[redacted]

Supplier Quality Management System Audit Report

Area audited (Auditee):	Life Science Outsourcing, 830 Challenger St, Brea, CA 92821 USA
Actual Dates of Audit:	12-December-2012
Date of Opening Meeting:	12-December-2012
Date of Closing Meeting:	12-December-2012
Lead Auditor:	[redacted]
Auditor(s):	Not Applicable
Audit Evidence / Circumstances:	The assessment was based on sampling and therefore nonconformities may exist which have not been identified.

Audit Scope and Objectives:	
Criteria / Standards covered: ☒ QSR (21 CFR820) ☒ ISO 13485 ☐ JPAL Ord. 169 ☐ CMDR ☐ MDD ☐ ISO 9001 ☐ OHSAS 18001 ☐ ISO 14001	**Objective:** Confirm compliance with applicable regulations and/or quality system standards *and compliance with the current Quality Assurance Agreement between* [redacted] *and the supplier.* **Scope:** - see Audit Plan / Agenda - assessment of the compliance with regards to products / services delivered to [redacted]

Certification:
We certify the audit as documented herein was conducted in accordance with the audit plan and according to the [redacted] Execution of Quality Audits".

Areas not covered, although within the audit scope:
N/A.

Audit Report Acknowledgement:

Function	Name	Signature	Date (dd-mmm-yyyy)
Lead Auditor	[redacted]	[redacted]	19 DEC 2012
Quality Manager / Management Representative	Mireya Lozano		

[redacted]

[redacted]

Confidentiality:

[redacted] Corporate Quality System Compliance, attests herewith that all matters discussed within the audit scope will be handled confidential and will be only shared between the auditee and employees of the companies belonging to the [redacted] Documents involving confidential or proprietary information will be suitably safeguarded by [redacted] at all times. No information marked by the auditee as "Confidential" will be transitioned to other parties, unless required by applicable legal and regulatory requirements (e.g. Certification Audits of Notified Bodies or inspections of Competent Authorities).

Audit Report Distribution List:	Mireya Lozano, QA/RA Manager *
	B. Kazemi, President and CEO, Life Science Outsourcing
	[redacted]
	[redacted]
	[redacted]
	[redacted]
	[redacted]

* = please communicate further into the organization as deemed appropriate

[redacted]

[redacted]

Audit Conclusions

Executive Summary

The audit objectives have been accomplished according to the audit plan.

There are no unresolved diverging opinions between the audit team and the auditee.

General Conditions and Comments

Positive:

- QMS structure appears well defined
- Facility organization and cleanliness is very good
- Staff knows the processes and documents are readily retrievable
- Training record effectiveness process is unique in how the record also contains a demonstration of the training was effective.
- The data analysis process

Concerns:

- none

Re-Audit:

Due to the Audit Result, there is no Re-Audit necessary.

[redacted]

[redacted]

Observations were identified in the following areas:
(Classification of Audit Findings see last page)

- none

Additionally **4** Comments were identified.
Comments (= Opportunities for Improvement) should be evaluated by the supplier management team and, if necessary, actions should be determined.

Comments

- Comment #1 – Section 4.2.3 of the Q-Manual appears to list the same paragraph twice in the document. The repeated paragraph should be removed as part of the current update being made to the Quality Manual.
- Comment #2 – The DCR form indicates whether training or validation is required via the use of a check box. It is suggested that the DCR form contain the rationale for not conducting training or not requiring validation as this would improve the robustness of the quality records
- Comment #3 - The Q-manual indicates the company complies with ISO 13845, 21CFR820, JPAL and CMDCAS. The Internal audit procedure only references the ISO standard and FDA regulation. It is recommended that the procedure be reviewed to ensure all applicable standards and regulations are being evaluated by the internal audit process.
- Comment #4 – As part of change control validations are reviewed to ensure the validation is not affected by the proposed change. It is recommended that LSO consider implementing a periodic review of all validations independent of the reviews conducted as part of the change control process. This independent review would allow LSO to ensure that compilation of changes over time has not impacted the validation.

Audit Follow-up:

For each audit observation identified as a result of Supplier QMS Audits, the supplier shall provide a Corrective and Preventive Action plan to [redacted] within 30 calendar days from the date of issue of the audit report.

It is expected that the supplier addresses [redacted] audit observations in a defined time.

Late or insufficient responses by the supplier may result in a reclassification of status and actions by [redacted], such as intensified incoming controls or blocking of the supplier.

The completion and effectiveness of actions will be verified in subsequent Supplier QMS Audits.

ATTACHMENTS

- Life Science Outsourcing Audit Notes – 4 pages

[redacted]

[redacted]

Classification of Audit Findings:

Classification	Description	Consequence
Critical Observation (A)	Indicates that a required element of the quality system has not been implemented at all or is highly ineffective.	**High priority**.
	Would likely result in significant regulatory action (i.e. warning letter or seizure, loss of certification / license).	Require immediate corrective action.
	Condition or issue that could directly effect (or did effect) the identity, quality, safety, "fitness for use" of a product. May lead to shipment of nonconforming product.	Re-audit and reporting, tracking within CAPA process.
	Could lead to severe product-, service- and/or patient safety issues.	Shall receive preference in allocation of resources.
Major Observation (B)	Indicates that a required element of the quality system has been incompletely implemented or is ineffective.	**Medium priority**.
	Likely to result in regulatory actions (i.e. FDA form 483 inspectional observation, withhold of certification / license).	Reporting and tracking within CAPA process.
	Significant number of minor observations in one area indicating a system weakness.	
	Repeats of previous minor observations, indicating ineffective or incomplete corrective action.	
	A condition or issue that could have a potential impact on the "fitness for use" and safety of product.	
Minor Observation (C)	Represents a lack of implementation within an element of the quality system, but is unlikely to result in significant regulatory action.	**Low priority**.
	A condition or issue where a potential impact on the "fitness for use" and safety of product is inconceivable.	Reporting and tracking within CAPA process.
	Improvement opportunities that have repeatedly not been considered.	May be escalated to "major" depending on frequency of occurrence.
Comment	Comments are used:	**Opportunity.**
	1] for issues or conditions that does not rise to the level of an observation.	Preventive actions may be indicated.
	2) to illustrate issues or conditions those have the potential to develop into an observation in the future and provide an improvement opportunity how to accomplish a task.	
	3] to present additional information related to an issue or observed condition.	
	4] to provide feedback on identified best practices.	
No observation	Evidence of conformity to a requirement.	**None**

End of Document

[redacted]