

Inomed Streamlines IEC 62304 Medical Device Software Certification

Inomed (www.inomed.com) is an international medical technology company that develops nerve protection instruments and systems for precisely targeted patient treatments.

Because there is no margin for error in the software driving these innovative devices, Inomed established extensive processes to ensure software integrity. Such full-lifecycle quality processes are essential for complying with IEC 62304, a "harmonized" medical device software safety standard that has been adopted by the European Union and the United States.

Inomed rapidly automated their established processes, enforced compliance with IEC 62034 coding standards, and introduced full requirements traceability by implementing the Parasoft Development Testing Platform. Moreover, the Development Testing Platform seamlessly integrated into Inomed's existing infrastructure which made implementation fast and simple. As a result, Inomed significantly reduced the work required to achieve and sustain the mandated IEC 62304 certification.

The Challenge: Streamline Certification for Medical Device Software

Working with doctors and users, Inomed develops new tools and methods in the fields of intraoperative neuromonitoring, neurosurgery, pain therapy and neurological diagnostics. Inomed supplies high-quality products to improve treatment outcomes and uses innovative technologies to ensure safety for both treatment providers and patients.

Jörg Wipfler, Inomed's Head of Development, explains, "Our products are used intraoperative. If any failure occurs during an operation, the operation might have to be aborted. Moreover, since we monitor nerves and their signals, incorrect interpretations and decisions made by our software could lead to wrong decisions by the user...and could cause injuries for the patient."

Because safety is so critical for medical devices, the IEC has recently taken an active role in regulating the software that is developed for medical devices used in Europe.

The IEC 62304 standard provides a framework of software life cycle processes with activities and tasks necessary for the safe design and maintenance of medical device software. It enforces traceability and repeatability of the development and maintenance process. The US FDA accepts IEC 62304 compliance as evidence that medical device software has been designed to an acceptable standard.

After establishing a largely manual process for achieving their initial IEC certification, Inomed wanted to automate their risk management processes. Their ultimate goal was to reduce the work involved in sustaining their existing certifications as well as streamline the certification process for their emerging innovations.

The Solution: Automating Risk Management Processes with Parasoft

Inomed determined that in order to streamline their risk management processes, they needed an integrated system to cover both application lifecycle management (ALM) and the standard's testing requirements for their C++ and .NET code.

After surveying the market, Inomed found a perfect fit with the Parasoft Development Testing Platform. Inomed's integrated Medical Device Compliance solution included Parasoft's C, C++, and .NET code analysis tools. The platform enables end-to-end control of the development testing process, according to Wipfler. "The results from C++ and .NET tests can be used in the development management tool . . . and planned activities can be transferred directly into our development environment."

The Development Testing Platform supports a broad range of environments, which made integration with Inomed's existing infrastructure fast and easy. Inomed's heterogeneous development environment also includes Visual Studio, Keil μ Vision, Bugzilla, and CVS. Moreover, the platform was deployed to Inomed via a fully pre-configured virtual machine—further jumpstarting the adoption process. Immediately after delivery, Inomed was able to start using the system to validate their software and manage their processes.

The Results: Increased Efficiency through Automation

The Parasoft Development Testing platform allows Inomed to adopt a standardized process for static analysis, code review, and unit testing across their C++, C#, and C++/CLI code. Wipfler appreciates the value of having an integrated, comprehensive solution. "We now have a solution doing automated unit tests with the same tool on different development environments and programming languages. Also, the test products are very easy [to use]. The automated application of predefined sets of test rules is very useful."

In addition to providing a range of software quality activities, Parasoft's Development Testing Platform can manage projects and document the process, as well as correlate requirements with automated and manual tests, source code, and development/testing tasks. The current level of verification for each requirement task (including task pass/fail status and coverage) is bidirectionally traceable to all associated tests. Full traceability is crucial for IEC compliance.

"We have [conformed to IEC 62304] before using Parasoft tools," Wipfler says, "but our previous approach was paper-based, and we needed much more time for this process. Using the Parasoft solution significantly increases our efficiency because many manual steps could be automated."

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Parasoft's Development Testing Platform was integrated into Inomed's process, which was certified by DQS auditors against IEC 62304. "We could show our auditor that we have absolute traceability from every requirement or task to source code and that we could be certain that all work we do is verified," remarks Wipfler. "Having automatically-generated traceability is a huge advantage."

Why Parasoft?

In summary, Wipfler cites the following reasons for choosing Parasoft:

- Easy adoption and minimal learning curve
- Seamless integration into the existing development process and environment
- Excellent support
- Deep understanding of their requirements and needs

Wipfler was also impressed with Parasoft's commitment to delivering a solution suited to Inomed's specific needs.

Parasoft made an extra effort to fully integrate Inomed's specialized software with the solution, Moreover, Inomed and Parasoft engineers collaborated to address some unique issues that had to be resolved in order to establish a natural process for the Inomed development team.

He concludes, "[Parasoft provides] absolutely great support. The engineers are well-qualified and every problem was solved very quickly. Also, we were impressed with their willingness to address company-specific questions and requirements. Parasoft's support is absolutely top-level!"

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