Consulting™

Advarra Consulting

Overview

Advarra Consulting's proactive, collaborative approach helps pharmaceutical, medical device, biopharmaceutical firms, as well as contract research organizations, academic institutions, health systems, and other research sites strengthen and grow their research enterprises. Advarra's experts will help your organization:

- **Maintain compliance and minimize regulatory risk**
- **Protect the safety and welfare of clinical trial subjects**
- **Improve performance and move research forward**

The Advarra Consulting Advantage

- US company with a global presence
- Industry-leading expertise in GxP auditing and compliance consulting
- International regulatory consulting for drug, device, biologic, biobanking research and other regulated activities
- Superior research administration and human research protection (HRP) consulting and solutions
- Highly customized services to fit your needs and requirements
- Proven methodologies including Quality by Design techniques and Agile project management
- Diverse service offerings for quality assurance (QA) and HRP resources and solutions
- Primary focus on quality needs and regulatory requirements
- Collaborative partnership with our clients
- Solutions for clients of all sizes and types

Specialized Consulting & Evaluation Services for Research

- GxP Auditing and Compliance Consulting
- Regulatory Affairs/ Human Research Protection/ Research Administration Consulting
- Global Capabilities
- Protocol Development

The Advarra Consulting Team

Advarra's highly knowledgeable team of GxP and regulatory professionals have served as physicians, research nurses, study coordinators, project managers, IRB members, IRB administrators, clinical monitors, data reviewers, and auditors. Team members typically have 10 to 35 years of relevant experience.

A Managing Director is assigned to each client to be responsible for quality oversight of services, deliverables and communications.

US Company/Global Services

- Proven expertise in clinical trial auditing support and assistance in developing clinical quality assurance (CQA) programs and infrastructure
- Expertise in non-clinical laboratory, bioanalytical, and good manufacturing auditing and advisory services
- Services that complement typical auditing practices, including:
  - Regulatory inspection readiness and preparedness: mock inspections, training, and support for sponsors and sites
  - Clinical vendor oversight management training and consulting
  - Virtual QA services – infrastructure support and planning, quality program plans, training, ad-hoc support
  - Quality systems and standards development – advisory consultation and development of optimal processes, workflow, and standards
- Solutions for institutions including:
  - IRB/HRP process development and program evaluations
    - » IRB, ethics committee, and data and safety monitoring board (DSMB) startup
    - » IRB education and training
    - » Accreditation services
- Biosafety process development and support
  - Institutional biosafety committee (IBC) startup and registration
  - IBC education and training
- Federal agency response advisory services
- Specialized and strategic ad-hoc consulting

Breadth of services, including:

- Clinical trial auditing support
- Clinical vendor support
- TMF review and consulting
- Pharmacovigilance support
- Quality management system review and risk evaluation
- CQA programs and infrastructure development assistance

Ready to make your research altogether better?

Contact Consulting@advarra.com to get started.

ADVARRA

advarra.com