CASE STUDY:

CQMS CONSULTING PROJECT FOR A CLINICAL-STAGE BIOPHARMACEUTICAL COMPANY

AUGUST / 2020

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Background

A clinical-stage global biopharmaceutical company with major hubs in the US and Japan requested The Avoca Group perform an in-depth review and assessment of its Clinical Quality Management System (CQMS) with a special focus on Vendor Oversight, Risk Management, Technology Business Requirements, and Quality Tolerance Limits (QTLs).

The project objectives were to identify and document current gaps relative to recently refined global regulations and industry leading practices, and to provide guidance in the design and development of vendor oversight practices, including centralized approaches for oversight and risk management to align and enhance their regional units to integrated processes and tools that enhance their comprehensive global CQMS. A focused section of this project included a Technology Business Requirements Analysis which was integrated into an ongoing global project at the company.

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 then author 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

The scope of work is outlined below:

Gap Analysis

- Avoca conducted a Vendor Oversight, Quality Governance, and Clinical Study Conduct Process Needs Assessment and Gap Analysis
    - 97 SOPs or related Work Instructions, Templates/Tools Reviewed
    - 26 Key Stakeholder Interviews for 45 minutes each
- Qualitative data collected from interviews helped Avoca assess the current state and identify potential gap areas relative to ICH E6 (R2) and current CQMS
- Technology Business Requirements Analysis
    - 20 voice-of-customer interviews with stakeholders and potential end-users from GCP and GLP groups
    - Review and analysis of 10 process maps, work instructions, and SOPs
- Eleven weeks after project kick-off, three Avoca SMEs provided a two-hour remote gap read-out session with the client's key stakeholders

Strategy Session

- Twenty weeks after project kick-off, Avoca conducted an onsite three-day Strategy Session with five SMEs and the client's key stakeholders to review the gaps identified, develop a draft implementation roadmap, and then determine the steps necessary for closing the gaps
- Avoca also conducted a one-day onsite Strategy Session to review and finalize the implementation steps for resourcing a central vendor oversight construct
- Avoca provided guidance on Avoca Quality Consortium tools that are available to close the gaps
- Avoca defined and documented Technology Business Requirements for Clinical Operations and Research Quality in a format that was acceptable to the company's IT department
- Avoca identified and supported prioritization of any gaps based on the gap assessment and implementation of roadmap deliverables

Project Communication

- Eight-month term of support with weekly check-in meetings to evaluate alignment of client's needs and Avoca support

Final Deliverables

(Including three months of Implementation Support following the Strategy Session)

- Process maps for Vendor-Level and Trial-Level Oversight
- Vendor Oversight and Capability Maturity Model Assessment
- Central Vendor Oversight Construct Proposal
- Clinical Vendor Risk Categorization (VRC) Tool
- CQMS Periodic Assessment SOP, Plan Schedule, and Scorecard
- Performance Metrics Catalog
- Authored or Revised SOPs, Work Instructions (WIs), and templates
    - 12 New SOPs, WIs, Templates Developed
    - 9 SOPs, WIs, Templates Revised
- QTL Training session and materials for use within LMS system
- Onsite workshop on metrics and the definition of QTLs on one pivotal trial
- Technology Business Requirements Interview Script
- Technology Business Requirements Stakeholder Interviews
- Technology Business User Assessment Report (BUAR)

Project Assumptions

- This support assumed ready access and availability of systems, documentation, and key personnel (authors, etc.)
- Out-of-pocket expenses passed-through to client
- Client coordinated the scheduling of meetings for attending participants and facilitated the logistics of the meeting location and corresponding needs

Results

The client received an integrated, holistic set of solutions that were designed with fit-for-purpose use across global regions, including US, Europe, Japan, and China to enable an integrated approach to align across their organizational units and to enable quality and compliance when contracting with and providing oversight for strategic and high-risk vendors. ICH E6 (R2) compliant risk-based approaches were established for vendor-level and trial level solutions.

Conclusion

The client obtained an enhanced understanding of global regulatory requirements and was delivered numerous fit-for-purpose SOPs, WIs, templates, tools, and training programs to elevate quality and compliance. These deliverables were available for immediate implementation.

To inquire about QMS consulting support for your organization, contact Dawn.Auerbach@theavocagroup.com.