

# Life Science Outsourcing Inc. (LSO) Assessment Report

To: Supplier File  
From: [REDACTED] (Director of QA) – Lead Auditor  
CC: Life Science Outsourcing Representatives, R. Bryan, [REDACTED]  
Report Date: Jun 4, 2012

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Audit Date: May 24, 2012  
Audit Location: Life Science Outsourcing, Inc. (LSO)  
830 Challenger Street  
Brea, CA 92821  
Auditee: Mireya Lozano, QA / RA Manager - Life Science Outsourcing (LSO)  
Auditor(s): [REDACTED]  
Attachment: Supplier On-site Audit Checklist [REDACTED]

Supplier assessment was performed to assess LSO Manufacturing Services capabilities in conformance to the requirements defined in ISO 13485:2003 and the applicable requirements of the Quality System Regulation (21 CFR Part 820).

The purpose of this supplier assessment / audit was to evaluate conformance to all applicable requirements with respect to the material procurement, manufacturing, testing and shipment.

The scopes of this supplier audit include LSO Quality System specific to those elements required to fulfill the role and responsibilities as [REDACTED] Contract Manufacturer.

Specific internal quality procedure and records examined during the assessment are referenced as evidence to support compliance in this report.

## **II Areas and elements of the Quality System covered during the assessment (for convenience only applicable ISO 13485:2003 sections have been referenced)**

- 4.0 Quality Management System (including parts 4.1 & 4.2)
- 5.0 Management Responsibility (including parts 5.1 - 5.6)
- 6.0 Resource Management (including 6.2, 6.3 & 6.4)
- 7.0 Product Realization (including 7.2, 7.4, 7.5 & 7.6)
- 8.0 Measurement, Analysis, and improvement (including parts 8.1 - 8.5)

### **Background / Executive Summary:**

[REDACTED] has made the strategic decision to partner with contract manufacturer who can provide the necessary resources and expertise to support the manufacturing of the [REDACTED] device for clinical and commercialization.

LSO has been chosen to be this long term partner to [REDACTED] with low-medium and complex manufacturing, with customized product commercialization solutions.