SIEMENS

MEDICAL DEVICES AND PHARMACEUTICALS

iThera Medical

Boosting engineering information management efficiency reduces time spent hunting for data by over 65 percent

Product

Polarion

Business challenges

Design diagnostic equipment based on novel technology

Comply with document requirements to meet regulatory standards

Acquire certifications

Keys to success

Ensure data consistency throughout all product-related documents

Use Polarion ALM as product data repository

Leverage Polarion work items for audit documentation

Results

Enhanced engineering information management efficiency, reducing time spent searching for data by more than 65 percent

Reduced time-to-market by 40 percent for optoacoustic imaging equipment

Leveraged the re-use and extension capabilities of Polarion to save costs and reduce the risk of unsuccessful regulatory submissions

Unified design and manufacturing data for verification

iThera Medical uses Polarion ALM to reduce time-to-market by 40 percent for optoacoustic imaging equipment

Listening to molecules

Today doctors can cure many injuries and diseases that were crippling or terminal only decades ago. Some of this is due to noninvasive medical imaging such as X-ray computed tomography (CT), magnetic resonance imaging (MRI) and ultrasound.

Researchers at the Helmholtz Zentrum München, a research center for health and the environment based in Munich, Germany, have pursued an approach to biomedical imaging based on the photoacoustic effect. Alexander Graham Bell discovered in 1880 that molecules emit sound when exposed to flashes of light. Each molecule sends its own distinctive sound signal, which also varies with the wavelength of the light input. The effect has been used to analyze matter; for instance, to measure the carbon dioxide (CO_2) concentration in other gases. Hit by light patterns from a pulsed laser, molecules in soft tissue respond with ultrasound in the wavelength bandwidth commonly used in medical diagnosis.

When photoacoustic imaging using multispectral optoacoustic tomography (MSOT) yielded promising results in 2010, two Helmholtz researchers established iThera Medical GmbH (iThera Medical) to find

iThera Medical was established in 2010 to design and manufacture photoacoustic imaging equipment using multispectral optoacoustic tomography for medical diagnostics. (all images courtesy of iThera Medical)

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Vice President, Quality Management and Regulatory Affairs
iThera Medical

practical medical applications and transform academic knowledge into clinical tools and commercial products.

One of the keys to the firm's success has been adopting Polarion™ ALM™ software to manage all product-related documentation for development and production. Polarion ALM is application lifecycle management (ALM) software that is part of the Siemens Xcelerator business platform of software, hardware and services.

High potential in medical diagnosis

MSOT equipment from iThera Medical superimposes visual information representing the molecules' responses on conventional ultrasound images. It can be used to distinguish between molecules with only slight differences; for instance, hemoglobin with higher or lower levels of oxygen saturation. Using a tunable near-infrared laser source, it can be used to interact with matter up to 40 millimeters (mm) below the surface. Taking a series of images using different laser light wavelengths and combining these using software algorithms makes MSOT a powerful diagnostic tool for many purposes.

MSOT is better suited than most other methods to visualize lymphatic vessels. This can be helpful in cancer treatment, where using MSOT makes it possible to detect and remove lymph nodes when there is certainty rather than just a suspicion about the affected area. Other worthwhile fields of application are neuromuscular disorders in children, where MSOT may facilitate a more objective measurement of disease progression than the routinely used functional tests.

Starting in 2014, iThera Medical engineers designed systems for applications in human diagnostics such as the MSOT Acuity Echo, for which the company has achieved CE certification.

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iThera Medical MSOT equipment is used to superimpose visual information representing the molecules' responses on conventional ultrasound images to distinguish between, for instance, hemoglobin with higher or lower levels of oxygen saturation.

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"MSOT can also be used to noninvasively detect biomarkers hinting at diseases such as ulcerative colitis or Crohn's disease," says Ingmar Thiemann, vice president of quality management (QM) and regulatory affairs (RA) at iThera Medical. "We believe it could be a game changer as it has the potential to reduce or even eliminate the need for invasive procedures such as an endoscopy."

Turning research into clinical equipment

The first iThera Medical product was the MSOT inVision series. The company has produced more than 100 units of this scanner, which is used for biomedical research applications involving small animals in laboratories around the world. Starting in 2014, iThera Medical engineers designed systems for applications in human diagnostics. Optimized for depth and resolution, the most advanced units are the Raster Scan Optoacoustic Mesoscopic (RSOM) Explorer for high resolution imaging and the MSOT Acuity Echo for deeper tissue penetration.

