SIEMENS
Ingenuity for life

Medical devices and pharmaceuticals

Sonova

Sonova reduces compliance documentation time by 80 percent with Polarion

Product

Polarion

Business challenges

Proliferation of software content in hearing care devices

Manage and trace software requirements, specifications, test cases, verifications and bug fixes

Comply with evolving medical device regulations worldwide

Keys to success

Implement Polarion ALM for software development

Phased implementation from verification to other applications

Support from Polarion experts

Results

Reduced compliance documentation time by 80 percent

Managed 180 software development projects

Standardized rules for collaboration among requirements, specification and testing

Polarion streamlines development of hearing care medical device

A longtime leader in hearing care solutions

Sonova, headquartered in Stäfa, Switzerland, is a leading provider of innovative hearing care solutions. The group operates through its core business brands Phonak, Unitron, Hansaton, Advanced Bionics and AudioNova. The company reaches consumers through multiple channels with a broad range of solutions – hearing aids, cochlear implants, wireless communication products, eSolutions and professional audiological care. Founded in 1947, Sonova currently operates in more than 100 countries across the globe and has a workforce of more than 14,000 dedicated employees pursuing its vision of a world where everyone can hear and live life without limitations.

Since the mid-20th century, Sonova has developed hearing solutions that leveraged a progression of technologies – transistors, miniaturization, digital signal processing, wireless connectivity and compatibility with other electronic devices – collecting more than 3,000 patents along the way.

Today, software is a crucial component of Sonova products. The company has about 400 employees involved in software development worldwide. Sonova-developed software includes firmware for the ARM processors in the hearing-assist devices, PC-based fitting software that hearing care professionals use to tailor hearing devices to individual users, and mobile Android and iOS applications.

"We had a small task force recreating the documents based on existing risk files in Polarion. We created the new documents for 12 different products in a matter of two weeks."

Lutz Dornbusch
Continuous Integration Engineer
Sonova

With connected hearing devices, the functions of the mobile apps have grown – besides remote control functionality like volume change and program adjustment, the apps also enable users to customize and personalize sounds to suit listening needs, report status information including battery charge and wearing time, and connect with hearing care professionals for remote, real-time fitting, adjustment and optimization. In aggregate, Sonova has developed and manages a codebase of approximately one million lines.

Growing software complexity

More than a decade ago, Sonova was using office automation tools in software development – Word documents and Excel spreadsheets. But as products and software grew in complexity and medical device regulations grew more stringent, the office automation tools could not support traceability.

"The movement to ALM in our company came from the verification teams," says Lutz Dornbusch, continuous integration engineer at Sonova. "Verification is one of the backbones of medical software reporting. You must prove that you verify thoroughly the whole application or the whole device. You are required to show that all requirements are tested in the final product. This is not possible in a word processing document – if you have a small number of requirements because your software is primitive, it's fine. As soon as you get into hundreds of requirements, office solutions are not maintainable."

Phased implementation of ALM

Polarion ALM™ software, part of the Xcelerator™ portfolio of solutions and services from Siemens Digital Industries Software, offered a solution. Using an early version of Polarion, Sonova's verification teams implemented tracking,

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management and reporting of defects and test cases, using the extensive customization capabilities of Polarion to build and document a system that fit its needs. Polarion consultants assisted Sonova in the deployment of their system, including configuration of several new features.

Once the software defects were managed in Polarion, developers were drawn to the central platform to find and fix bugs. The developers then pushed to have software requirements and specifications included in Polarion, so that they could have visibility to what needed to be fixed, and in what way.

Still, some functions like marketing and risk management continued to use word processing and office application database tools. Around 2014, marketing moved all requirements engineering from Word into Polarion. A few years later, to more easily comply with rapidly changing regulations for medical device software, the company moved risk management functions from Access into Polarion, thereby achieving traceability and reusability.

Medical device regulatory compliance

Because of Sonova's global presence, the company must comply with a variety of national and international regulations for medical devices, which have become more stringent in the last decade. Though there are local nuances among these regulations, there is some uniformity in the deliverables. "We have to provide a requirements document, which is basically the order of our marketing team," explains Dornbusch. "Our R&D group then creates a detailed specification of how we want to build this to fulfill requirements. These specifications are then tested and verified. The verification team must provide a traceability table linking the requirements, specifications and test cases to document the results."

