Department of Health and Human Services

Food and Drug Administration

Pacific Region
Los Angeles District
19701 Fairchild
Irvine, CA 92612-2506
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June 10, 2014

Mr. Mireya Lozano
Director of Quality
Life Science Outsourcing, Inc.
830 Challenger St
Brea, CA 92821-2946

Dear Mr. Lozano:

The U.S. Food and Drug Administration (FDA) conducted an inspection at 830 Challenger St, Brea, CA 92821-2946 ending on March 20, 2014. Effective April 1, 1997, when the Agency determines an inspection is closed under 21 C.F.R. 20.64 (d)(3), FDA releases a copy of the inspection report to the inspected firm.

You will find a copy of the FDA Establishment Inspection Report attached. FDA may have redacted some information in accordance with the Freedom of Information Act (FOIA) and Title 21, Code of Federal Regulations, Part 20. Firms may request a copy of their FDA inspections completed prior to April 1, 1997 through FOIA.

FDA is working to make its regulatory process and activities more transparent to the regulated industry. Part of this effort is releasing a copy of your inspection report or summary to you, or acknowledging that the state provided you a copy at the close of their inspection.

Please contact our office if you have questions.

Sincerely,

Steven Porter
Deputy District Director

Enclosure:
FEI: 3001236549
FMD: 871800

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SUMMARY

This was a pre-announced, routine inspection of a medical device contract manufacturer conducted under FACTS assignment # 8717740. The inspection was performed in accordance with Compliance Program 7382.845 utilizing the QSIT Level I technique. PAC code 82845A was covered and profile codes PRF and MTL were reported.

The previous inspection was performed in April 2011 and classified NAI. That inspection was a post-market inspection of the [redacted] and owned by [redacted] The current inspection found that the firm no longer packages this product for the PMA applicant.

I covered the Production and Process Controls and CAPA subsystems during the current inspection. Records reviewed included standard operating procedures, equipment maintenance records, device history records, CAPA records, and NCMR records.

No FDA-483 observations were noted and no samples were collected. No refusals were encountered.

ADMINISTRATIVE DATA

Barry Kazemi, President/CEO is the owner and most responsible person who has oversight of all the firm's daily activities.

Mireya Lozano, RA/QA Manager remains responsible for implementing the firm's Quality System including handling complaints and CAPAs, document control and quality assurance activities, regulatory affairs and auditing. She reports to Mr. Kazemi.

Future correspondence should be addressed to Ms. Mireya Lozano.

MANUFACTURING OPERATIONS

Life Science Outsourcing manufactures medical devices in accordance with their customer's specifications and protocols. Design controls and validation activities are handled by each customer as required. Design files, validation protocols and reports, and device history records can be maintained at either LSO or their customer's site as outlined in each contract agreement. Raw materials and components are usually supplied by each customer to LSO for final assembly, labeling, and packaging. Sterilization for sterile products is carried out at the contract sterilization facility chosen by their customer, or in-house if the products are steam sterilized. Ms. Lozano explained that the firm currently has 216 active customers and the largest customers are [redacted]

CAPA

Corrective and preventive actions are handled according to procedure, "Corrective and Preventive Action System" rev. E05, DCR #5493. I reviewed the CAPA logs for 2011 - 2014 and a total of 89 CAPAs have been opened. I chose to review 6 CAPA records. No deficiencies were found during review of these CAPAs; however, I told Ms. Lozano that the CAPA procedure should be revised to include all data sources (e.g. customer complaints, internal audit results, NCRs,). Currently, the procedure only calls out NCRs as a CAPA source. Ms. Lozano showed me a pie chart that identified all of the sources that have been used to open CAPAs and explained that these were the data sources used. I saw no deficiencies with the data sources that were identified on the pie chart, but I told her that they should be added to the procedure. My suggestion was well received.

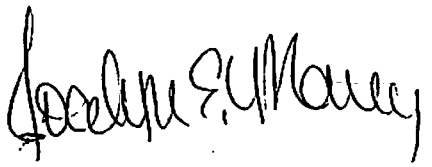
Complaints are handled in accordance with procedure, "Customer Complaint System" rev. C03, DCR #5493. I reviewed the complaint log for the current calendar year and a total of 13 customer complaints have been opened. I chose to review 3 complaint records. No deficiencies were found during review of these complaints however, I did note that communication/response records (e.g. emails) between the complainant and LSO were not included with each file. Prior to closing the inspection, Ms. Lozano printed up all emails for each complaint record received this year and told me that she plans to continue to update each file with all email communications between LSO and the firm's complainants.

EXHIBITS COLLECTED

No exhibits included.

ATTACHMENTS

1. FDA-482 Notice of Inspection dated 3/19/14.



Jocelyn E. Massey, Investigator