NSAI
National Standards Authority of Ireland
Údarás Um Chaighdeáin Náisiúnta na hÉireann

NSAI Inc. (US Office)
402 Amherst St., Suite 100
Nashua
NH 03063, USA
T: (603) 882-4412
F: (603) 882 1985

NSAI Headquarters
1 Swift Square
Northwood
Dublin 9
Ireland
T: (01) 807 3800
F: (01) 807 3844

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: ☐ Headquarters ☐ Manufacturing / Support location
		Site 2 Address: (Manufacturing / Support location)
		Site 3 Address: (Manufacturing / Support location)
	No. of employees	67
	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 ☐ ISO 14001:2004 ☐ AS 9100 ☐ TL 9000 ☐ OHSAS 18001:2007 ☐ Z1000:2006 ☐ Z10:2005 ☐ IECQ -	☐ 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	Jim Stanley
	NSAI Audit Team Members	
	Date(s) of Assessment / Audit	April 17-20, 2012
	Duration of Assessment / Audit	3.5 on-site auditor days
	Scope of Certification	The contract Manufacturing, package testing, warehousing 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. The provision of cleaning and decontamination services for orthopaedic screws and implants.
	Type of Audit	Re-assessment

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 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. 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.

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:
Laboratory Testing	Nelson Laboratories Salt Lake City, UT	AClass ISO 17025 exp. 3/16/13
Laboratory Services Sterilization Indicators	NAMSA Northwood, OH	TUV SUD America ISO 13485 exp.5/ 5/ 2012
SGS Northview Labs	Nicrobiological testing	BSI ISO 9001:2008 exp. 3/14/13

(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 utilized a database ERP system known as DBA. Documentation was found to be well written and in conformance with the standard.

Complaints were reviewed and their handling was found to be complete and timely.

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 Management System conformity and effectiveness.

Management Review

The last management review was held on Feb 1, 2011.

Trends between audits

The following trends were noted (relative to objectives and targets):
- RGAs are maintained at a very low level < 3 per month
- Reduction in CAPAs down to 0 or 1 per month, down from 5.

Continual improvement / Continued Effectiveness

The continued effectiveness of the management system has been verified, the following examples demonstrate this: Metrics show positive trends, adoption of Len and 5S initiatives.

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:
- Very clean and well organized production areas
- A clear commitment to quality improvement
- The addition of new services including EO sterilization.

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	3	4
Signatures	**Audit Team Lead:**		**Organization Representative:** 4.20-12	

AUDIT SCOPE

Refer to Audit Plan and the applicable Program Tracking Form.