GENBIOCA
*Domain Led, Technology Services Company*

# WE ARE THE TRUSTED

## REGULATORY COMPLIANCE PARTNER

**GenRAC**

A GenBioCa Product

| 25 | 3285 | 3-Layer | 24/7 |
|---|---|---|---|
| Regulatory Framework | Compliance Rules | Enforcement Engine | Sentinel Monitoring |

Automated scoring | Evidence analysis | Sentinel auto-detection | Risk quantification in INR

**The only compliance platform that doesn't just track rules — it enforces them.**

**Stop Reacting to Compliance. Start Shaping It.**

"First Time Right"
— Your Path to Continuous Audit Readiness

## The Industry Challenge

Life Sciences, Pharmaceutical, Medical Device, and Healthcare organisations face mounting regulatory pressure from agencies worldwide.

HIPAA violations attract penalties up to $1.5 million per incident. A single FDA import alert can shut down an entire product line. GDPR fines have exceeded EUR 20 million. India's DPDPA imposes penalties up to Rs.250 crore. Yet most organisations still prepare for audits using spreadsheets, fragmented filing systems, and manual checklists — a process that consumes hundreds of person-hours per audit cycle and leaves gaps that inspectors find in minutes

### Hundreds of Hours Lost

Manual audit preparation consumes resources that should drive innovation

### Massive Financial Risk

FDA import alerts, HIPAA penalties up to Rs.12.5 Cr per violation & DPDPA Rs.250 Cr

### No Single Source of Truth

Evidence scattered across drives, inboxes, and filing cabinets — impossible to retrieve under inspection

## The Solution: GenRAC

GenRAC is a unified, AI-powered compliance automation platform built by GenBioCa's domain experts in Life Sciences and Healthcare regulation. It transforms compliance from a reactive, manual burden into a proactive, data-driven strategic asset. Whether you are a 50-bed hospital seeking NABH accreditation or a multinational pharmaceutical company managing cGMP, 21 CFR Part 11, and GDPR simultaneously — GenRAC delivers continuous audit readiness from a single platform.

What sets GenRAC apart is the 3-Layer Compliance Enforcement Engine — the platform doesn't just collect compliance data, it actively enforces rules, auto-detects violations, scores evidence in real time, and escalates issues before they become audit findings.

# Platform Capabilities

### 25 Regulatory Frameworks, 3,285 Rules, One Dashboard

Manage HIPAA, GDPR, ISO 13485, NABH 6th Edition (623 OEs), cGMP, 21 CFR Part 11, DPDPA, SOC 2, EU MDR, EU IVDR, MDSAP, FDA 510(k)/PMA, CE Marking, HITRUST, WCAG/ADA, FSMA/HACCP, IEC 62304, REACH/GHS, and more — all from one unified dashboard. Every framework ships with prepopulated rules, assessment questions, best practices, and weighted scoring criteria. Our proprietary unified taxonomy maps a single piece of evidence across multiple frameworks simultaneously, eliminating redundant assessments.

### 3-Layer Compliance Enforcement Engine

**Layer 1 —** Middleware Guards: Five real-time interceptors that block non-compliant actions before they happen. Assessment completeness guard ensures 100% rules are assessed before submission. Cycle consumption guard prevents audits without available cycles. Score threshold guard triggers sentinel events when scores fall below critical levels.

**Layer 2 —** Controller: Six API endpoints orchestrate the compliance workflow: score assessments, analyse evidence, browse sentinel events, run manual scans, view compliance dashboard, and perform what-if scenario analysis.

**Layer 3 —** Engines: Scoring Engine calculates weighted compliance percentages using the formula (scoreAwarded/maxScore) x weight across all rules. Evidence Analysis Engine extracts keywords from regulatory rule text and matches against uploaded evidence — automatically setting compliance levels (80%+ compliant, 50-79% partial, below 50% non-compliant). Sentinel Engine runs 5 auto-detection checks every 15 minutes: overdue CAPAs (auto-escalation at 7/14/30 days), expiring evidence, score degradation, repeat non-conformities, and cycle exhaustion.

### Evidence-Based Scoring with Risk Quantification

Upload evidence documents and GenRAC automatically analyses them against framework rule requirements using keyword matching. Coverage ratio determines compliance level. Risk quantification translates non-compliance into financial exposure in INR — HIPAA at Rs.41.5 lakh per rule, GDPR scaled from EUR 20M, DPDPA at Rs.250 crore per instance. The What-If Analyser lets management ask: "If we improve this process from 60% to 90%, how much penalty risk do we eliminate?"

### Knowledge Bank & FAQ

Self-service knowledge base with FAQs browsable by framework, section, chapter, objective element, and rule — covering all 25 frameworks. Search across questions and answers. Community voting surfaces the most helpful answers. Reduces support tickets and accelerates team onboarding.

