Regulatory Consulting

Our regulatory consultants take action and move your research forward. If you're looking for help in the development of innovative life science and digital health products, then Advarra® is the answer.

Why Advarra?

Whether in the United States, Canada, or around the globe, Advarra regulatory experts provide the answers you need to take action and accelerate your clinical trials. We track and address the ever-changing regulatory landscape and generate noteworthy content for publications and professional presentations in the clinical trial field.

Diverse Expertise

Drug, device, biologic, & dietary supplement clinical trial regulatory requirements	Clinical trial agreements	Biorepository creation and management	Clinical trial recruitment campaigns	ICF development
Online research	Genetic research	Gene transfer research	Stem cell research	AAHRPP Accreditation
HRPP development	GxP guidelines	Institutional jurisdiction and authorization agreements	Specimen collection and procurement	Participant recruitment through social media
Research using mobile technology	IRB reviews	IBC reviews	IACUC reviews	Research exemptions
HIPAA and PIPEDA	21 CFR Part 11	Product marketing research		

Regulatory Compliance

Advarra's experts help clients navigate and understand the changing regulatory landscape. Our trained regulatory attorneys and compliance professionals have direct expertise in providing effective solutions to complicated clinical trial and product development scenarios. If your goal is to stand up effective compliance programs, Advarra provides the direct support, training, procedures, and implementation plans to help achieve your objectives.

Strong Representative Portfolio

- Prepare organizations for agency inspections
- Draft responses to Form 483 findings and warning letters to reduce further agency action
- Implement Part 11-compliant systems, including appropriate controls for closed and open systems as well as electronic signatures
- Assess HIPAA compliance and elminate gaps
- Re-engineer GxP procedures and processes
- Conduct clinical research audits
- Produce corrective and preventative actions for HRPP noncompliance
- Develop conflict of interest policies and provide ongoing review of management plans

Advarra delivers knowledgeable and reliable regulatory advice and compliance solutions tailored to the needs of leading CROs, hospital systems, academic medical centers, and independent researchers.

Need help navigating the evolving regulatory landscape?
Contact Consulting@advarra.com to get started.

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