The MSOT Acuity Echo has received the European Conformity CE mark as a medical device in 2021. As it currently still lacks the regulatory approval for use in a particular clinical indication, it is so far used exclusively in clinical research. One step on the way to achieving this goal is the multicentric international EUPHORIA study with several universities and clinics using MSOT to diagnose inflammatory bowel diseases.

Embedded in a network of development partners, iThera Medical uses customized laser, ultrasound and electronic hardware to build the diagnostic equipment. Developing image processing algorithms is a core competency of iThera Medical, while the implementation in software code is conducted jointly with external partners.

Pursuing documentation integrity

iThera Medical needs to comply with the International Organization for Standardization (ISO) 13485 standard that contains a comprehensive quality management system for the design and manufacture of medical devices. As early as 2012, iThera Medical started using a fully digital approach in pursuing ISO 13785 qualification. "The medical device regulation EU 2017/745 requires all documents to be easily available and searchable," Thiemann points out. "I know from experience before I joined iThera Medical how much more difficult if at all possible this is to achieve on paper."

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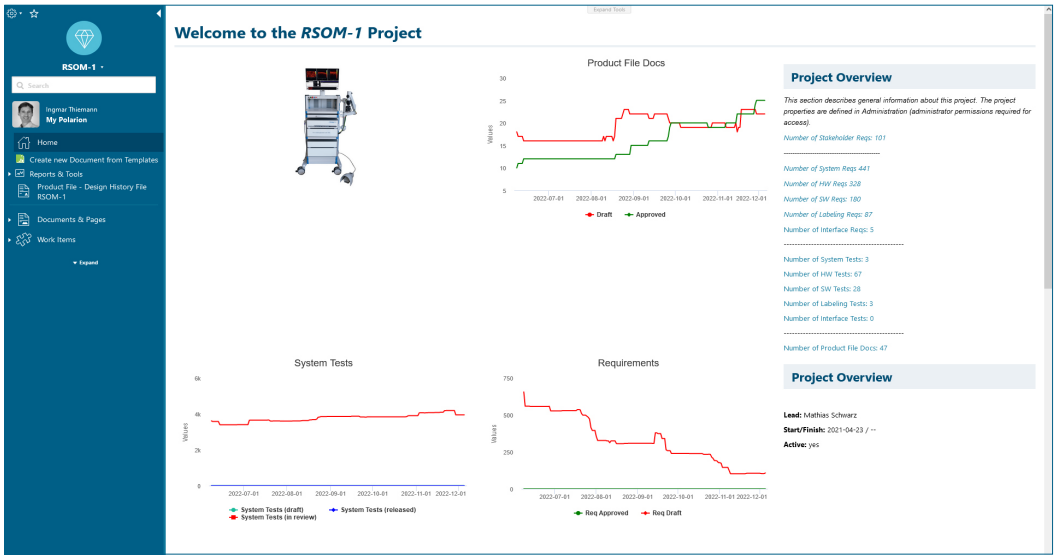
iThera Medical uses Polarion ALM as an application development platform. The photoacoustic imaging experts turned to Avasis Solutions, a Siemens Digital Industries Software technology and implementation partner specializing in solutions for medical applications based on Polarion ALM. These include applications for requirements engineering, risk analyses and verification as well as quality management tailored to the needs of medical equipment manufacturers.

This software is now an integral part of the company’s quality management system (QMS). Nearly all of the 50 iThera Medical staff in Germany and the U.S. have access to the system. They use it to manage all product-related documentation for development and production. This includes design history files, device master records, quality management and risk management information as well as usability specifications and clinical evaluation data. They also create their own custom application modules, finding it easy to configure the software without compromising full traceability.

Polarion ALM and the company’s enterprise resource planning (ERP) software can be used to communicate with representational state transfer (REST) application programming interfaces. As a small company at the start of a long journey from research and development (R&D) to product serialization, iThera Medical needed an adaptable solution that could grow with the company. “Polarion ALM provides us with a solid foundation for efficient engineering information management,” says Thiemann. “We reduced the time spent searching for data by more than 65 percent.”