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# Platform Capabilities

### AI-Powered Audit Analysis
Generative AI analyses uploaded evidence against regulatory rules, generates compliance scores, identifies gaps, and recommends best practices — delivering insights that would take human auditors weeks to compile.

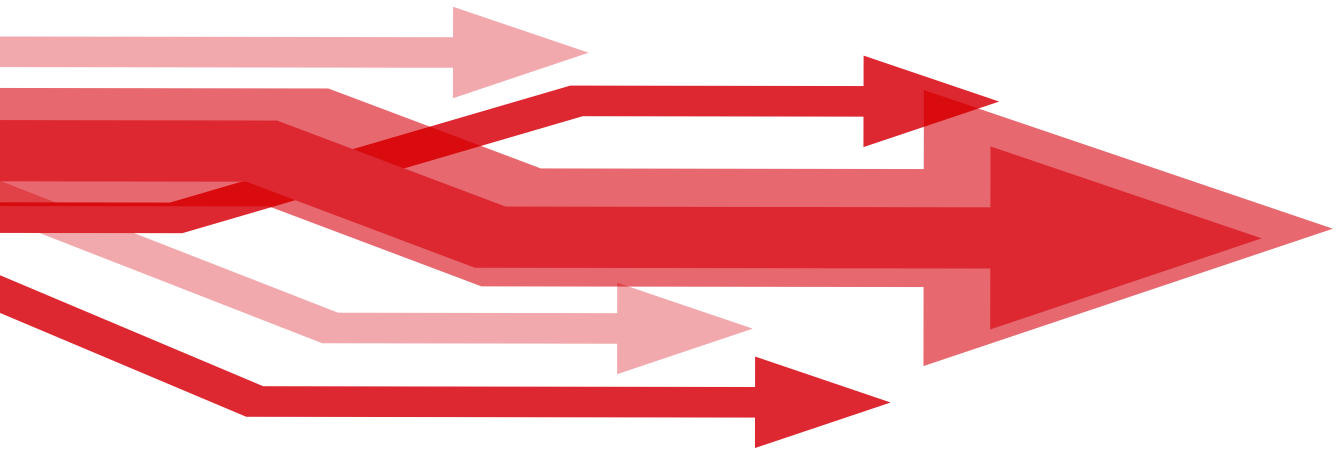
### Three Audit Types
Internal audits by your team, external audits via our Auditor Marketplace (browse certified auditors by specialisation, rating, and rate), and AI-powered audits — all managed as cycle-based subscriptions.

### Automated CAPA Lifecycle with Sentinel Auto-Escalation
Corrective and Preventive Actions auto-generated from audit gaps with severity-based due dates (15 days for critical, 30 days for major). Root cause analysis tools (5 Whys, Fishbone, FMEA). Sentinel Engine auto-escalates: 7 days overdue to supervisor, 14 days to admin, 30 days auto-terminated with critical event. Full remediation tracking with effectiveness verification per ISO 9001 Clause 10.2.

### 21 CFR Part 11 Compliance Built In
Immutable, hash-chained audit trail with HMAC-SHA256 digital signatures. Electronic signatures with re-authentication, mandatory reason capture. Every data modification logged: who, what, when, old values, new values, IP address. Your compliance tool is itself compliant.

### Enterprise Security
Fully managed SaaS on AWS or private on-premises deployment behind your firewall via Docker and Kubernetes. Your data sovereignty, your choice.

### Deploy Your Way
Self-service knowledge base with FAQs browsable by framework, section, chapter, objective element, and rule — covering all 25 frameworks. Search across questions and answers. Community voting surfaces the most helpful answers. Reduces support tickets and accelerates team onboarding.



# Why Customers Choose GenRAC

**80% Reduction in Audit Preparation Time:** Automated checklists, AI gap analysis, 3,285 prepopulated rules, and evidence-based scoring eliminate hundreds of manual hours per cycle.

**Quantified Risk Reduction:** Real-time dashboards show compliance risk in INR, enabling data-driven remediation prioritisation.

**Regulatory Peace of Mind:** The platform itself is compliant with DPDPA, HIPAA, GDPR, ADA/WCAG, SOC 2, and 21 CFR Part 11.

