DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	07/11/2022-07/25/2022* FEI NUMBER 3003463852

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David J. Dagampat, Plant Manager

FIRM NAME	STREET ADDRESS
Rockwell Medical	4051 Freeport Pkwy Ste 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Grapevine, TX 76051-2316	Medical Device Manufacturer

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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Procedures for corrective and preventive action have not been adequately established.

Specifically,

The Corrective and Preventive Action procedure (SOP 900-026, Rev K, 03/05/2019) documents that your firm will initiate a new CAPA for identified failures of effectiveness. The new CAPA may require an addendum to the original source document, creation of a CAPA Report Form (form 900-026.F1) and approval by QA, the area Manager and the individuals assigned responsibility for the new CAPA action. The new CAPA will be assigned an appropriate CAPA Effectiveness Check plan.

However, CAPA(s) that failed effectiveness were repeatedly opened without a CAPA Effectiveness Check Plan.

For example,

(a) CAPA # CA21-27 was opened 09/29/2021, in response to a failed effectiveness check for CAPA # CA21-09.

CAPA # CA21-09 (05/24/2021) was also opened due to a failed effectiveness check for CAPA # CA20-27 (12/21/2020). (All repeat issues)

On 11/29/2021, an effectiveness check was done. The CAPA was deemed "effective".

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	Jocelyn C Turner, Investigator Olalere D Fasipe, Investigator	X Jocelyn C Turner Investigator Signed By: Jocelyn C. Turner -S Date Signed: 07-25-2022 11:05:45	07/25/2022

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However,

The corrective action which required that the Plant Manager signed all due PM(s) and calibrations within (b) (4) between 10/31/2021 and 11/29/2021, had not been completed.

(b) CAPA # CA21-28 was opened 10/07/2021, in response to CAPA # CA21-19 Failed Effectiveness Check.

On 11/29/2021, an effectiveness check was done. The CAPA was deemed "effective".

However,

My review of records from 10/19/2021 to 11/29/2021 found continued recording errors for cleaning times on the (b) (4) Cleaning Checklist and the (b) (4) Log Sheets for this period.

(c) CAPA # CA21-26 was opened 09/30/2021, in response to a failed effectiveness check for CAPA CA21-03.

CAPA # CA21-03 (04/20/2021) was also opened due to a failed effectiveness check for CAPA # CA20-23 (10/29/2020). (All repeat issues)

On 11/17/2021, an effectiveness check was done. The CAPA was deemed "effective".

However,

My review of approximately 15 records showed that the raw material consumption was not evaluated within a (b) (4) period from QA release of the batch between 10/15/2021 and 11/17/2021 for (b) (4)/15 ((b) (4)%) records.

(d) The Corrective and Preventive Action procedure (SOP 900-026, Rev 12, 03/17/2021), documents that your firm will be analyzing processes, work operations, concessions, quality audit reports, quality records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems and use statistical methodology where necessary to detect recurring quality problems. CAPA(s) will be opened to address these issues.

However,

(i) A review of the 2022 Complaint log shows that (b) (4) out of 15 complaints ((b) (4) %) received since January

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2022 have been for shipping errors. This is recurring but a CAPA was not opened.

(ii) Your firm has received multiple complaints, Complaint # C20-144 (6/12/2020), Complaint # C21-234 (10/1/2021) and Complaint # C21-262 (11/08/2021) in 2020 and 2021 referencing (b) (4) purchased by a 3rd party.

Your firm did not open a SCAR in response to these issues or keep the original complaints referencing this purchased item open until reviewed and approved.

OBSERVATION 2

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically,

Your firm's Complaint procedure (SOP # 900-001, Rev 19, 05/25/2021) documents that the site QA Manager (Devices) or designee, will coordinate and document the root cause analysis investigation and define appropriate corrective actions. As required, other internal and external resources will support the investigation and provide documentation to support the final report where necessary. A copy of the final report, including supporting documents, will be maintained in a Quality file and the electronic word document uploaded to the designated quality server complaint folder.

One out of four complaints that were reviewed from the Complaint Binder (2022), Complaint # C22-103 (6/07/2022) referenced a customer reporting a slight difference in hue in several bottles of L4-116 (CitraPure Liquid Acid).

You state that a risk analysis lists the possible causes could be due to (b) (4) .

However, these causes were not documented as investigated.

OBSERVATION 3

Procedures to ensure equipment is routinely calibrated, inspected, checked and maintained have not been adequately established.

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Specifically,

Your firm's test equipment/instrument calibration procedure, Calibration Program (Manufacturing and Test Equipment), (SOP 600-003, Rev D, 10/28/2016), was not established.

For example,

Your firm did not calibrate all your equipment used in the manufacturing of dry mix and liquid Acid Concentrates powders and liquids which are indicated for use in acute and chronic hemodialysis.

Your firm initiated several CAPAs since 12/21/2020 for the lack of calibration and maintenance.

However, there were no documented evidence that PM checks and calibrations were always conducted per your established procedure.

In addition, calibrations of scales were not done for the (b) (4) of 2022 as required by the TX Operations Equipment List and Preventive Maintenance Calibration Form (Form 600-002.WB3, Rev 35, 10/26/2021).

OBSERVATION 4
Schedules for the adjustment, cleaning, and other maintenance of equipment have not been adequately established.

Specifically,

Your firm has not established your Equipment Maintenance procedure (SOP 600-002, Rev 7, 06/04/2020).

Your firm did not document all maintenance activities on an appropriate form or log as required by your procedure.

Your procedure requires the use of the following forms:

(b) (4)

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(b) (4)

However, your QA Manager stated that equipment maintenance activities are documented in an NCR.

I observed on Thursday, 07/14/2022, that the (b) (4) operation, which manufactures your liquid concentrate solutions for hemodialysis, had a malfunction of the Case Labeler in the afternoon.

On Monday, 07/18/2022, I asked the QA Manager if any NCR(s) had been written in the last week and he stated there had not been any documented.

In addition,

There were (b) (4) of 32 ((b) (4) %) NCR(s) documented in 2021 and (b) (4)/15 ((b) (4) %) NCR(s) documented in 2022, as "Equipment failures".

These NCR(s) also did not have documented equipment maintenance activities.

***DATES OF INSPECTION**

7/11/2022(Mon), 7/12/2022(Tue), 7/13/2022(Wed), 7/14/2022(Thu), 7/15/2022(Fri), 7/18/2022(Mon), 7/19/2022(Tue), 7/20/2022(Wed), 7/22/2022(Fri), 7/25/2022(Mon)

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Promised to correct

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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 judgment, 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."