

GxP Quality Excellence for Every Project at Every Stage

Life sciences companies of all sizes rely on Advarra as a trusted and proven partner to achieve GxP excellence in their current and future studies. With a flexible engagement model, an ethics-driven approach, and established reputation, Advarra can help you establish, review, or make corrections to your quality programs wherever you are in the development journey.

Comprehensive GxP Expertise You Can Trust

With over 1,500 GxP projects completed annually across pharma, biotech, and medical device research, Advarra is one of the largest and most experienced GxP services providers in the world. You can be assured that Advarra brings extensive depth of knowledge to reviews and audits for GCP, GCLP, GLP, GMP, GVP, CSV, and more.

Global Reach, Local Expertise

With experience in 75 countries over the last 25+ years, Advarra can help you wherever your study is based. Our auditors speak 32 languages, and each have over a decade of experience in international and local regulatory requirements, so you can be compliant everywhere you conduct studies.

Services That Are Fit-For-Purpose

Whether you are a small organization with your first product or a large multi-national company with hundreds, Advarra is ready to work with you at any scale. We can advise on any part of your project — from system setup to mock inspections, and anything in between — to help you ensure robust quality control processes are in place and that all applicable regulatory guidelines are met.

Advarra Consulting brings a standardized approach and an unparalleled depth and breadth of expertise to on-site, hybrid, and remote audits, including:

- GxP audits
- Investigator site audits
- Pharmacovigilance audits
- Clinical & specialty laboratory audits
- Computer systems validation audits
- Process or system audits
- TMF audits
- M&A and integrations due diligence
- Internal assessments and gap analyses
- Directed and for-cause audits
- Inspection readiness and mock inspections

Make Quality Your Competitive Advantage

Planning, running, and inspecting your quality efforts doesn't have to be a challenge with Advarra GxP Consulting. Advarra can provide the following services to ensure your quality systems are as robust as possible.



Quality Management System (QMS) Development & Maintenance

Translate industry standards for quality management systems into an agile, fit-for-purpose solution designed to scale with your growing organization. Available services include:

- Systems evaluation and gap analyses for existing or planned QMS build
- Developing templates, processes, and SOPs to manage risk
- Support from cross-functional team of quality experts



Inspection Preparation and Readiness

Take proactive steps by staging simulated inspections to identify and address potential issues prior to an official inspection by the FDA, EMA, etc. Advarra can provide:

- Gap analyses
- Mock inspections
- Review debriefs and coaching
- Situational competency training
- Storyboard development



Process Optimization for ICH GCP E6(R3) Readiness

Ensure that all policies, procedures and processes include new guidance and changes from ICH before they become regulatory requirements, such as:

- Updated data governance
- Security of essential records
- Quality-by-Design in protocols and processes
- Risk-based approach to quality
- Patient-first and data-first policies
- Clearly defined roles and responsibilities



Staffing Services for Quality Management

For companies that need their teams to scale on-demand, Advarra can easily assimilate into teams of all sizes and at all stages to get you up and running as quickly as possible. With Advarra, you can staff:

- Senior consultants
- Subject matter experts (SMEs) with 20+ years of experience in quality management
- Industry practitioners
- Short and/or long-term project managers
- and more