



Engineering Solutions, Inc.

info@engineering-solutions-inc.com

www.engineering-solutions-inc.com

Trusted advisors for regulated industries, growth-stage companies, and public agencies.

Case Study: CMS/FHIR Integration & Regulatory Readiness

Client: Confidential US-based Healthcare Technology Provider

Industry: Healthcare / Digital Health / Healthcare

Engagement Type: Interim CIO Advisory & Compliance Engineering

Challenge

The client faced an accelerated deadline to meet CMS interoperability and FHIR compliance requirements. In addition to technical integration challenges with multiple EHR and payer systems, the organization needed to ensure HIPAA, 21 CFR Part 11, and cybersecurity readiness ahead of an upcoming regulatory audit.

Approach

- Conducted rapid current-state assessment across IT, product, and compliance workflows.
- Designed phased FHIR implementation roadmap integrating CMS mandates with long-term data strategy.
- Established compliance controls covering HIPAA, 21 CFR Part 11, SaMD, and ISO 13485.
- Coordinated with EHR vendors, payers, and internal product teams for API integration and testing.
- Delivered executive-level risk reporting and readiness dashboards for board and regulators.

Results

- Achieved full CMS/FHIR compliance ahead of regulatory deadline.
- Reduced integration errors by 40% through API standardization.
- Passed third-party HIPAA & cybersecurity audit with zero critical findings.
- Enabled real-time payer-provider data exchange, improving care coordination.
- Created repeatable compliance playbook for future regulatory updates.

Core Capabilities Provided

- CMS/FDA readiness: HIPAA, 21 CFR Part 11, SaMD, cybersecurity
- FHIR, EHR, and payer system integration strategies
- Interim CIO/CTO advisory for healthcare organizations
- Risk assessment and compliance engineering
- Cross-functional program governance