Kinetiq 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 Kinetiq is the answer.

Why Kinetiq

Consulting is our passion. Whether in the U.S., Canada, or around the globe, Kinetiq regulatory experts provide the answers you need to **take action—and accelerate your clinical trials.** We track and address the ever-changing regulatory landscape. We hold the professional degrees and certifications you'd expect. Plus, we generate noteworthy content for publications and professional presentations in the clinical trial field.

Regulatory Compliance

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

Diverse Expertise

- Drug, device, biologic, and dietary supplement clinical trial regulatory requirements
- Clinical trial agreements
- Biorepository creation and management
- Clinical trial recruitment campaigns
- Informed consent development
- Online research
- Genetic research
- Gene transfer research
- Stem cell research
- AAHRPP accreditation
- HRPP development
- GCP
- Institutional jurisdiction and authorization agreements
- Specimen collection, specimen procurement
- Participant recruitment through social media
- eConsent implementation
- Research using mobile technology
- IRB review
- IBC review
- IACUC review
- Research exemptions
- HIPAA, PIPEDA
- Part 11
- Product marketing research

Strong Representative Portfolio

- Prepare organizations for agency inspections to ensure readiness
- 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 and electronic signatures
- Assess HIPAA compliance and eliminate gaps
- Reengineer GCP procedures and processes
- Conduct clinical research site audits
- Produce corrective and preventative actions for HRPP noncompliance
- Develop conflict of interest policies and provide ongoing review of management plans

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

Contact us at info@KinetiqIdeas.com for more information.

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