[redacted]

SITE VISIT AGENDA

1/29/13 – 1/30/13

LIFE SCIENCE OUTSOURCING (LSO)

Visitor:

[redacted], Sr. Director RA/QA & Compliance, Lead Auditor

SCOPE: A previous visit of LSO facility was conducted in April of 2011 when the production transfer of [redacted] products to LSO was initiated. The scope of this visit was an in-depth review of the quality system and [redacted] products manufacturing at LSO. The audit was conducted according to the requirements of FDA QSR 21 CFR Part 820 and ISO 13485:2003. LSO is a critical contract manufacturer of the finished goods for [redacted] providing services such as device assembly, packaging, and labeling. These products include:

[redacted]

In addition, LSO performs testing services such as accelerated aging and distribution studies for [redacted].

LSO also performs cleaning, steam sterilization, and inspection of [redacted] reusable surgical instruments and trays such as [redacted] and [redacted] sets and [redacted]

Different elements of QSR and ISO quality system were reviewed during the audit; refer to the schedule for the list of audited elements.

LSO still holds an FDA registration and ISO 13485:2003 certificate. The last FDA inspection was conducted in April of 2011 for a customer PMA device application. The last ISO 13485:2003 audit was conducted in April 2012. The ISO 13485:2003 certificate will expire in June 2015.

LSO currently has 70 employees, organization chart was reviewed.

Quality system requirements, CFR 820.20, 22, 25
Quality manual and top level SOPs were reviewed. Samples of following documents were reviewed:
Management review is performed once a year. SOP doc 4-01, rev C01. The last management review was performed in February of 2012, meeting minutes of this review was evaluated.
Organization chart, job descriptions review, and personnel qualifications were reviewed.
Training and job description, SOP 6-22, Rev D01. Job descriptions of Gary Fulbright, Dir. of Materials and Logistics and Ryan Kazemi, Quality Specialist were reviewed.
Training SOP 6-01, Rev C03 and training matrix were reviewed.

CAPA system, CFR 820.100
CAPA SOP, CAPA log, and two CAPA files were reviewed. The CAPAs were closed in a timely manner.
In 2012 there were 29 CAPAs issued at LSO, SOP CAPA 8-08, Rev E02.
[redacted]

Complaint system, CFR 820.198
Complaint SOP, complaints log, a sample complaint file were reviewed.
Complaint SOP 5-02 Rev C01. 51 complaints were issued in LSO system in 2012.
[redacted]

Internal audits, CFR 820.22
Internal audits SOP, internal audit log, and samples of internal audits were reviewed.
Internal audit SOP 8-01 Rev C02- All the 2012 internal audits are closed. Internal audits are performed once a year. The following internal audits were reviewed:
08-12, validation, steam sterilization
12-12, package test
05-12, warehouse, identification, traceability

2013 internal audits are scheduled for May 2013.

Production and process controls, CFR 820.70, 820.75
Clean room visit
Component cleaning room and assembly rooms
Clean room certifications
Cleaning process capabilities
Cleaning process validation
Bioburden control

Clean room SOPs, [redacted] product MPs, and routers, and actual product assembly per applicable MP were reviewed.
SOP 6-05, Rev C05, Manufacturing process control
SOP 6-08, Rev D02, Controlled environment practices.
Quarterly bioburden tests are performed in the clean room. All the levels were acceptable for the last 12 months. The bioburden sample collection is performed according to SOP 6-11, Rev E0.1, the samples are taken from different locations in the clean room.
SOP 6-21, Rev A01- Water system requirements- LAL testing of clean room water is performed quarterly. All the levels have been acceptable.
Clean room air pressure is checked daily by clean room staff.
Ultrasonic cleaner LSO-318T and LSO-170T were verified for calibration.
Clean room certificate was verified. The certificate is renewed every year and is issued by CIPA, Class 7, Due date 7/2013.
Assemblies of the following devices were verified against the applicable MPs in the clean room.
[redacted], Rev E, Sections 10.1, 10.2, and 10.12 were verified.
The operators are well trained, they follow the MP and are able to locate the MPs and applicable sections. All the parts in the clean room are properly identified with part number, lot number, and quantity.
[redacted]- Section 7.10 was verified, lot number 41494-2 was being assembled.
[redacted]

Document management, records, and training, CFR 820.40
Related SOPs, review of related routers and MP, review of sample training records for MPs, routers, and SOPs
SOP 4-04, Rev C03- Documentation system
SOP 4-06, Rev E02, Document change request. A sample DCR package was reviewed for completion and closure.
Three DHR records were reviewed for accuracy, completion, and closure.

Labeling and packaging controls, CFR 820.120 and 820.130
Review of related procedures and MPs, packaging and labeling equipment, and required tests per [redacted] product MPs, P/M and calibration records

Packaging-
Tray sealer LSO-114T was verified for calibration; timer, temperature and pressure controls all have separate calibration stickers.
Pouch sealer LSO-174T- was verified for calibration, due date 7/2013.