Using Polarion ALM to ensure consistency of information across documents, iThera Medical engineers save costs and reduce the risk of unsuccessful audit submissions.

Solutions/Services

Polarion ALM
siemens.com/polarion-alm

Customer's primary business

iThera Medical GmbH is a leading manufacturer of opto-acoustic imaging equipment for laboratory and clinical applications. Established in 2010 in its two main sites in Germany and the U.S., the company employs 50 scientists and engineers.
https://ithera-medical.com/

Customer location

Munich
Germany

Solutions partner

Avasis Solutions GmbH
www.avasis.biz/en

Re-using information

The medical device regulation (MDR) EU 2017/745 for the clinical investigation and sale of medical devices for human use replaces an earlier EU medical devices directive (MDD) and needs to be implemented by 2024. Until then, all documentation needs to comply with both standards, making it necessary to make smart re-use of existing documentation.

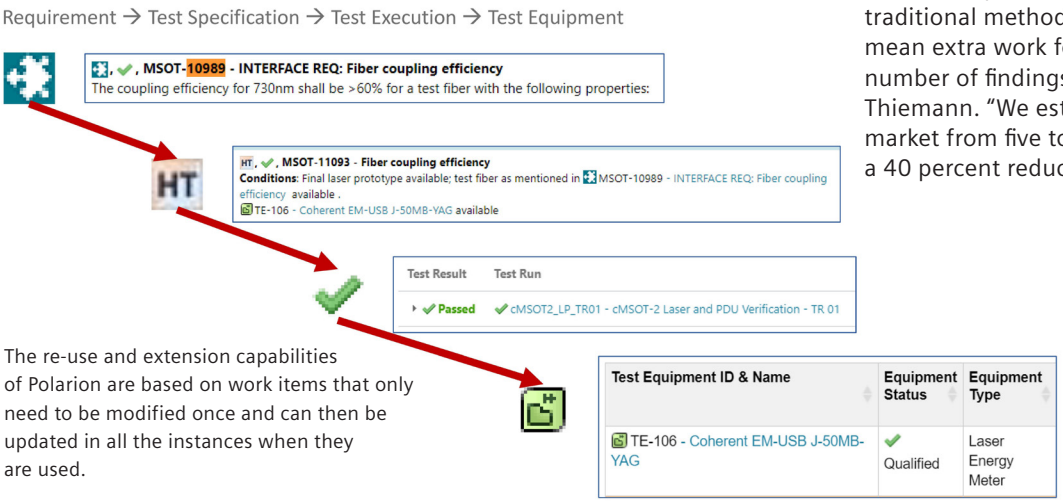
Thiemann is part of an initiative to define a unified, fully digital data model for medical devices using Medical Device Knowledge Units. These can be based on Polarion work items, which provides consistency of information across documents. Much like instancing objects in object-oriented software development, Polarion work items only need to be modified once and they can then be updated in all instances.

Using Polarion work items, iThera Medical successfully resubmitted an MDD-compliant file to the regulatory body. They derived the file within a short time from previously created MDR-compliant documentation. "The re-use and extension capabilities of Polarion save costs and reduce the risk of unsuccessful submissions," says Thiemann. "They are essential for regulatory clearance in other markets, such as China, Japan, Brazil and the U.S."

Passing audits during trying times

This also proved particularly useful to pass two ISO 13485 audits. Both of them took place during critical phases of the COVID-19 pandemic. To protect production employees, iThera Medical required its engineers to work from home and the auditor also had tight restrictions for time spent on-site. "Using Polarion ALM, we were able to provide the auditor with stringent, robust technical documentation with full searchability and traceability," Thiemann confirms. "Due to the audit-proof presentability of all required information, the audits were successfully completed online." In future audits, iThera Medical plans to grant the regulatory body direct access to the data in Polarion ALM for even better cooperation.

Using Polarion ALM enabled iThera Medical to significantly reduce the time required to create compliant documentation. "Using traditional methods, documentation would mean extra work for two people and a number of findings in each audit," says Thiemann. "We estimate reducing time-to-market from five to three years, a 40 percent reduction."



The re-use and extension capabilities of Polarion are based on work items that only need to be modified once and can then be updated in all the instances when they are used.

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