GENBIOCA

Domain Led, Technology Services Company

WE ARE THE TRUSTED



Validation Services Partner

Computer System Validation (CSV) Services: Secure Your Systems. Safeguard Your Science.

Validation, Evolved: Smart, Risk-Based Compliance for the Digital Age.

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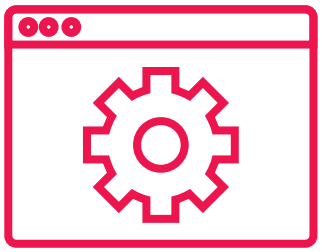
Computer Validation Services

In the digital age, a system is only as reliable as its validation. Outdated, paper-based processes are a major source of inefficiency and audit risk. Regulatory agencies like the FDA and EMA demand a risk-based approach that proves your systems are fit for purpose.

GenBioCa specializes in Computer System Validation (CSV) and GAMP 5 compliance. We don't just generate paperwork; we implement a modern, risk-based validation strategy that leverages automation to reduce the validation lifecycle. With us, you are not just compliant, you are audit-ready, 24/7.







Comprehensive CSV Services for the Pharmaceutical Industry

GenBioCa delivers intelligent Validation Services that ensure compliance and efficiency in the critical Pharmaceutical landscape.

The GenBioCa Advantage: Risk-Based Validation, Digital-First

Our approach is rooted in precision and efficiency, validated by our commitment to Quality (ISO 9001) and Information Security (ISO 27001).

- **Risk-Based Precision:** We focus validation efforts on high-risk areas, maximizing resource efficiency with digital documentation and tracking.
- **Digital-First Efficiency:** Our advanced digital platforms streamline documentation, enhance traceability, and provide real-time insights for faster, more transparent validation.
- **End-to-End Expertise:** From planning to lifecycle management, our comprehensive services are powered by digital systems for superior control.

We ensure compliance with key regulations like 21 CFR Part 11 and Annex 11.

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Our Intelligent Validation Services

Risk-Based Validation Planning & Strategy:
Tailored plans based on thorough risk assessments, digitally managed for optimal resource allocation.

Computer System Validation (CSV):
Expert, risk-based CSV ensuring compliance through integrated digital tools.

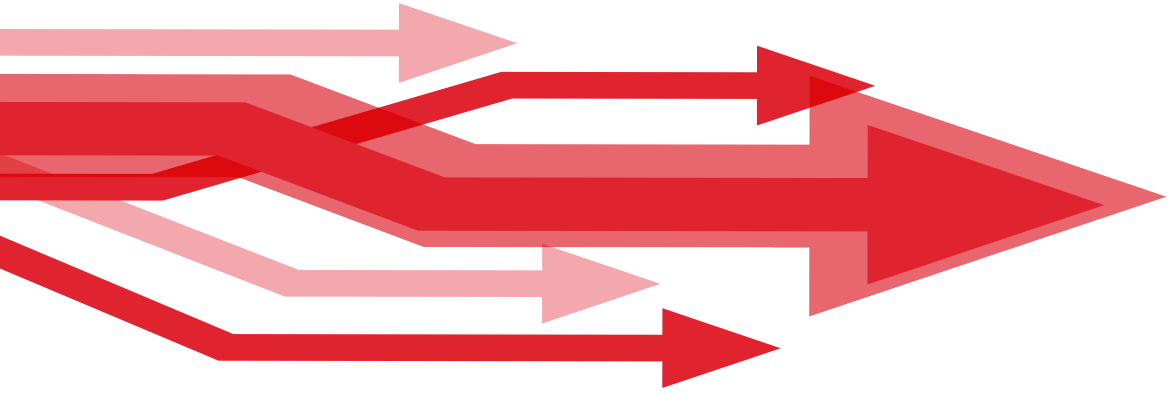
Equipment & Instrument Qualification (IQ, OQ, PQ)
Meticulous qualification with digital data capture for accuracy and streamlined reporting.

Process Validation
Risk-based approach utilizing digital platforms for data-driven insights and control.

Clean Room Validation:
Robust protocols with digitally managed testing and documentation for effective environmental control.

Method Validation:
Rigorous validation employing digital platforms for accurate and reliable analytical methods.

Validation Lifecycle Management:
Comprehensive support managed through integrated digital systems for enhanced control and traceability, ensuring a validated state.



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Benefits of Choosing GenBioCa

Enhanced Regulatory Confidence:

Achieved through risk-based, digital documentation that stands up to scrutiny.

Increased Efficiency & Reduced Timelines:

Digital tools and a focused strategy accelerate your time-to-market.

Improved Data Integrity & Traceability:

Secured via secure digital platforms that ensure all data is auditable.

Data-Driven Decision Making:

Real-time insights and comprehensive reports enable superior control.

Reduced Costs:

Optimizing investment through a risk-focused approach and digital efficiency.

Ready to Secure Your Digital Systems?

Contact us today to implement a smart, risk-based validation strategy and achieve continuous audit readiness.

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Website

www.genbioca.com

Enquiry

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