
FDA QRC
From Clinical to Commercial. FDAQRC Has Your Compliance Covered.
FDAQRC.COM

FROM CLINICAL TO COMMERICAL

CLINICAL COMPLIANCE
GCP, clinical operations, BIMO, and inspection support

LABORATORY COMPLIANCE
GLP, GcLP, laboratory quality systems, and compliance assessments

QUALITY SYSTEMS
QMS development, implementation, assessment, and optimization

GMP COMPLIANCE
Manufacturing quality, quality systems, remediation, and inspection readiness

AUDITING & ASSESSMENTS
GxP audits, gap assessments, and compliance evaluations

INSPECTION READINESS
Mock inspections, preparation, investigator support, and 483 responses

VALIDATION & QUALIFICATION
Computerized System Validation (CSV), processes, equipment, and facilities

REGULATORY SUPPORT
Regulatory strategy, submissions, responses, and compliance guidance

REMEDIATION
Root cause analysis, CAPA, remediation planning, and implementation

SAFETY & PHARMACOVIGILANCE
Pharmacovigilance (PV/GVP), safety systems, REMS, and safety compliance

COMMERCIAL COMPLIANCE
Support for quality and compliance as products move toward and through commercialization

FDA|QRC

CONTACT US

info@fdaqrc.com

+1 (866) 400.8996

Global Experts | **fdaqrc.com**

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About

FDAQRC (FDA Quality and Regulatory Consultants) provides GxP expertise and practical quality and regulatory support to life sciences organizations worldwide. Since 2009, we have helped pharmaceutical, biotechnology, medical device, and other regulated organizations navigate complex compliance challenges and strengthen their quality and regulatory programs.

Our team brings together experienced industry professionals and former health authority investigators with expertise across GCP, GLP, GcLP, GMP, GDP, pharmacovigilance, BIMO, CSV, quality management systems, auditing, inspection readiness, and regulatory compliance. We provide practical support ranging from proactive quality assessments and inspection preparation to remediation and regulatory response.

COMPLIANCE ARCHITECTS® FDAQRC recently acquired Compliance Architects, expanding our capabilities across GMP, quality systems, commercial operations, remediation, and inspection preparedness while complementing our established expertise in clinical, laboratory, and regulatory compliance. Together, our expanded team supports clients across the product lifecycle—from clinical development and laboratory operations through manufacturing, commercialization, and beyond.

With a global network of professionals and experience across diverse regulatory environments, FDAQRC helps organizations identify risks, strengthen quality systems, prepare for inspections, and navigate compliance challenges with confidence.

70+ Countries

We provide quality, regulatory, and compliance support to life sciences organizations across global markets.

500+ Consultants

Our global network includes experienced quality, regulatory, compliance, and legal professionals with specialized industry expertise.

Since 2009

FDAQRC has helped life sciences organizations navigate complex quality and regulatory challenges.

Former FDA & Health Authority Experts

Our team includes professionals with firsthand experience working with the FDA and other global health authorities.

Clinical to Commercial

We support clients across the full product lifecycle, from clinical development and laboratory operations through manufacturing and commercialization.

Quality, Regulatory & Legal Support

Our multidisciplinary expertise helps organizations address compliance challenges from multiple perspectives and develop practical solutions.

Looking Ahead: The Future of Compliance Is Intelligent.

FDAQRC will be bringing enterprise search, document intelligence, and private AI together in a secure, governed environment designed for regulated organizations in 2027.

It's time to think ahead and explore how AI can help your team find information faster, understand documents in context, and turn regulated data into actionable insights—without losing sight of access, traceability, or human oversight.

Ask us about the Key to Compliance demonstration and see what's possible.

What's Next?

Whether you're preparing for an inspection, addressing a compliance gap, strengthening your quality systems, or planning for the next stage of your product lifecycle, FDAQRC is here to help. Our team brings practical GxP expertise, regulatory insight, and specialized industry experience to help you identify risks, navigate challenges, and move forward with confidence.

Let's talk about what's next for your organization.



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