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QUALITY MANAGEMENT SYSTEM
MEDICAL DEVICE AUDIT REPORT

Details of Assessment	Company Name / Address: (Legal Manufacturer)	Life Science Outsourcing Inc. 830 Challenger Street Brea, CA 92821
		Multi-Site ? ☐ Yes ☒ No
	Address of Audited Site(s):	Site 1 Address: ☐ Headquarter ☐ Manufacturing / Support location
		Site 2 Address: (Manufacturing / Support location)
	No. of employees	57 persons
	Management Representative / Regulatory Correspondent	Mireya Lozano
	Position in Organisation	Management Representative
	Audit Criteria (Standards, regulations assessed)	☒ ISO 13485:2003 ☐ ISO 9001:2000 ☐ 93/42/EEC ☐ 98/79/EC ☐ 90/385/EEC ☐ 2000/70/EEC ☐ 2003/32/EC ☐ CMDR ☒ Other
	NSAI Lead Auditor	Stuart Campbell
	NSAI team members	n/a
	Date(s) of Assessment	07 – 10 Apr 2009
	Duration of Assessment	3.5 on-site auditor days
	QMS Scope	The contract Manufacturing, package testing, warhousing and distribution of non-active invasive and non-invasive surgical devices, diagnostic equipment and active electro-medical device including surgical and monitoring probes and contract moist heat sterilization services in accordance with ISO 17665-1:2006
	Type of Audit	Re-assessment audit

AUDIT CONCLUSION:

This audit was conducted on-site using methodology including document review, interviews with management and operational staff, observation of processes and surroundings, review of records, and a comparison of the Quality Management System, as documented and implemented, with the requirements of the above referenced standard(s) and/or regulations.

The method of assessment sampled the organization's activities to assess these for conformance with:

- the effective interaction between all elements of the system;
- the overall effectiveness of the system in its entirety;
- demonstrated commitment to maintain the effectiveness of the system.
- compliance with all applicable regulatory requirements

Because the assessment is based on a sample of the organisation's activities, the findings reported do not purport to include all issues within the system.

Based on the audit and a review of available objective evidence, it is the conclusion of the Lead Auditor that the above named company is:

☐ RECOMMENDED:
The company can be recommended for certification / continued certification to the above listed standards, and has been found in general compliance with the applicable regulatory requirements listed above.

☐ RECOMMENDED - Corrective Action Closure Required (Category 1 findings):
The company may be recommended for certification / continued certification, based upon satisfactory closure of all category 1 findings, and if applicable, a satisfactory corrective action plan for all Category 2 findings as shown in this report.

☐ Corrective actions DO NOT require an on-site re-audit to verify effective implementation
☐ Corrective actions require an on-site re-audit by NSAI to verify effective implementation

☒ RECOMMENDED - Corrective Action Plan Required (Category 2 findings only):
The company may be recommended for certification / continued certification, based upon the acceptance of a satisfactory corrective action plan for all Category 2 findings as shown in this report. Effective implementation of corrective actions will be reviewed during the next surveillance audit.

☐ NOT RECOMMENDED AT THIS TIME:
The company cannot be recommended for certification / continued certification at this time.

Appeals

The attention of the Client is drawn to the existence of the NSAI Appeals Procedure.

The following comprise this report	☒	Audit Findings
	☒	Audit Administrative Information
	☒	Audit Details (Processes/Areas audited, Closure of previous findings)
These documents may be given to the client, on request.	☐	*Database Information Sheet*
	☐	*Audit Plan for Next Visit (if not included, must be sent at least 10 days before next audit event.*
	☐	*Checklist (if used)*
	☐	*Audit Trail*
	☐	*Other (please specify)*

Signatures: 10 Apr 09 — Stuart Campbell, NSAI Lead Auditor

10 April 2009 — Mireya Lozano, Audited Organization

EXECUTIVE SUMMARY

Summary and Conclusion

Company overview

Life Science Outsourcing Inc. with headquarters located at 830 Challenger Street Brea, CA 92821 (Administration, Purchasing, contract Manufacture, Warehouse, Distribution, Sterilization, calibration) the following products (multiple product families) for use in the area of (multiple areas as defined by the Customer who owns the product)

The following activities occur at these locations:

Facility Address	Activities at location	Products at location
830 Challenger Street Brea, CA 92821	(Administration, Purchasing, contract Manufacture, Warehouse, Distribution, Sterilization, calibration,)	Customer Owned Products, ranging from complete assembly & sterilization to simple pouch and packaging

Outsourced processes:
The client does outsource critical processes.

Critical outsourced processes are described as follows:

Product conformity
Critical Outsourced processes

Outsourced Process	Supplier Name / Address	Certified by:
Offshore manufacturing	[redacted] Tijuana, Baja California	TUV [redacted] ISO 9001:2000
Biological & Microbial testing	Northview Laboratories 1880 Holste Road, Northbrook, Illinois 60062	BSi for ISO 9001:2000 Certificate # FS 40654

Based upon a review of the client's management of the outsourced processes:

a.) The client's management of outsourced processes is sufficiently defined and controlled. Critical suppliers do not need to be visited as part of this audit.

Sterilization:
The clients' products are supplied both sterile and non sterile.

Sterilization

Device family	Method	Sterilized by:
Various customer products	Gamma	Steris Isomedix Services 1000 S.Sarah Dr., Ontario, CA 91761 BSi cert# MD 89745
Various customer products	Eto	Centurion Sterilization Services 301 Catrell Drive, Howell, Michigan, 48843 BSi cert# MD 502195
Various customer products	E beam	Nutek Corporation 30958 San Antonio St, Hayward, CA 94544 TUV cert# SD 60012963 0001

QMS documentation

Records related to the sterilization process were reviewed as part of this audit, and the sterilization process **does appear** to be in compliance with applicable sterilization standards and practices.

Internal audit process

The documented system is in place and documents were readily retrievable during the course of the audit.

Management Review

Trends between audits

The internal audits show that they are being executed according to the programme and their effective role within the management system is demonstrated by the clear reports produced and audit schedule in place. A good degree of reliance can be placed on the internal audit process in monitoring system conformity and effectiveness.

Continual improvement

The last management review was held on 18 September 2008 & the next is currently scheduled to occur August 2009.

Competence

The following trends were noted (relative to objectives and targets):
- 13% of Capa in 2008 did not meet the stated objective of having the investigation completed in ≤ 30 days
- 78 Customer complaints recorded in 2008 V's 18 YTD in 2009

Regulatory compliance / Effectiveness of QMS

The continual improvement process is performing adequately , the following example demonstrates this:
- Use of Just in Time process strategy in the purchasing process

Positive observations

A sample of the organisation's personnel have been audited and found to have evidence to demonstrate adequate competency for the process audited.
The appropriate regulatory requirements are being met, and the organisation's quality management system is systematically capable of meeting customer requirements. Please submit the corrective action plan for the category 2 findings to [redacted] and [redacted] by 10th May 2009.
The following positive observations were noted during the audit:
- Open positive approach to the audit throughout & good control & documentation evident in the training system.

Summary

Overall, the management system, with the exception of the findings noted on page 3 is compliant and its effectiveness has been demonstrated by the review of objective evidence provided during this audit.