Sonova products typically have 600 to 800 requirements; these translate into thousands of specifications and 2,000 to 4,000 test cases and their results. The documentation – including product requirements, specifications, architecture documentation, verification reports including test runs, and risk analysis – typically runs to 1,000 to 1,500 pages per product. These files (in the form of a PDF with clickable links) are part of our technical files, a collection of the complete documentation of a product. Authorities are requesting these documents for their approval. "Sonova is a medical company, and it is vital to have these documents," says Dornbusch. "Without the documents, there is no product."

Streamlining audits with Polarion

In audits conducted by regulatory agencies, Sonova employees meet with representatives of the regulatory bodies

Solutions/Services

Polarion ALM
siemens.com/polarion/

Customer's primary business

Sonova AG is a leading provider of innovative hearing care solutions. The group operates through its core business brands (Phonak, Unitron, Hansaton, Advanced Bionics and AudioNova) and reaches consumers through multiple channels; this diversity lets them benefit from a broad range of solutions – hearing aids, cochlear implants, wireless communication products, eSolutions, and professional audiological care – in the way that best suits their individual needs.
www.sonova.com

Customer location

Stäfa
Switzerland

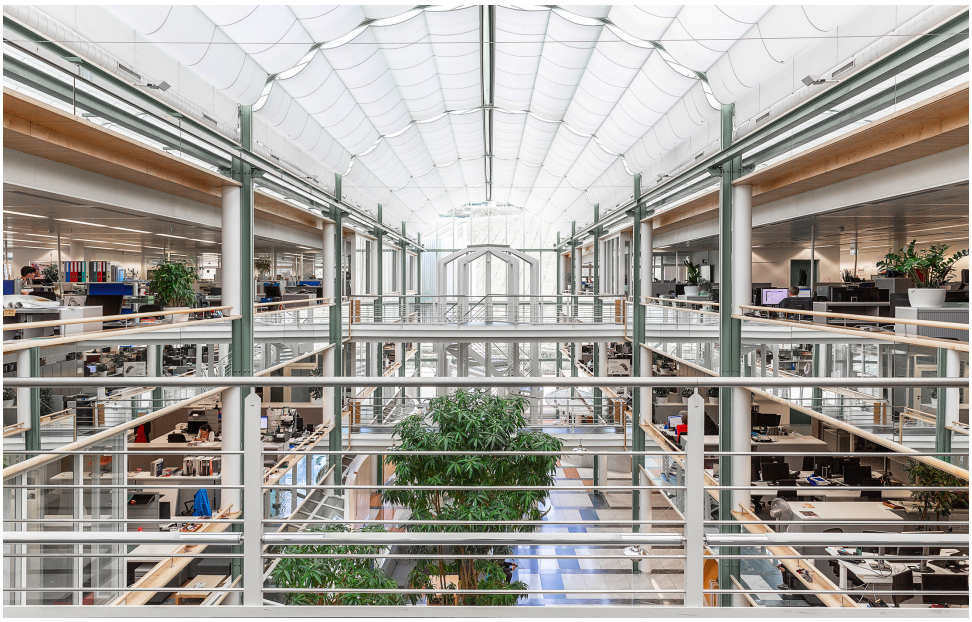
over several days. The regulators can ask any Sonova employee what they are working on and where their processes are documented. They view the PDF technical files for the product and investigate a sampling of test runs, bugs, fixes and other details to confirm the entire line of traceability, rather than examining every detail in the full description of the product.

"Because we have everything in Polarion, everything is quite easily documented," Dornbusch says. "When auditors see that we are working with Polarion, they already know Polarion and are pretty relaxed, because they understand that we can easily provide answers."

Significant time savings

Polarion has helped Sonova to dramatically reduce the time required to create, review and assemble the documentation required for regulatory approval. "To create documents from scratch or from a copy, transfer them to every stakeholder and get their feedback is a large task," says Dornbusch. "Polarion helps us by reducing the time to 20 percent of the time it would require using word processing tools."

These time savings are especially beneficial when Sonova launches earlier-generation devices into new global markets or when medical device regulations change. "We wanted to release some devices built by third-party suppliers into different countries that had updated their medical compliance requirements," Dornbusch explains. "The old risk management Excel documents did not fulfill the new requirements. We had a small task force recreating the documents based on existing risk files in Polarion. We created the new documents for 12 different products in a matter of two weeks, enabling us to sell tens of thousands of devices in the new market.



Siemens Digital Industries Software

Americas +1 314 264 8499
Europe +44 (0) 1276 413200
Asia-Pacific +852 2230 3333

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