

Healthcare & Life Sciences

Covered Entities, Business Associates & Digital Health Platforms

"Protect patient data. Satisfy regulators. Never fail an audit."

Healthcare organizations face some of the most complex and consequential compliance obligations in any sector. A single breach can result in OCR investigations, multi-million dollar fines, and irreparable reputational damage. Auditerra gives healthcare entities and their business associates the combined platform and human auditor expertise to achieve HIPAA compliance, HITRUST certification, and SOC 2 assurance — and maintain it continuously.

HIPAA 2024

HITRUST CSF v11

SOC 2

21 CFR Part 11

NIST CSF 2.0

The Challenge

- HIPAA Modernization (2024 updates) introduces stricter requirements for PHI access controls, audit logs, and breach notification timelines.
- Business Associates are equally liable for PHI breaches yet often lack the internal resources to maintain compliance independently.
- HITRUST CSF r2 is complex — organizations frequently underestimate the evidence burden and fail interim assessments.
- Digital health platforms handling ePHI face overlapping SOC 2, HIPAA, and 21 CFR Part 11 obligations with no single roadmap.
- Annual risk analyses are required but rarely sufficient — threat environments evolve faster than yearly review cycles.

Compliance Frameworks We Cover

HIPAA 2024

Covers the Privacy Rule, Security Rule, and updated Breach Notification requirements. 2024 modernization tightens access controls, response timelines, and patient rights provisions.

HITRUST CSF v11

A certifiable framework that maps controls across HIPAA, ISO 27001, NIST, and PCI-DSS. Particularly valued by health plans, hospitals, and digital health vendors seeking third-party assurance.

SOC 2 Type II

Demonstrates security, availability, and confidentiality controls to healthcare partners and payers. Increasingly required in vendor agreements and procurement processes.

21 CFR Part 11

FDA regulation governing electronic records and electronic signatures for life sciences companies. Audit trails, system validation, and access controls are core requirements.

NIST CSF 2.0

Provides a risk-based framework for identifying, protecting, detecting, responding to, and recovering from cybersecurity threats — aligned to healthcare's critical infrastructure designation.

How Auditerra Engages — Our Process

Step 1 — Demo

A no-pressure, industry-tailored demo so you see exactly how our platform and auditors work together before any commitment.

Step 2 — Readiness Check

We conduct a gap assessment to map your current compliance posture, identify risk areas, and build a prioritized remediation roadmap.

Step 3 — Active Engagement

Our certified auditors don't hand you a to-do list. They work alongside your team — reviewing evidence, walking through controls, and personally resolving gaps in real time.

Step 4 — Continuous Monitoring

Compliance doesn't end at certification. Auditerra monitors your posture year-round, alerts you to drift, and keeps you audit-ready at all times — not just during audit season.

Why Not Big 5 or SaaS-Only?

Provider	What You Get	What's Missing
Big 5 Consulting	Deep expertise, global reach	Enterprise pricing — out of reach for most
SaaS-Only Platforms	Evidence collection platform	No human auditor — you're on your own
Auditerra	Platform + certified human auditors	Nothing. Custom pricing. Full engagement.

PHI Protection, Breach Readiness & Business Associate Management

For healthcare organizations, compliance failure is not an abstraction — it's OCR investigations, settlement agreements, and front-page exposure. Auditerra conducts a structured annual risk analysis aligned to HIPAA Security Rule requirements, develops and tests your incident response plan against HIPAA's 60-day breach notification clock, and manages your Business Associate Agreement (BAA) inventory to ensure third-party risk is documented and controlled. For life sciences clients, we layer 21 CFR Part 11 system validation requirements into the same continuous monitoring workflow — eliminating the compliance silos that create audit exposure.

What You Get with Auditerra

- ✓ HIPAA Security Rule risk analysis and remediation roadmap (annual)

- ✓ HITRUST CSF readiness assessment and certification support
 - ✓ SOC 2 Type II audit preparation and evidence management
 - ✓ Business Associate Agreement inventory and third-party risk monitoring
 - ✓ Breach notification readiness planning and tabletop exercise facilitation
 - ✓ Continuous control monitoring with real-time drift alerting
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Ready to See It in Action?

Book your no-obligation demo at auditer.com/demo or reach out directly at compliance@auditer.com. We'll tailor the conversation to your industry, your frameworks, and your timeline — no generic pitch decks.