Quality Management System Consulting Service

The Avoca Group’s Consulting Service for the design, development, and implementation of a Quality Management System (QMS) aims to help sponsors and CROs develop a culture of risk prevention rather than one of managing issues, to ensure patient safety, improve data quality, provide data integrity, and increase inspection preparedness.

- Collaboratively work with stakeholders to develop the project charter and define the roles and responsibilities.
- Interview key stakeholders to assess the current state and define the desired state.
- Review relevant SOPs or procedures and associated tools and work instructions.
- Identify gaps related to external regulations and leading practice.
- Provide a gap assessment report and implementation roadmap to close the gaps.
- Provide leading practices, tools, and templates to build a fit-for-purpose toolkit.

Based on the identified gaps and implementation roadmap, Avoca experts assist with:
- Development of:
  - Customized training materials.
  - Metrics.
  - Staffing requirements.
  - The strategy and setting the stage for change management, including execution of the communication plan across the organization.
- Revisions to SOPs and/or work instructions.
- Training sessions.
- Conduct of mock audits.
The Avoca Group Advantage

Gain Peace of Mind
This service is based on our 20+ years of experience with risk mitigation, quality improvement, and commitment to efficiency in clinical trial execution.

The Avoca Group’s 12 Components of a Leading Practice QMS
The Avoca Group’s consulting team developed a 12-component construct to facilitate comprehensive, robust gap assessments of your existing QMS:

- Quality Agreements
- Quality Metrics Taxonomy
- KPIs and KQIs
- Policies/Procedures
- Vendor Management/Oversight
- Training
- Clinical Risk Management
- Knowledge Management
- Quality Culture
- Inspection/Audit Management
- Issue Management and CAPA
- Documentation and TMF/eTMF

Remove the Guesswork
Using our construct, we help to ensure your QMS is compliant with current regulatory requirements (e.g., ICH E6 (R2)) and leading industry practices and standards.

Fill the Resource Gap
We alleviate time, staff, and other resource constraints that prevent compliance and preparedness assurance — allowing your team to focus on their core responsibilities. To simplify and streamline the successful implementation of your company’s QMS, we leverage the more than 400 quality management and inspection readiness leading practices, tools, and standards developed and refined by the Avoca Quality Consortium® (AQC).

To ensure your QMS is appropriate and compliant, email us at info@theavocagroup.com.