

A. (b) (4) cleaning of the ISO5 hoods is performed using (b) (4). The cleaning solution is made in the ISO7 cleanroom by mixing the sterile (b) (4) with sterile (b) (4) in a non-sterile bucket that is stored in the ISO8 ante room. The bucket is wiped with (b) (4) before being transferred into the ISO7 cleanroom. A sterile lint-free wipe is dipped into the bucket of non-sterile cleaning solution and used to clean the inside of the ISO5 hoods.

B. Your environmental monitoring identification results show recoveries of spore-forming organisms in the ISO classified spaces, which suggests your cleaning program is not effective. For example:

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Date of recovery	Location	Organism Identification
12/27/2018	Personnel	*Bacillus circulans*
01/24/2019	ISO 7(Bench)	*Bacillus kyongiensis*
03/06/2019	(b) (4) Hood	*Bacillus halosaccharavans*
03/14/2019	ISO 5 (b) (4) Hood (b) (4)	*Bacillus circulans*
03/16/2019	ISO 5 (b) (4) Hood (b) (4)	*Bacillus parlichenformis*
04/20/2019	ISO 7(Bench)	*Paenibacillius provencensis*

C. Your procedure, SOP 003 *Environmental Monitoring of the Cleanroom* does not require additional cleaning activities in the cleanroom areas to take place in the event there is an environmental excursion such as temperature, humidity, or pressure differential. Furthermore, there is no procedure established for cleaning activities required after a recovery in the ISO5 hood.

D. Your procedure, SOP 002 *Cleaning and Maintenance of the Cleanroom Facility*, is not always followed. For example, your firm does not always document (b) (4) cleaning on Log 005, Cleaning and Maintenance of the Clean Room Unit each (b) (4)

THIS IS A REPEAT OBSERVATION

OBSERVATION 5

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

Specifically,

Environmental monitoring in the cleanrooms and the surrounding supporting clean areas is deficient in that it does not represent the working conditions during multiple steps of processing. For example:

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A. Formulation of bulk drug solutions takes place in non-classified areas. On 05/07/2019, we observed the formulation of Bupivicaine 0.125% / Ropivicaine 0.2% Injection Solution lot #05072019:88 in non-classified space.

B. Air and surface sampling is not conducted in the non-classified areas or the cleanrooms during the (b) (4) of bulk drug products. On 05/07/2019, we observed the (b) (4) of Bupivicaine 0.125% / Ropivicaine 0.2% Injection Solution lot #05072019:88 from non-classified space into the ISO5 hood without any air or surface sampling in the non-classified area, ISO7 cleanroom, or ISO5 hood while the connection was being made or while the solution was being (b) (4)

C. The air and surface sampling locations in the ISO8, ISO7, and ISO5 areas have no rationale to support the chosen locations. On 05/07/2019, we observed the filling of Bupivicaine 0.125% / Ropivicaine 0.2% Injection Solution lot #05072019:88 and noticed settling plates in the far left and right corners of the ISO5 hood. The left corner plates were on top of the (b) (4) approximately six inches above the working surface, while the right corner plates were blocked by the large (b) (4) drug product solution and away from the working surface.

THIS IS A REPEAT OBSERVATION

OBSERVATION 6

Equipment and utensils are not cleaned at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

The process for cleaning equipment used for batch formulation and (b) (4) is not validated to show removal of drug product residue. For example:

A. (b) (4) used during (b) (4) of drug product is reused. The (b) (4) is cleaned as follows: (b) (4) For example, Ascorbic Acid 500 mg/mL lot #12122018:20.

B. Mixing (b) (4) meant for single-use are reused to (b) (4) in the non-classified area for multiple (b) (4) batches of drug product such as ascorbic acid and sodium bicarbonate.

C. Stainless steel (b) (4) used for (b) (4) are purged with (b) (4) without any additional steps and stored in the non-classified areas.

D. Stir bars and luer lock used in bulk formulation are washed with kitchen dish soap, rinsed with deionized water and subsequently (b) (4) For example, Ascorbic Acid 500 mg/mL lot #12122018:20.

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OBSERVATION 7

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

A. Your firm does not initiate change controls when necessary and in a timely manner. For example, according to your quality assurance unit, a change control was not initiated for the decommissioning of (b) (4) and the movement of (b) (4) from room 215 to room 211.
B. Your quality control unit failed to initiate an OOS investigation for out of specification product yield in batch records reviewed, for example, Trypan Blue 0.06% lot #01032019:60.
C. Training records are not maintained by the quality assurance unit and are often incomplete. For example, five employee training records were observed to not have been fully completed for tasks related to sterile compounding.
D. Your firm does not follow change controls that are opened to effect change. For example, Change Control 2019-074 opened on 03/04/2019 and closed on 04/18/2019 addressed using (b) (4) (b) (4) for the (b) (4) of drug products. According to your Quality Manager, your firm has not updated all records to reflect this change and continues to re-use (b) (4) hat has been (b) (4) by your firm.
E. Your quality assurance unit initiated and authorized the relabeling of PHEN 10% CYCLO 1% TROP 1% KETO 0.5% OPTH lot #03142019:95 on 03/27/2019 to extend the BUD without proper justification. Additionally, the relabeled BUD exceeded its true expiry.