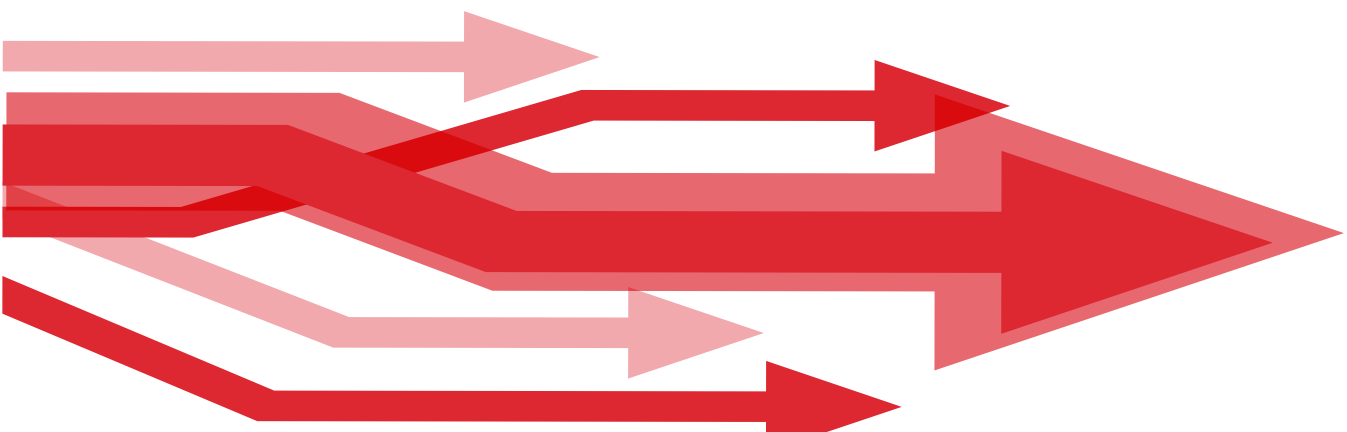
**Continuous Monitoring:** Sentinel Engine detects issues every 15 minutes — overdue CAPAs, expiring evidence, declining scores, repeat non-conformities — before they become audit findings.

**Self-Service Knowledge Bank:** Framework-wise, section-wise, rule-wise FAQs for all 25 frameworks reduce support dependency and accelerate team competence.

**Built for Scale:** Multi-tenant architecture supporting 1,000+ concurrent users with 4-level organisation hierarchy (Organisation > Location > Unit > Department).

## Industries We Serve

| Industries | Key Frameworks Covered |
|---|---|
| Pharmaceutical & Biotech | cGMP, 21 CFR Part 11, GLP, GAMP 5, ICH E6 GCP |
| Hospitals & Healthcare | NABH 6th Ed, HIPAA, DPDPA, FHIR, SNOMED/DICOM |
| Medical Devices | ISO 13485, EU MDR, IEC 62304, REACH/GHS |
| Clinical Research (CRO) | ICH E6 GCP, GLP, 21 CFR Part 11, CDISC/SDTM |
| Health Insurance & Payers | HIPAA, SOC 2, HITRUST CSF, GDPR |



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## 25 Frameworks — 3,285 Prepopulated Rules

| Industries | Rules |
|---|---|
| NABH 6th Ed (India) | 623 |
| FHIR/CDISC/SDTM | 301 |
| EU MDR 2017/745 | 155 |
| HITRUST CSF | 150 |
| EU IVDR 2017/746 | 116 |
| REACH/GHS/CLP | 101 |
| WCAG/ADA 2.2 | 86 |
| ISO 9001 | 78 |
| cGMP (21 CFR 211) | 64 |
| EU Cosmetics | 55 |
| SNOMED/DICOM | 50 |
| GLP | 44 |
| GAMP 5 | 40 |

| Industries | Rules |
|---|---|
| HIPAA | 402 |
| MDSAP | 202 |
| SOC 2 | 151 |
| DPDPA (India) | 123 |
| IEC 62304 | 104 |
| GDPR | 99 |
| ISO 13485 | 78 |
| FDA 510(k)/PMA | 66 |
| ICH E6 GCP | 57 |
| CE Marking | 50 |
| FSMA/HACCP | 49 |
| 21 CFR Part 11 | 41 |
| Total | 3285 |

## Flexible Plans for Every Organization

| Starters | Growth | Enterprise | On-site |
|---|---|---|---|
| ✓ 5 users<br>✓ 3 frameworks<br>✓ 10 cycles / framework<br>✓ Email support<br>✓ Knowledge Bank access | ✓ 25 users<br>✓ 10 frameworks<br>✓ 50 cycles / framework<br>✓ AI audit credits<br>✓ Priority support<br>✓ Sentinel Engine | ✓ Unlimited users<br>✓ All 25 frameworks<br>✓ 200 cycles / framework<br>✓ White-label option<br>✓ Dedicated CSM<br>✓ Full Sentinel + AI<br>✓ SLA 99.9% uptime | ✓ Your firewall<br>✓ Docker / Kubernetes<br>✓ Full data sovereignty<br>✓ Custom integrations<br>✓ Dedicated support |

For more info contact gbc@genbioca.com

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# Our Offices


## Visit www.genbioca.com/genrac-automation-tool/

## Ready to Transform Your Compliance Journey?

Schedule a personalized demo and see GenRAC in action with your own regulatory frameworks.

## Mail us at gbc@genbioca.com