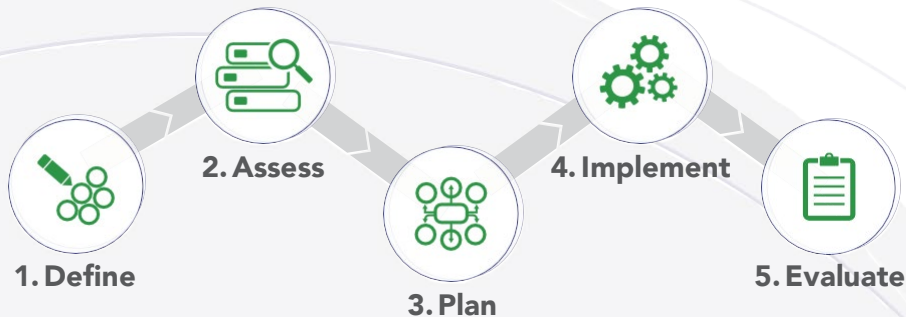


## Quality Management System Consulting Service

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**.

### IDENTIFYING THE GAPS

### CLOSING THE GAPS



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



Move from *readiness* to *preparedness*.

**Readiness:** Being ready only for a *single* inspection event

**Preparedness:** Always prepared for *any* inspection event

## 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).

**Gain Peace of Mind. Remove the Guesswork. Fill the Resource Gap.**

To ensure your QMS is appropriate and compliant, email us at [info@theavocagroup.com](mailto:info@theavocagroup.com).