



S I L U R U S
S O F T W A R E

Case Studies

Medical Device Software Development

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Cloud-Based Medical Algorithm Hosting Platform

Client: Leading German MedTech company

Duration: 30 months

Team: 3 developers, 1 delivery manager

CHALLENGE

Research institutions and university hospitals needed to deploy their proprietary contouring algorithms for radiotherapy planning, but lacked the infrastructure to host and scale them. The client required a centralized platform to onboard third-party algorithms without burdening individual facilities with hardware costs.

WHAT WE DELIVERED

A cloud-native microservice platform that hosts, executes, and scales medical image contouring algorithms. The system manages data flow between hospital PACS environments and algorithm execution pipelines, with full DICOM integration and healthcare-grade data security.

RESULT

Multiple universities and research institutions now deploy algorithms through the platform without local infrastructure investment. Hospital radiotherapy departments access advanced contouring capabilities on-demand, reducing treatment planning preparation time.

CASE STUDY 02

Ongoing Development and Feature Engineering for a Medical Imaging Platform

Client: Leading German MedTech company

Duration: 8+ years (ongoing)

Team: Senior developers integrated into client .NET engineering teams

CHALLENGE

The client maintains a mission-critical medical imaging and radiotherapy platform under continuous development following strict IEC 62304 lifecycle processes. Demands are high: new features, evolving DICOM standards, security hardening, performance optimization, and complex bug investigations. Every code change must be traceable, risk-assessed, and verified. Scaling internal teams fast enough to cover all workstreams while maintaining regulatory compliance is difficult given the specialized domain knowledge required.

WHAT WE DELIVER

- Feature development within a large-scale .NET codebase following IEC 62304 software lifecycle
- Adoption of new DICOM standard versions and protocol updates
- Security improvements and performance optimization
- Monitoring, logging, and diagnostics infrastructure
- Complex bug investigation and resolution, including customer complaint handling
- Risk-aware development with traceability from requirements through implementation and verification
- Full compliance with the client's quality management system, development processes, and review workflows

RESULT

Our developers are indistinguishable from internal staff in terms of process adherence and output quality. The client has maintained this partnership for 8+ years, consistently expanding the scope of work entrusted to our team.

Medical Software QA and DevOps

Client: Leading German MedTech company

Duration: 8+ years (ongoing)

Team: 10 specialists across functional teams

CHALLENGE

The client's medical software portfolio required a modern, automated QA and DevOps infrastructure to keep pace with EU MDR and FDA requirements. Existing processes relied heavily on manual, repetitive work, slowing down release cycles and reporting. The client needed to build and optimize the entire CI/CD platform and testing infrastructure from design through implementation.

WHAT WE DELIVER

- Design, build, and continuous optimization of the full CI/CD platform and release pipelines
- Automated DLL/EXE signing for cybersecurity compliance
- Virtualized test environments for reproducible, isolated test execution
- Overnight automated regression test suites with next-morning reporting
- Code coverage measurement and systematic code quality improvement protocols
- Multi-layered testing strategy: unit, integration, system, SMOKE, automated UI, performance, and security testing
- Full traceability documentation from requirements through test results and deployment verification
- Modernization and automation of previously manual QA workflows

RESULT

Significant reduction in manual, redundant work across the QA and release process. Automated overnight testing provides daily quality feedback, drastically reducing regression cycle time while increasing coverage and reporting quality. The client maintains continuous regulatory compliance through multiple EU MDR and FDA audit cycles with faster, higher-quality reporting than before.

CASE STUDY 04

Medical Lab Device Software Refactoring and IEC 62304 Validation

Client: Dutch university medical center

Duration: 3 months

Team: Dedicated development team

CHALLENGE

The client operated a custom-built laboratory device used in drug clinical trials. The existing software (desktop GUI and embedded firmware) had grown organically and lacked the documentation, testability, and traceability required for validated use in clinical trial settings. Without formal validation, the device could not be used in regulated drug trials.

WHAT WE DELIVERED

- Complete code refactoring of both the desktop application and the embedded firmware
- Restructured the codebase for testability: dependency injection, simulation mode for hardware-free testing, modular architecture
- Full IEC 62304-compliant documentation package including validation plan, requirements specifications, verification plan, test reports, and end-to-end traceability matrix
- Architecture documentation: baseline analysis, software architecture, mid-project status reports

RESULT

The laboratory device is now validated and fully documented for use in drug clinical trials. The client's research partners can use the equipment with regulatory confidence, supported by complete traceability from user needs through verified test results. The modular architecture enables the client's own team to maintain and extend the software independently.

IEC 62304 Gap Analysis for Embedded Medical Device Firmware

Client: Polish MedTech company

Duration: 3 weeks

Team: Senior embedded C developer, project manager

CHALLENGE

The client developed a therapeutic medical device with embedded firmware controlling safety-critical hardware. The codebase had been built by a single developer and had reached a point where regulatory compliance gaps, undocumented workarounds, and discrepancies between design documentation and implementation needed to be systematically identified before the product could advance through the regulatory process.

WHAT WE DELIVERED

- Review of software documentation (SRS, SyRS, SDS, architecture design) for completeness and consistency against IEC 62304 software lifecycle requirements
- Static review of the firmware codebase across all components, assessing code quality, structure, and alignment with the documented design
- High-level assessment of the current software process against IEC 62304, FDA, and MDR expectations
- Identification of critical bugs including safety-relevant control logic errors, protocol implementation discrepancies, and unresolved fault conditions
- Structured gap analysis report with categorized findings, prioritized observations, and recommendations for remediation

RESULT

The client received a clear, prioritized picture of every gap between their documentation and codebase, assessed against regulatory expectations. The report provided the foundation for informed decisions about their next development phase and regulatory submission timeline.