ADVARRA®
advancing better research

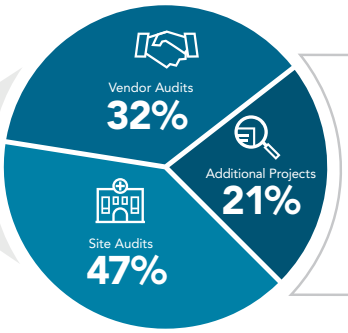
GxP Auditing, Compliance, & Specialized Consulting

Capabilities & Services Menu

Advarra's experts can work directly with your team to provide consulting and evaluation services related to GCP, GMP, GLP, GVP, GDP, and quality assurance (QA).

Proven Processes & Support

2,500+
Projects

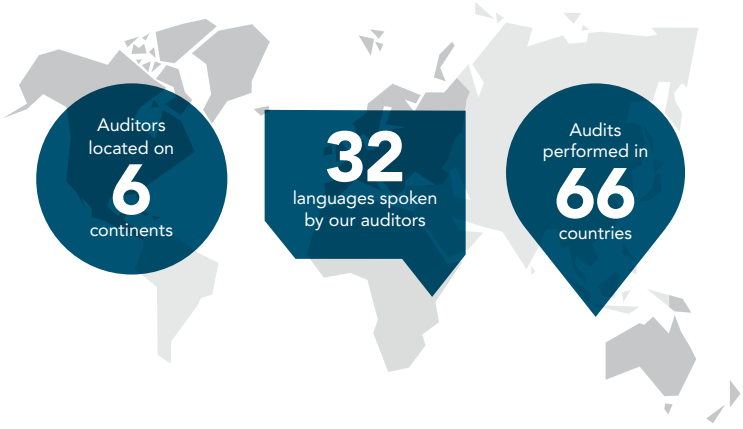


- **168** Mock inspection and inspection readiness programs
- **151** Document audits
- **60** SOP writing/gap analyses
- **49** Internal assessments
- **35** GxP training programs
- **63** Other

- Each client is assigned a **dedicated** project manager
- **Extensive** experience in pharmaceutical, biotech, & medical device research
- Experience with **leading** clinical quality management systems (QMS)

10+ years
Minimum auditor experience across more than 100 employees and qualified contractors

Providing customized GxP support for over
19 years



Data collected from 2016-2019

Files are shared via Advarra's secure cloud-based file share system or the client's preferred system.

Services Menu

Qualification Assessments & GxP Auditing

- Investigator site audits
- Vendor assessments and audits
  - CROs, Phase I units, imaging, packagers, distributors, clinical and non-clinical laboratories, eSystem providers, registries, and institutional review boards (IRBs)/ institutional ethics committees (IECs)
- Document audits
  - Investigator brochure
  - Protocol
  - Informed consent form (ICF)
  - Clinical study reports
  - Safety narrative audits
  - Regulatory submission document audits (e.g., clinical summaries, safety update reports, integrated summaries of efficacy [ISEs]/integrated summaries of safety [ISSs])
- Trial master file audits
- Clinical data audits
  - Tables, figures, and listings (TFL) and databases

Virtual or On-Site Clinical Quality Assurance (CQA)

- CQA program development and infrastructure planning
- Development of CQA program plans and audit plans
- CQA support
- GCP training
- Ad hoc CQA consultancy

Quality System & Written Standards Development

- Quality system/SOP gap analysis
- Internal systems and process assessments/mapping
- SOPs/policies development
- SOP administration and system development

Virtual or On-Site GxP Training

- Investigators and coordinators
- Clinical research associates/clinical trial managers
- Clinical vendor oversight/management
- Regulatory inspection preparedness

Document Management System Support

e.g., electronic document management system (eDMS), trial master files (TMFs)

- Trial master file development
- Inspection readiness preparation
- Quality control
- Quality assurance

Regulatory Inspection Readiness & Preparedness

- Mock regulatory inspections
- Sponsor/CRO and investigator site preparedness
- Inspection support, facilitation, and response

Clinical Document Quality Control

- Investigator brochures/package inserts
- Protocols and ICFs
- Clinical study reports and subject safety narratives
- Regulatory submission packages and periodic safety update reports
- Common technical document (module 2) clinical summaries, ISE, and ISS documents
- TMF quality control and support

Safety & Pharmacovigilance Support

- Safety surveillance and pharmacovigilance systems audit support
- Sponsor internal assessments
- Pharmacovigilance system master file assessments
- Marketing partners
- Risk evaluation and mitigation strategy (REMS) assessments

Ready to make your research **altogether better?**

Contact **consulting@advarra.com** to get started.

ADVARRA®

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