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MANAGEMENT SYSTEM ASSESSMENT / AUDIT REPORT

Details of Assessment	Company Name / Address: (Legal Manufacturer, Corporate Office, Central Management Group or Headquarters)	**Life Science Outsourcing, Inc.** 830 Challenger Street Brea, CA 92821
		Multi-Site? ☐ Yes ☒ No
	Address of Audited Site(s):	Site 1 Address: Life Science Outsourcing, Inc. 830 Challenger Street; Brea, CA 92821 ☒ Headquarters ☒ Manufacturing / Support location
		Site 2 Address: (Manufacturing / Support location) N/A
		Site 3 Address: (Manufacturing / Support location) N/A
	No. of employees	76
	No. of Shifts	1
	Management Representative / Regulatory Correspondent	Mireya Lozano
	Position in Organization	Management Representative
	Audit Criteria (Standards, regulations assessed)	
	☐ ISO 9001:2008 ☒ ISO 13485:2003 ☐ EN / ISO 13485:2012 ☐ ISO 14001:2004 ☐ AS 9100 ☐ TL 9000 ☐ OHSAS 18001:2007 ☐ Z1000:2006 ☐ Z10:2005 ☐ IECQ - ☐ ISO 27001:2005	☐ 93/42/EEC ☐ Annex II ☐ Annex V ☐ Annex VI ☐ 98/79/EC ☐ Annex III ☐ Annex IV ☐ Annex VII ☐ 90/385/EEC ☐ Annex II ☐ Annex V ☐ 2003/32/EC ☐ 2000/70/EEC ☐ CMDCAS / CMDR ☐ Other
	NSAI Audit Team Lead	Denise Woodward
	NSAI Audit Team Members	N/A
	Date(s) of Assessment / Audit	April 16 – 17, 2013
	Duration of Assessment / Audit	2 on-site auditor days
	Scope of Certification	The contract Manufacturing, package testing, warehousing, distribution, cleaning and decontamination 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	Surveillance

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 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 organization'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 1findings, 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. Appeals should be sent to the attention of the CEO, NSAI Inc., Nashua NH.

The following comprise this report	☒	Audit Findings
	☒	Audit Administrative Information
	☒	Audit Details (Processes/Areas audited, Closure of previous findings)
	☐	Appendix A: MEDICAL DEVICE AUDIT ONLY
	☐	Appendix B: TL 9000 AUDIT ONLY
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)*

EXECUTIVE SUMMARY

Company overview

Summary and Conclusion

Life Science Outsourcing, Inc. is a contract manufacturer located at one location in Brea, CA. They were founded in 1997 and provide services for: manufacturing, package testing, steam sterilization, fulfillment and distribution services.

LSO is in substantial conformance with the standard except as noted in the findings section. , with headquarters or central management group located at (address).

Product conformity
Critical Outsourced processes

Outsourced processes:

The client does outsource critical processes.

Critical outsourced processes are described as follows: (Delete it if it is not applicable)

Outsourced Process	(Medical Device Program Only)	
	Supplier Name / Address	Certified by:
EO Sterilization, Biological & Microbial Testing	Centurion Sterilization Services Centurion Way, Williamston, MI 48895; USA	ISO Certification from BSI – ISO 13485:2003 Certificate: FM502198 Expires on 6/17/2015; ISO 13485:2003 Certificate: MD 502195 - Expires on 7/23/2015. FDA Registration #1824710
EO Sterilization, Biological & Microbial Testing	Parter Medical 17115 Kingsview Avenue; Carson, CA 90746, USA	ISO 1345:2003 Effective on 07/06/2012. Expires on 07/06/2015; ISO 11135-1-2007.
Gamma Sterilization, Biological & Microbial Testing	Steris IsoMedix Services Industrial Drive; Libertyville, IL 60048; USA	ISO Certificate from BSI – ISO 13485:2003 and EN ISO 13485:2012. Issued on 1/18/2013. Expires on 3/12/2015
E-Beam Sterilization, Biological & Microbial Testing	Nutek Corporation 1001 Whipple Road; Hayward, California, 94544, USA.	ISO Certificate from BSI. MD#540153 Registration includes: 11137-1:2006; Issued: 01/13/2012 and Expires on 8/02/2015. FDA Registration: 2950103;
Mechanical Testing (Package Testing)	Pira International 15361 Electronic Ln; Huntington Beach, CA 92649; USA.	Reviewed the ISTA Accreditation and copies of their certificates were found in a manual and from the website. ISO 17025 Certificate compliant.
Laboratory Services	NAMSA (North American Science Associates, Inc.) 6750 Wales Road; Northwood, OH 43619; USA.	ISO Certification by TUV – Effective Date 5/6/2012; Expires on May 5, 2015.
Laboratory Services	Nelson Laboratories, Inc.; 6280 S. Redwood Road; Salt Lake city, UT 84123	ACLASS – ANSI –ASQ National Accreditation Board/ACLASS – ISO/IEC 17025:2005 – Testing. Certificate issued on 2/27/2013, expires on 3/16/2015. FDA registration #3000233845.
Laboratory Services	SGS Life Science Services 616 Heathrow Drive; Lincolnshire; IL 60069; USA	ISO registration from BSI (FS 40654). Issued on 02/13/2013; Expiry Date: 03/14/2016. FDA Registration #1418028;

(Medical Device Program Only)

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

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.

