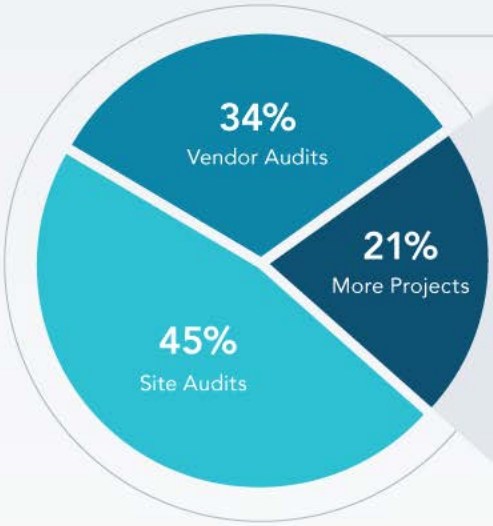
Consulting™

GxP Auditing, Compliance, and Specialized Consulting

Capabilities and Services Menu

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

Proven Processes and Support



6,900+ GxP-related projects

- **250+** Mock inspection and inspection readiness programs
- **860+** Document audits
- **50+** SOP writing and gap analyses
- **160+** Internal assessments
- **350+** TMF
- **90+** GxP training programs
- **65** Other*

*Includes for-cause, staff augmentation, ad-hoc, etc.

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

10+ years
Average auditor experience across more than 140 employees and qualified contractors

75 countries
Auditors located on six continents performing audits in 75 countries

23+ years
Providing customized GxP support

32 languages
Spoken by our auditors

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

Data collected from 1999-2022

Services Menu

Qualification Assessments and 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 and 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 and 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 and 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