Consulting™

GMP Auditing, Compliance, and Specialized Consulting

Capabilities and Services Menu

Advarra® helps clients minimize risk and maintain compliance with good manufacturing practice (GMP) and good tissue practice (GTP).

Providing GMP Auditing, Compliance, and Specialized Consulting for Over 13 Years*

GMP Areas of Expertise

- Validation
- Quality Assurance (QA) and Quality Control (QC)
- Vendor Qualification/In-Process/For-Cause
- Readiness Inspections (Sponsor and Vendor)
- Training
- Internal Assessments
- Quality Management Systems (QMS)

Collaborative Client Partnerships:

- ✓ Pharmaceutical
- ✓ Biosimilars
- ✓ Biotech
- ✓ Cell Therapy
- ✓ Medical Devices
- ✓ Proteomics
- ✓ Combination Products
- ✓ Cannabis

Each client is assigned a **dedicated** project manager

Proven processes and solutions

Experts in GMP and GTP

Experience with **implementing and maintaining** QMS

ADVARRA™

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

Services Menu

Validation From facilities factory acceptance testing (FAT) support to high-level validation approaches to detailed on-site services, our professionals can help:	• Facilities and utilities commissioning and qualification • Equipment qualification • Laboratory/analytical equipment and instrument qualification	• Computer systems validation • Manufacturing and packaging processes validation • Cleaning validation • Ad-hoc consultancy
Master Plans An effective validation master plan ensures aligned expectations, informed commitments, and improved budgeting, scheduling, and project management. Our experts can help develop a plan to:	• Meet regulatory requirements • Coordinate commissioning, qualification, and validation activities	• Control cost and schedule • Ensure best practices • Ad-hoc consultancy
Regulatory Our experienced regulatory consultants can assist with early-stage strategy discussions through IND submissions for US, EU, and other regions worldwide, including:	• Technical authoring or review of regulatory submissions • Chemistry manufacturing and controls (CMC)	• Ad-hoc consultancy
Compliance Programs Successful compliance requires knowledge of the current regulatory environment and effective quality/risk management. We can help with:	• Assessing existing quality systems • Conducting risk assessments • Developing effective and "right-sized" compliance programs and quality systems	• Ensuring best practices in cGMP, GLP, GTP, ISO, CLIA • Ad-hoc consultancy
Audits Credible audits are essential for demonstrating and maintaining compliance. Our professionals can help with:	• Third-party audits/supplier selection audits • Benchmarking and gap analysis • Quality improvement	• Regulatory inspection readiness • Critical phase audits/reviews • Development through commercial manufacturing
Training We can help develop and promote employee behavior that aligns regulatory requirements with business goals, including:	• Training for GxP compliance • Quality assurance strategies	• Report writing, deviation reporting, and root cause workshops

Ready to make your research altogether better?

Contact Consulting@advarra.com to get started.

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