[redacted]

AUDIT REPORT

General Information	
Company Name	Life Science Outsourcing
Address	830 Challenger Street, Brea California 92821

Audit Information	
Audit Date	April 7, 2011
Lead Auditor	[redacted]
Co-Auditor(s)	
Participants	Mireya Lozano

Signatures		Date
Lead Auditor	[redacted]	4-22-2011
Co-Auditor	N/A	N/A

Attachments
Quality Agreement
Quality Manual
Supplier Questionnaire
Organizational Chart
SOP Listing
Work order routing
ISO Certification

Executive Summary

On April 7, 2011, [redacted] Inc. completed an audit of Life Science Outsourcing's (LSO) Quality Management System (QMS). Below is the executive summary from the audit report:

LSO is a Medical Device Contract manufacturer with headquarters in Brea, California. LSO was established in 1997. The Brea facility is a 56,000 square foot facility consisting of 10,000 sq. ft. of Class 10,000 clean room, 3,000 sq. ft. of office space and the remainder dedicated to storage and warehousing. LSO is registered in the state of California with the Department of Health Services (63626), Food & Drug Branch, also FDA certified (2031093) and NSAI (ISO) registered. NSAI certification is for contract manufacturing of non-active, invasive and noninvasive surgical devices, diagnostic equipment and active Electro-Mechanical Devices. LSO is an ISTA certified package testing laboratory and has also has an onsite steam sterilization capability

Findings/Observations

There are no findings/observations which require a Corrective Action plan to be submitted. The prior audit from 2009 had one finding which was closed and acceptable. The packaging validation of the [redacted] product was completed in June 2010 and a copy is on file at LSO and [redacted]

One complaint was initiated for the [redacted] product resulting from a single label incorrectly placed on a box. A document change order was initiated/approved and training conducted. There has been no recurrence to date.

Strengths

The facility is organized and clear material identification and segregation was noted during the tour. In the warehouse, the responsible department for identified stock locations is posted.

Review of the Environmental results for the clean room indicates consistent control levels for particulate and air/surface microbial.

Communication of customer expectations to the LSO staff is done on a routine basis and a wall centrally located outside of the clean room displays metrics related to on-time delivery, tracking of workmanship issues by area, audits, etc. These metric were also reviewed in the February 28, 2011 Management Review.

Recommendations

A process for periodic review of released documents should be implemented. This is based on the following two examples.

- It is recommended that procedure 4.21-01, Quality Resource Management be reviewed and additional clarification provided. During the review of procedures, several procedures reference a Director of QA/RA, yet this is not reflected on the current organizational chart provided.
- A review of the EM procedure (4.09-07) describes that logs for recording the pressure differential of the CER are discarded after 6 months.

[redacted]