Management System / Documentation

The management system documentation is well established and utilizes an ERP database system known as DBA . Documentation procedures/forms were well written and in conformance with the standard.

	Complaints were reviewed and their handling was found to be handled through the quality management system appropriately.
Internal audit process	Internal audits are being performed according to a defined internal audit program. A good degree of reliance that can be placed on the internal audit process in regards to monitoring the Management System conformity and effectiveness.
Management Review	The last management review was held on Feb. 28, 2013. All inputs and outputs required by the standard are being reviewed in the annual meeting.
Trends between audits	The following trends were noted (relative to objectives and targets): –24 External audits for 2012, 30 External Audits were conducted in 2011; –13 internal audits were conducted by LSO; Six (6) DCR's were assigned to the 13 internal audit observations. –Customer Feedback – LSO has a total of 51 complaints in 2012. Prior year was 40. (19 related to MDM Workmanship; 8 related to MDM Labeling; 18 related to MDM Shipping, material and DHR discrepancies and 6 related to SVS-Sterilization Validation Services). –54 RGA in 2012 prior year were 20. –176 Non-Conformance Reports. –27 CA's processed in 2012 with 27 in prior year (8 related to audit findings, 5 related to SVS, 9 related to MDM, 5 CAPA's were related to MDM shipping, lot history and DHR's.
Continual improvement / Continued Effectiveness	The continual improvement process has been verified, and the following examples demonstrate this: - Overall across the company the percentage of NCR's to the number of work orders decreased. - Customer feedback by division on the company website received 9 testimonies of customer satisfaction reports. - Continuing to establish scrap codes for all new manufacturing customers and trending results. 2013 Quality Objectives will continue to work through these scrap codes.
Competence	A sample of the organization's personnel have been audited and found to have evidence to demonstrate adequate competency for the process audited.
Regulatory compliance / Effectiveness of Management System	The appropriate regulatory requirements are being met, and the organization's management system is systematically capable of meeting customer requirements.
Positive observations	The following positive observations were noted during the audit: –Supplier Management files is well documented and maintained. –Production floor very neat, well labelled, and organized. –Overall procedures and the quality documentation system are very complete and thorough. –Customer focus and feedback is very important to the organization and the drives continuous improvement (ex. Moving the ETO Sterilization process internally).
Diverging Opinion between NSAI Auditor / Client ?	No (If yes, details are required)
Summary	The outcome of this assessment presents:

	Category		
	1	2	3
Outstanding or unresolved Audit Findings from previous report (Remarks: Any outstanding or unresolved audit findings should be escalated as Cat 1 and reported clearly in the summary and conclusion of this report.)	0	0	0
Number of Audit Findings raised during this Audit (include outstanding Audit Finding)	0	2	3

Signatures	**Audit Team Lead:** Denise Woodward	**Organization Representative:** Mireya Lozano

AUDIT SCOPE

Refer to Audit Plan and the applicable Program Tracking Form.

AUDIT FINDINGS and CATEGORIES

Satisfactory response including cause(s), correction and corrective action and/or corrective action plan shall be submitted to NSAI as per the following timelines for each non-conformity. Otherwise, registration may be reduced, suspended or withdrawn.

Category of Finding	**Receipt by NSAI of Satisfactory Corrective Action Response / Plan**	**Effective Closure of Issues(s) Raised**
1 (Major)	30 Calendar Days Corrective Action / Plan are due on N/A	90 Calendar Days (or less if indicated) Evidence of Action is due on N/A
2 (Minor)	30 Calendar Days Corrective Action / Plan are due on 05/17/2013	At next audit event. If not satisfactorily addressed, the issues will be escalated as Category 1 finding
3 (Comment / OFI)	No Formal Response is required	No Requirement

* During Pre-assessment audits, the audit findings are not formally categorized.

Audit findings must be comprehensively reviewed and evaluated by the Client for possible impact, implication, or application within additional areas (e.g. other processes, products, facilities, records, etc.).

Response to audit findings must include:

- **Cause** - the actual or "root" cause of issue.
- **Correction** (if necessary) - Fix what was found during audit.
- **Corrective action** - Prevent the issue from recurring

The time allowed to implement correction and corrective action will be consistent with the severity of the non-conformity and the impact on regulatory requirements. All nonconformities must be reviewed, the cause(s) determined and identified, and the effectiveness of corrections and corrective actions verified within the time agreed. Otherwise, registration may be reduced, suspended or withdrawn.

NOTE:
Corrective action responses for Category 1 and Category 2 audit findings must be submitted utilizing NSAI Non-Conformity Report (NCR) form # RF-00-15