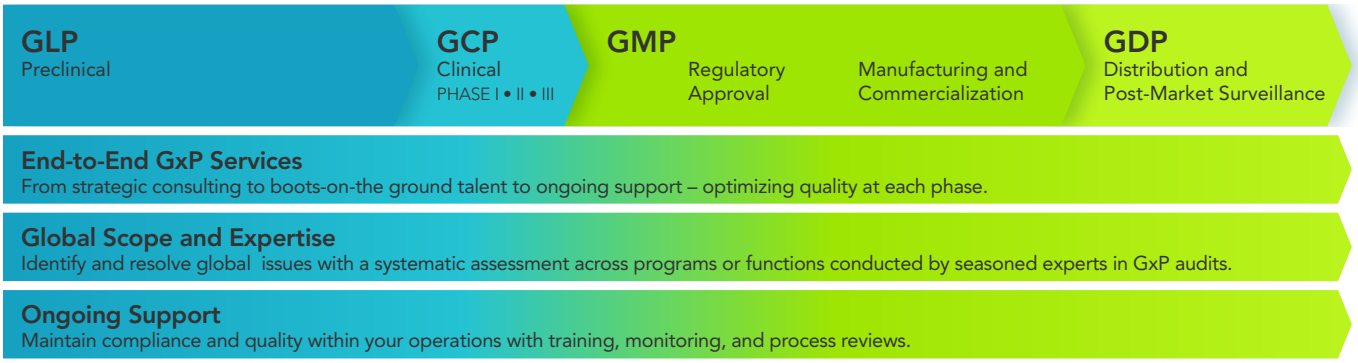
Consulting

Quality Center of Excellence

Make quality your competitive advantage



Delivering Industry-Leading GxP Solutions for the Clinical Research Life Cycle

Quality Solutions and Services

Our subject matter experts offer the skill and experience to support our clients across the full development lifecycle, including: Good Clinical Practices (GCP), Good Documentation Practices (GDP), Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP), and Good Pharmacovigilance Practices (GVP), and IT Quality. Our foundational solutions are customized to the unique needs of our clients and represent a sampling of the value our team can deliver.

Advarra's Quality Center of Excellence Helps:

- Establish quality programs that bridge organizational silos and achieve company objectives
- Proactively reduce the risk of non-compliance
- Address immediate, critical failures with speed and agility
- Diagnose and remediate the root cause of broader, more complex quality concerns

As value chains extend around the globe, regulations evolve, the need to maintain and optimize quality management systems has become more critical.

> " A company with a highly developed culture of quality spends, on average, $350 million less annually fixing mistakes than a company with a poorly developed one."
>
> -Harvard Business Review

Quality Management Systems

Program optimization for:

- Major regulatory, organizational, or market changes
- Mergers and acquisitions
- Emerging biotech and biopharma
- System non-conformities
- Compliance training

Audits

- Investigator clinical sites
- Vendors
- IT/lifecycle management
- Data integrity
- Process or system audits
- Pharmacovigilance
- Due diligence (M&A)

Health Inspection Readiness and Remediation

- Readiness evaluation and preparation support for sponsors and sites
- Mock inspections
- Inspection support and facilitation
- Remediation

Let Our Experience be Your Advantage

Our subject matter experts are accomplished industry practitioners. Together we ensure the efficient, compliant progression of your product from preclinical and clinical phases through to approval, manufacturing and distribution—optimizing quality at each step. Our quality team includes professionals with life-long careers working alongside regulatory agencies and certifying bodies as well as professionals who worked within them. We use our extensive experience developing and utilizing industry best practices to bring practical, risk-based thinking to our client organizations.

Advarra Consulting Centers of Excellence

- Quality
- Regulatory
- Clinical
- Institutional Research

Featured Subject Matter Experts in Quality

Joan Versaggi, MBA
Principal, Quality CoE
Former Director at Merck

Joan leads a diverse team of quality experts offering their in-depth experience and knowledge across GxPs to deliver solutions that ensure quality and compliance across the clinical research lifecycle.

Anthea Dransfield
Former Senior Director of Quality Management at ProSciento, Inc.

Arti Bajpai
Former Senior Director R&D Compliance & Process at Shire

Claudia Malcolm
Former Senior Clinical QA Manager at ICON

Dawn Wydner
Former FDA Consumer Safety Offcer, LCDR

Liz Wool
Former Global Head of Training at Barnett International, Inc.

Peter Marks
Former Head of Quality & Continuous Improvement at Merck Sharp & Dohme Corp.

Penelope Przekop
Former Senior Director of Global Quality Assurance & Training at Theradex Systems

Steffen Engel, PhD
Former Executive Director of Analytical Development at West-Ward Pharmaceuticals

To learn more, contact our Consulting Team at Consulting@advarra.com

ADVARRA
advarra.com