

## Consulting Services for Inspection Readiness

The Avoca Group's Consulting Services for Inspection Readiness provide full management through point-of-need support for inspections. We aim to help sponsors and CROs develop a **culture** and **mindset** that are **committed to quality** through **proactive risk management**, ensuring an inspection readiness state throughout the entire clinical program.

## The Avoca Group Advantage

Our inspection preparedness model offers a comprehensive system that provides confidence for our clients.



**Failed inspections can cost \$200M or more in opportunity costs and direct costs associated with remediation.\***

\*Boston Scientific Resolves FDA Warning Letter; Wall Street Journal, August 11, 2010

## Leverage Our Expertise

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

We develop strategies, plans, and tools to navigate the diverse, changing inspection environment.

- Leveraging our knowledge and information from daily inspection experiences.
- Utilizing the Avoca Quality Consortium® (AQC) Knowledge Center repository of global regulatory agency approaches to inspections and other industry experiences.
- Proactively aligning all Avoca processes and materials with new regulatory guidelines (e.g., ICH E6 (R2)).

Clients benefit from a full team of dedicated subject matter experts (SMEs) who are paired to each project based on expertise and ability to assess the areas of need.

- Support for inspection readiness.
- Quality and compliance consulting/remediation support.
- Dedicated, embedded inspection lead to manage and report on inspection preparation activities.

## Trust Our Proven Process

Our agile inspection preparation process is based on industry-leading practices and tools for inspection readiness and proactive, ongoing inspection preparedness developed in collaboration with the 120+ AQC Member companies.

### The Avoca Group's Agile Inspection/Audit Preparation Process



## Be Inspection Ready

With The Avoca Group's Consulting Services for Inspection Readiness, you can:

- Discover trial-related issues with sufficient time to effectively manage the inspection risk.
- Avoid delayed product launches and internal remediation costs resulting from inspection findings.
- Gain insight into the inspection focus of regulatory authorities.
- Provide your staff with the experience and tools needed for inspection preparedness and the situational competency to handle inspectors and auditors in either a face-to-face or virtual setting.
- Develop storyboards or other tools to articulate the changes in processes or plans due to COVID-19 mitigations.
- Organize and collate trial-related documentation so it is as organized/comprehensive as possible before a true inspection/audit.

### Leverage Our Expertise. Trust Our Proven Process. Be Inspection Ready.

To ensure your organization is inspection ready, email us at [info@theavocagroup.com](mailto:info@theavocagroup.com).