OBSERVATION 8

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically, time limits for sterile drug production have not been established or evaluated to demonstrate that preparing and holding drug products in unclassified areas is acceptable to assure the quality of finished sterile drug products. For example, Ascorbic Acid 500mg/mL lot #12122018:20 was prepared and mixed on (b) (4), it was then left in the non-classified area until filling operations resumed on (b) (4) This lot was released for sale. Your firm has not provided any scientific evidence to justify the use of a (b) (4) hold time to produce sterile drug products that are held and stored in the non-classified areas prior to being (b) (4) and filled in the ISO 5 hood.

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OBSERVATION 9

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

Specifically,

A. Members of the quality assurance unit lack the proper qualifications for their job duties. For example, there is no documented training for a quality control technician who is responsible for lot release, batch record review, overseeing the media fill program, and overseeing the environmental monitoring program. This technician reviewed and released PHEN 10% CYCLO 1% TROP 1% KETO 0.5% OPTH lot #03142019:95 for distribution.

B. There is no documented training for the pharmacist in charge who has been employed by your firm for approximately one year and in this role since November 2018.

C. Visual inspection training does not include a challenge set that operators must pass in order to be qualified to inspect products. Additionally, all product types are not used to train employees and it is left up to the technicians to admit proficiency amongst various container types during the visual inspection process.

D. Your quality assurance unit, pharmacist in charge, and production leadership do not confirm that personnel are trained for the task performed prior to an employee conducting the task.

OBSERVATION 10

The number of qualified personnel is inadequate to supervise the manufacture, processing, packing and holding of each drug product.

Specifically, the quality unit is inadequately staffed to keep up with the pace of production. For example, there is currently one quality unit member responsible for all out of specification and complaint investigations. In 2019, there have been more than 75 out of specification results obtained, each requiring an investigation.

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OBSERVATION 11

Laboratory controls do not include a determination of conformance to appropriate specifications for drug products.

Specifically,

A. Drug products produced at your facility do not have specifications, when appropriate, for preservative content, visible particles, or sub-visible particles.

B. Endotoxin specifications for each drug product are not established by your firm. Pharmacists enter the maximum patient dosage information at the time of sample submission to determine the endotoxin limit. The dosage entered is at their discretion and is not standardized. For example, Methylcobalamin 10 mg/mL lot 01022019:53.

SEP 6/6/19

fwd 06/06/2019

OBSERVATION 12

Routine checking of mechanical equipment is not performed according to a written program designed to assure proper performance.

Specifically,

A. The (b) (4) scale in room 213 has not been qualified for use, and Deviation DV-2019-007 states that the scale should be verified (b) (4) This verification is not recorded on Log 017 LUMAC - Log of Use, Maintenance, and Cleaning for this equipment. As of 05/03/2019, approximately (b) (4) lots used materials that were weighed using this unqualified and unverified scale.

B. The (b) (4) temperature and humidity monitoring system data loggers have a maximum read temperature of 215F, however, validated (b) (4) for (b) (4) is (b) (4).

OBSERVATION 13

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to the quarantine storage of drug products prior to release.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	SEP JMS	Sarah E. Rhoades, Investigator Jazmine N. Still, Investigator	06/06/2019

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139 Industry Information: www.fda.gov/oc/industry	5/6/2019-6/6/2019* FEI NUMBER 3011509553

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Edward J. Zatta, CEO and Founder

FIRM NAME	STREET ADDRESS
RXQ Compounding LLC	340 W State St Unit 9
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Athens, OH 45701-1564	503B Outsourcing Facility

Specifically,

Released and quarantined drug products were observed stored in the same refrigerator or storage rooms, for example:

A. On 05/06/2019, we observed quarantined and released drug products stored in the same refrigerator #0051 located in the gowning room.
B. On 05/06/2019, we observed boxes of quarantined product that were stopped from being shipped due to an out of specification test result stored in room 134d with released product.

Furthermore, there have been at least four customer complaints that addressed product mix-ups.

OBSERVATION 14

The container labels of your outsourcing facility's drug products are deficient.

Specifically, your containers do not include the directions for use, including, as appropriate, dosage and administration.

Examples of your container labels that do not contain this information:

- Ascorbic Acid 400mg/mL Injection Solution
- Pyridoxine (MDV) 100 mg/mL Injectable Solution
- Magnesium Chloride Hexahydrate (PFV) 20% INJ SOLN
- Buffered Lidocaine HCL (PF) 1% Injection Solution (PF)
- Ascorbic Acid 500 mg/mL (Non-Corn) INJ SOLN (MDV)
- Edetate Calcium Disodium 150mg/mL Injectable
- Dexpanthenol 250mg/mL (MDV) Injection Solution
- Vitamin B Complex 100 (PFV) Injection Solution
- Sodium Bicarbonate 8.4% (1 mEq/mL) INJ SOLN

***DATES OF INSPECTION**

5/06/2019(Mon), 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), 5/28/2019(Tue), 5/29/2019(Wed), 5/30/2019(Thu), 5/31/2019(Fri), 6/05/2019 (Wed) 6/06/2019(Thu)

SER 6/6/19

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Sarah E Rhoades Jazmine N. Still	Sarah E. Rhoades, Investigator Jazmine N. Still, Investigator	06/06/2019