



GENBIOCA
Domain Led, Technology Services Company

WE ARE THE TRUSTED



Validation Services Partner

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

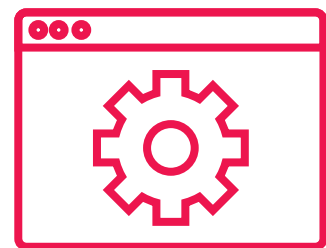
Validation, Evolved: Smart, Risk-Based Compliance
for the Digital Age.



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 Outdated, paper-based processes are a major source of inefficiency and audit risk.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.



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:

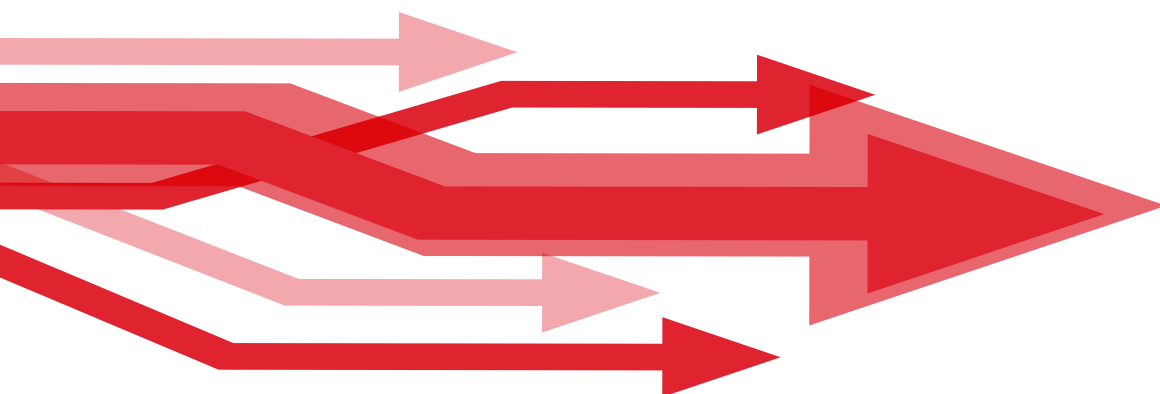
Robust protocols with digitally managed testing and documentation for effective environmental control.

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.





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.



GENBIOCA
Domain Led, Technology Services Company

Our Offices



Website

www.genbioca.com

Enquiry

gbc@genbioca.com