GENBIOCA
Domain Led, Technology Services Company

WE ARE THE TRUSTED



Regulatory and Compliance Partner

Regulatory and Compliance Services:
Navigate the Regulatory Maze.
Accelerate Time to Market.

Technology-Powered Compliance for the Life Sciences Sector

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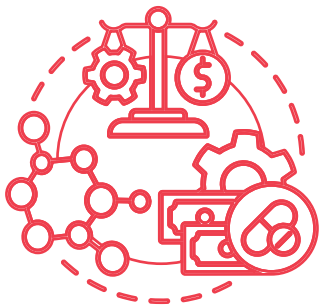
Regulatory and Compliance

Regulatory complexity isn't just a hurdle—it's a major source of delay and risk. In a landscape of constantly evolving global regulations, staying compliant is more challenging than ever.

GenBioCa provides the expertise and digital tools to turn compliance from a reactive burden into a strategic advantage. We integrate AI-powered documentation management and RegTech solutions to automate repetitive tasks, reduce human error, and ensure your submissions are flawless from the start. We help your innovations reach the market swiftly and safely.





The GenBioCa Advantage: Intelligent Compliance

We go beyond traditional consulting, offering technology-driven regulatory compliance services that streamline processes, minimize risks, and foster proactive adherence.

Our Core Differentiator:

Deep integration of technology with regulatory expertise for efficient and future-proof compliance management.

Compliance Focus Areas

GxP Compliance (GLP, GCP, GMP, GDP)
Global Data Protection (GDPR, HIPAA)
Digital Records (21 CFR Part 11)
Quality & Devices (13485, 510K, 4xx, 8xx, SOC 2, FHIR)

Proactive Compliance Culture:

We help you anticipate challenges, backed by our commitment to quality standards like ISO 9001 and HIPAA validation.

Specialized Support:

Filing NDA/ANDA, Submissions, e-CTD, and Addressing Warning letters.

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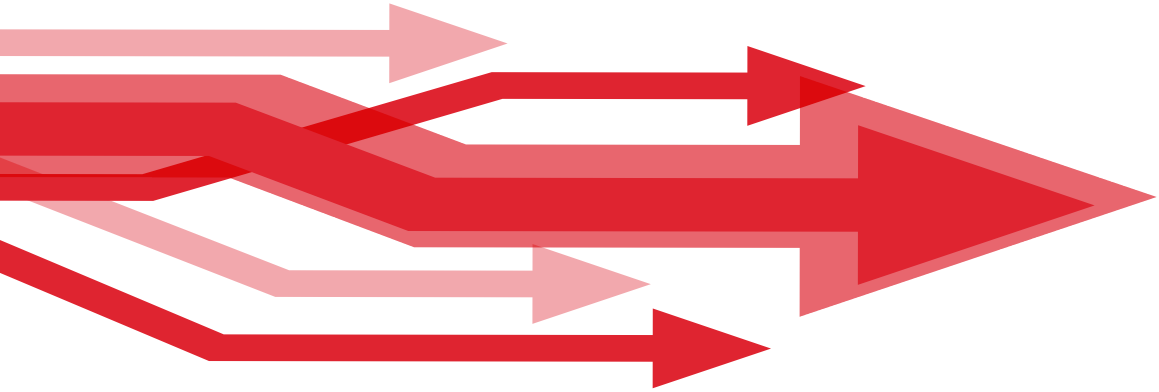
Our Tech-Enabled Compliance Services

Multi-model Framework Compliance (GenRAC):
Utilizing our integrated digital platform (GenRAC) for centralized documentation, automated workflows, and real-time visibility to minimize errors and enable faster audits.

Audit Readiness & Support:
Employing Real-Time Data Analytics to provide data-driven insights and risk identification for confident and successful audits.

Regulatory Intelligence & Change Management:
Proactive monitoring and automated alerts to stay ahead of evolving global regulations and ensure timely adaptation.

Submissions & Dossier Preparation:
Expert support and digital tools for streamlined e-CTD and filing processes.



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Benefits of Choosing GenBioCa: Your Success Metrics

Reduced Risk of Non-Compliance:

Our proactive, technology-driven processes minimize regulatory exposure.

Increased Efficiency and Reduced Costs:

Automation and optimized processes streamline your compliance efforts.

Improved Transparency and Accountability:

Centralized digital systemsprovide full visibility into all compliance activities.

Faster Time-to-Market:

Efficient submissions and streamlined compliance accelerate your path to approval.

Enhanced Audit Readiness:

We ensure all documentation is complete and accessible for successful inspections.

Scalable and Adaptable Solutions:

Our framework is tailored to grow with your business and adapt to regulatory changes.

Ready to Turn Compliance into a Strategic Advantage?

Contact us today to streamline your regulatory journey and accelerate your innovations to market.

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Website

www.genbioca.com

Enquiry

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