DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 FAX: (718) 662-5661 Industry Information: www.fda.gov/oc/industry	March 04/05/06/10/11/20, 2014
	FEI NUMBER 3005287250

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Hymie Aruch, Pharmacy Manager

FIRM NAME	STREET ADDRESS
Region Care, Inc.	200 Community Drive
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Great Neck, NY 11021-5504	Outsourcing Facility (OF)

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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) Your firm has failed to conduct and document an investigation into the reported sterility failure of Protonix 80mg/100ml 0.9% NaCl; lot # 19P-12125112-R6, which was compounded on 12/12/2013. You did not identify the root cause of the reported (sterility) failure and you did not perform a risk evaluation to determine the impact of this deviation (i.e. other lots of sterile drug products potentially affected).

B) Review of the "Gloved Fingertip Sampling Log" found failing results on 12/11/2013, 12/20/2013, and 02/03/2014 for fingertip samples taken from the same pharmacy technician during the compounding of sterile drug products. [redacted] (b) (4) exposed on the referenced dates were observed to contain one (1), two (2), and three (3) colony forming units (CFU), respectively. However, there was no investigation into these environmental monitoring (EM) sample failures to identify a root cause, evaluate risk, or take appropriate corrective/preventive actions (CAPA). It is noted this is the same pharmacy technician who compounded the batch of drug product which failed sterility testing, as described in Observation 1(A), above.

OBSERVATION 2

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

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Robert C. Horan	Robert C. Steyert, Investigator Robert C. Horan, PhD, Investigator	03/20/2014

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Your current environmental monitoring (EM) program is deficient in that:

A) It does not include daily surface or viable air sampling within the ISO-5 classified areas during sterile compounding (production) activities.

B) You do not monitor non-viable particles in ISO-5 classified areas under dynamic conditions.

C) There is no environmental monitoring conducted during media fills (process simulations).

D) Review of your [redacted] (b) (4) Environmental Testing Log found [redacted] (b) (4) (viable) air samples and surface samples taken from the ISO-5 classified laminar airflow workstations (LAFW) are not incubated and checked for [redacted] (b) (4) as required.

E) You never monitor air-pressure differentials between your ISO-6 classified clean room & ISO-7 classified ante-room; or between the ISO-7 classified ante-room & unclassified general pharmacy area. However a panel inside the ante-room holds several manometers, which you acknowledge are not being monitored and may not even be working.

OBSERVATION 3

Buildings used in the manufacturing and processing of a drug product are not maintained in a good state of repair.

Specifically,

During a tour of the ISO-6 classified clean-room we observed peeling paint, chipped dry-wall, and acoustic ceiling tiles with cut out holes; all of which facilitate dust formation and create a contamination risk.

OBSERVATION 4

Written procedures are lacking which describe in sufficient detail the receipt, identification, storage, handling, sampling, testing, approval, and rejection of components, drug product containers, and closures.

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Specifically,

A) There is a failure to establish acceptance criteria for incoming drug substances, drug product containers and closures, and other components used in compounding sterile drug products; including, but not limited to: hydromorphone active pharmaceutical ingredient (API), [redacted] (b) (4), sterile tamper-evident syringe caps, and sterile empty glass syringes.

B) There is no written procedure and documented practice for the review of certificates of analysis received from component suppliers and control testing laboratories.

OBSERVATION 5

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance with such requirements.

Specifically,

Given the observed inadequate environmental controls, testing is deficient in that:

Each batch of compounded sterile drug product is released for distribution prior to the completion of bacterial endotoxin testing (BET) and sterility testing. Protonix 80mg/100ml 0.9% NaCl; lot # 19P-12125112-R6 was recalled due to a sterility failure.

OBSERVATION 6

Clothing of personnel engaged in the compounding of sterile drug products is not appropriate for the duties they perform.

Specifically,

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Sterile drug products are aseptically manipulated by the cleanroom operators who wear booties, gowns, face-masks, and hair nets which are non-sterile. The only apparel that is sterile is the gloves worn by operators working in the ISO-5 classified areas.

OBSERVATION 7

The labels for the drug products do not contain information required by section 503B(a)(10).

Specifically,

Labeling of compounded sterile drug products, including, but not limited to Fentanyl 12.5 mcg/ml - Bupivacaine 0.1875% in 0.9% NaCl do not contain the statement "This is a compounded drug." In addition, the labels do not contain the firm's phone number, the date of compounding, an NDC number or specific storage/handling instructions.

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