



CASE STUDY:

**Quality Management System for
Clinical-Stage Biopharmaceutical
Company**

JULY / 2019

Background

A clinical-stage biopharmaceutical company requested The Avoca Group perform an in-depth review and assessment of its Quality Management System (QMS).

The project objectives were to identify and document gaps and to provide guidance in the design and development of a comprehensive QMS that would complement the company's existing QMS.

The company also requested that Avoca review the requirements and implications of ICH E6 (R2) and their bearing on the company's current processes and recommend modifications required to achieve compliance.

Because the company was a Member of the [Avoca Quality Consortium](#)[®] (AQC), Avoca's project team leveraged AQC leading practices, where applicable.

Solution

Based on discussions with the client, the scope of work outlined below was executed by The Avoca Group.

Gap Analysis

- Avoca reviewed up to 75 relevant client documents and SOPs.
- Avoca SMEs interviewed up to 10 key stakeholders from the client's team. Interviews were approximately 45 minutes in length.
- Qualitative data collected from interviews helped Avoca assess the current state of the company's QMS and identify potential gap areas relative to ICH E6 (R2).
- Within six weeks of kickoff, Avoca SMEs provided a two-hour remote gap readout session with the client's key stakeholders.

Strategy Session

- Avoca conducted a two-day onsite strategy session with the client's key stakeholders to review the gaps identified, discuss the draft implementation roadmap, and determine the steps necessary for completion in the implementation phase.
- Avoca provided guidance on Avoca Quality Consortium tools available to close the gaps.
- Avoca identified and supported prioritization of gaps based on the gap assessment and implementation roadmap deliverables.
- The strategy session took place 12-14 weeks into the project.

Project Communication

- For a term of four months, bi-weekly meetings were held to evaluate alignment of client's needs with Avoca support.

Final Deliverables

1. The strategy session slide deck, including the gaps that were identified and prioritized.
2. A refined implementation roadmap from the strategy session.
3. An SOP tracker identifying the key gaps and recommendations for each document reviewed.

The introduction of ICH E6 (R2) has increased the requirements for a Quality Management System (QMS).

Project Assumptions

- Ready access and availability of systems, documentation, and key personnel (authors, etc.).
- Out-of-pocket expenses passed through to client.
- Client coordinated meetings and facilitated meeting logistics.
- Remediation assistance would begin after conclusion of strategy session.

Remediation Assistance

- Avoca provided several hours of remediation consulting hours to close any gaps identified in the QMS gap analysis, including but not limited to organizational trainings that were required.

Conclusion

The client was provided with a clear understanding of the gaps, potential risks, and best practices available to mitigate and remediate the gaps.

To inquire about QMS consulting services for your organization, contact Dawn Auerbach at dawn.auerbach@theavocagroup.com.