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	56
	No. of Shifts	n/a
	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	Stuart Campbell
	NSAI Audit Team Members	n/a
	Date(s) of Assessment / Audit	20th – 21st April 2011
	Duration of Assessment / Audit	2 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	Surveillance Audit

CLIENT CONFIDENTIAL

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. 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)

Product conformity
Critical Outsourced processes

Outsourced processes:

The client dose outsource critical processes.

Critical outsourced processes are described as follows:

Outsourced Process	(Medical Device Program Only)	
	Supplier Name / Address	Certified by:
Offshore manufacturing	[redacted] Tijuana, Baja California	TUV [redacted] ISO 9001:2008 Exp May 2013
Biological & Microbial testing	Northview Laboratories 1880 Holste Road, Northbrook, Illinois 60062	BSi for ISO 9001:2008 Certificate # FS 40654 Exp March 2013
Biological & Microbial testing	North American Science Associates Inc 9 Morgan Avenue Irvine, CA 92618	TUV for 13485 Certificate # S 951 06 3775 Exp 5th May 2012

(Medical Device Program Only)

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.

Management System / Documentation

The management system documentation is in place and documents were readily retrieved during the course of the audit.

Complaints were reviewed and their handling was satisfactory

Internal audit process

Internal audits are being performed according to a defined internal audit program. A good degree of reliance 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 the 28th February 2011.

Trends between audits

The following trends were noted (relative to objectives and targets):

- Reducing trends noted in both the number of capa issued and the number of complaints received in 2011 year to date versus 2010 figures.

Continual improvement / Continued Effectiveness

The continued effectiveness of the management system has been verified, the following examples demonstrate this: 5s teams have been implemented since the last audit

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:

- Good improvement noted in the control of the Capa & NCR systems since the last audit
- Open positive approach to the audit noted

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	1	1

Signatures	Stuart Campbell 21 APR 11	Mireya Lozano 4-21-11
	Audit Team Lead: Stuart Campbell	**Organization Representative: Mireya Lozano**

AUDIT SCOPE

Refer to Audit Plan and the applicable Program Tracking Form.