GENBIOCA
Domain Led, Technology Services Company

GenRAC™ Pharma & Med Devices

GxP, QMS & Data Integrity Compliance Automation

Eliminate Compliance Gaps Across Manufacturing, Lab, and Clinical Workflows.

GenRAC transforms high-stakes life sciences quality compliance from periodic panic into a structured, continuous operating system.

820+	90 Days	< 24 Hrs	Zero
Pre Loaded	To Audit-Ready	Gap-to-Owner	Audit Scrambles
Ready-to-deploy evidence	Baseline readiness score	Auto-assigned with SLA	100% pre-compiled packs

Core Challenges vs. The GenRAC Solution

Facility Sector	Regulatory Focus Area	GenRAC Operating Advantage
Pharma Manufacturing & CROs	GxP workflows, batch records, laboratory data integrity, and internal QMS.	Controlled Evidence Management: Timestamped, immutable audit logs, user attribution, and SOP change governance.
Medical Device Manufacturers	Device history records, standard renewals, quality control tracking, and supplier audits.	Continuous Risk Monitoring: Scheduled verification cycles, certification expiry alerts, and SLA-driven escalation
Digital Health & Data Fiduciaries	Patient privacy, consent governance, clinical trial data, and security controls.	Automated Data Protection: 109 pre-built DPDPA 2025 templates for consent, breach response, and grievance handling

Key Capabilities Built for Healthcare

Multi-Framework Rules Engine

Pre-loaded for GxP, 21 CFR Part 11, internal QMS, and DPDPA 2025 frameworks.

Version Control & Immutability

Historical compliance states preserved for retrospective regulatory reviews.

Intelligent Gap Escalation

Automatic identification of non-conformances with SLA-driven resolution tracking.

Instant Regulatory Submissions

Auto-indexed, structured evidence packages compiled with a single click.

Validated Architecture
Multi-site support, tenant data isolation, and dedicated environments.

Industry Standards
ISO 27001:2022 certified, CMMI Level 3 SVCS, and secure modern tech stack.

Contact us for a demo and assessment

Visit **genbioca.com**
Contact **gbc@genbioca.com**

GenBioCa Sciences Pvt. Ltd.,
Thane, Maharashtra 400604 India