Labeling-
[redacted] box labels were verified. Labelview program is used for printing the labels. Labelview program version 6.0 and 8.56 were revalidated in October 2012- report V-LSO-005.
A barcode scanner is used for verifying the accuracy of barcodes for all the printed labels.

Nonconforming products, CFR 820.90
Review of procedures and materials handling

SOP 8-13, Rev. D03
Three NCRs were reviewed for completion and closure; 4080-12, 4055-12, and 4031-12.

Acceptance activities, CFR 820.80, 820.86
Receiving and Incoming inspection, review of procedures and [redacted] products DMR, CCP counts, inspection sample size requirements, handling of nonconforming materials

Identification and traceability and handling/storage/distribution, CFR 820.60, 820.65, 820.140, 820.150, 820.160
Warehouse and materials management, review of procedures, warehouse conditions, shipping records to Sterigenics
All [redacted] parts are identified with part number, lot number and quantity.

Inspection, measuring, and test equipment, CFR 820.72
Review of Accelerated aging equipment, distribution test equipment, test procedures, and P/M or calibration records
The following [redacted] were checked and verified at incoming inspection:
[redacted], cartons
[redacted]' Guidewire IFU
[redacted] Trays
All these parts are inspected according to the DMR.

Cleaning, sterilization, and inspection of reusable surgical, FDA Guidance document, May 2011
Instruments and trays- [redacted] and [redacted]
Review of procedures, MPs, and routers
Review of applicable tools and equipment (sterilization equipment), maintenance records (P/M and calibration)
Review of internal validation studies, IQ, OQ, PQ
Review of [redacted] trays processing records

SOP 6-17, Rev D01, Cleaning and disinfection of reusable instruments
SOP 6-19, Rev C01, Mixing and disposal solutions
Work instructions [redacted], cleaning of [redacted]

Three DHRs for processing of reusable instruments were reviewed:
[redacted]

Conclusions-
There was no observation or non-conformity from this site audit at LSO. The quality system is in compliance with the applicable elements of FDA QSR Part 802 and ISO 13485:2003.

SCHEDULE OF EVENTS:

Tuesday 1/29/2013

10:00 am	**Arrive at facility**
10:00 – 10:30 am	**Review of the audit agenda and summary of LSO quality system changes since last audit** Review of FDA registration and ISO 13485:2003 certificate Review of last FDA inspection and ISO 13485:2003 audit reports
10:30 - 11:00 am	**Quality system requirements, CFR 820.20, 22, 25** Quality manual and top level SOPs review, Management reviews, organization chart, job descriptions review, and personnel qualifications
11:00 - 11:30 am	**CAPA system, CFR 820.100** CAPA SOP, CAPA log, review of three CAPA files
11:30 - 12:00 pm	**Complaint system, CFR 820.198** Complaint SOP, complaints log, review of three complaint file
12:00 - 1:00 pm	**Lunch**
1:00 - 1:30 pm	**Internal audits, CFR 820.22** Internal audits SOP, internal audit log, review of three internal audits
1:30 - 3:00 pm	**Production and process controls, CFR 820.70, 820.75** Clean room SOPs [redacted] product MPs, and routers, review of actual product assembly per applicable MP
3:00 - 4:00 pm	**Document management, records, and training, CFR 820.40** Related SOPs, review of related routers and MP, review of sample training records for MPs, routers, and SOPs

Wednesday 1/30/2013

8:00 - 8:30 pm	**Clean room visit** Component cleaning room and assembly rooms - Clean room certifications - Cleaning process capabilities - Cleaning process validation - Bioburden control
8:30 - 9:00 am	**Labeling and packaging controls, CFR 820.120 and 820.130**

	Review of related procedures and MPs, packaging and labeling equipment, and required tests per [redacted] product MPs, P/M and calibration records
9:00 - 9:30 am	**Nonconforming products, CFR 820.90** Review of procedures and materials handling
9:30 - 10:30 am	**Acceptance activities, CFR 820.80, 820.86** Receiving and Incoming inspection, review of procedures and [redacted] products DMR, CCP counts, inspection sample size requirements, handling of nonconforming materials
10:30 - 11:00 am	**Identification and traceability and handling/storage/distribution, CFR 820.60, 820.65, 820.140, 820.150, 820.160** Warehouse and materials management, review of procedures, warehouse conditions, shipping records to Sterigenics
11:00 - 12:00 am	**Inspection, measuring, and test equipment, CFR 820.72** Review of Accelerated aging equipment, distribution test equipment, test procedures, and P/M or calibration records
12:00 – 1:00 pm	**Lunch**
1:00 – 2:00 pm	**Cleaning, sterilization, and inspection of reusable surgical, FDA Guidance document, May 2011** Instruments and trays- [redacted] and [redacted] - Review of procedures, MPs, and routers - Review of applicable tools and equipment (sterilization equipment), maintenance records (P/M and calibration) - Review of internal validation studies, IQ, OQ, PQ - Review of [redacted] trays processing records
2:00 - 3:00 pm	**Audit summary and closure** Review of observations and non-conforming found during the audit