BIOTECH CLIENT, *MASSACHUSETTS, USA*

CASE STUDY

Qualified Person Guidance on Internal QMS Remediation Plan to Comply With EU GMPs

Quality, Compliance & Regulatory

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Overview

- Review gap assessment against EudraLex Volume 4 and assist in determining a path-forward for clinical/commercial phase-appropriate development of manufacturing quality systems.
- Conduct a site-visit to interview manufacturing stakeholders, gain a deeper understanding of the current state of quality systems, and collaborate with client on closing the gaps.

Challenge

A review of the methodology associated with the Consolidated GAP Assessment identified the fact that this was not a rigorous, line by line, fully traceable exercise. The exercise was rather a process to collate known GMP gaps to act as a baseline for remediation planning.

On that basis, the focus of the site visit pivoted to a collaborative workshop for each of the following areas:

- Facility Tour
- EM & Cross contamination
- Change Management
- Quality Systems Oversight, Metrics & Internal Auditing Program
- Manufacturing Control Strategy
- Verification and Validation
- Regulatory Strategy
- Product Specifications
- Material Specifications
- Risk Management
- Training
- Supply Chain and Vendor Management
- Gap Assessment Review
- Deviation & CAPA Systems
- Document Control
- Maintenance
- Data Management and Integrity
- Stability
- QP Certification Legal Structure
- Quality Culture
- E&L

In addition to the QMS the Consultant also highlighted the lack of program and project management controls in place as a significant risk to project success.

WHY CAI?

We were brought in because of our Global reach. CAI had an EU Qualified Person available who was an expert on EU GMP requirements. Our onsite personnel were able to rapidly set up a meeting between our EU resource and the Client.

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Solution

The general methodology employed during these workshops was as follows, this approach was made possible by the high level of familiarity with the CAI Consultant with Chapters and Annex's of Eudralex:

Scope of Area » **Identification of GAPs** » **Remediation Plan Reviews** » **Discussion of Timelines** » **Recommendations**

Results

The client was provided a high-level road map to remediate all gaps identified in QMS with respect to EU GMPs.

CAI subsequently led a workshop to develop an integrated project plan for the Client.