

The Situation

Ottobock HealthCare, part of the Ottobock group of companies, has divisions for Prosthetics, Orthotics, Neurorehabilitation, Mobility Solutions and MedicalCare. It enjoys a worldwide reputation for the high quality of its technologically outstanding products and services that help individuals by restoring—or protecting existing—mobility.

Founded more than 90 years ago, Ottobock (known as Ottobock within the U.S.) has more than 6,000 employees worldwide, and a network of distribution and service companies that brings its life-changing products and services to 50 countries around the globe.

As a manufacturer of products in the field of medical technology, Ottobock faces strict regulatory standards and requirements, which places high demands on process and project management. Applicable regulations include

ISO 22675, ISO 62304, ISO 66101, ISO 13485, ISO 10328 and RoHS. These in turn require verification, validation and documentation.

Ottobock created its own project management system for requirements and document management, but found the system to be limited. For instance, documents and requirements could only be managed loosely and without linking. As a result, the required traceability took considerable time and effort. The company needed to find a better solution.

The Solution

Ottobock chose Polarion® ALM™, the fully integrated application lifecycle management solution, after a nearly 2-year period of evaluating Polarion and competing products.

Ottobock considered finding the best ALM tool so important to its commitment to meeting regulatory demands and ensuring the continued high quality of its products, that it committed to a substantial evaluation of possible solutions. Among its demands were finding the best solution for managing requirements, test management processes, and supporting team collaboration.

The search and evaluation period included consideration of a number of products, including FMD and IBM DOORS. During the process, a team member saw positive reviews of Polarion while doing web searches, and Polarion was brought into the evaluation process.

Impressed with what its internal evaluation team found, Ottobock interviewed Polarion reference customers Sartorius AG in Göttingen and GETEMED medical and information technology AG in Berlin.

The positive references confirmed Ottobock's own internal evaluation. Ottobock valued the high configurability of Polarion, and found its unified, 100% browser-based approach to be ideally architected to help solve its requirements management and test management challenges, as well as to ensure comprehensive traceability.



Environment

429 Users (mainly from Germany (Duderstadt and Königsee) and Austria (Vienna))



System Specs

Self hosted Windows Server (2008R2)

- Virtualized with ESX
- 4 cores of Intel® Xeon®
- . CPU X5690 @ 3.47 GHz
- 40 GB RAM

2 Servers (productive, staging) 129 projects repository size 26 GB Number of revisions in the repository: 175750



Polarion ALM Polarion REQUIREMENTS

The Benefits

Ottobock has enjoyed a number of benefits since deploying Polarion ALM, including strong requirements management, traceability and predictability, enhanced collaboration, improved visibility, and tighter security.

Strong Requirements Management

Deploying Polarion has given Ottobock what it needed most: an improved, uniform and transparent process for requirements and test management.

Polarion ALM has also greatly simplified management and tracking of documentation, including functional specifications, tests and test reports.

Gaining Traceability & Predictability

Ottobock developers and testers enjoy the full traceability they have gained through use of Polarion. With Ottobock's earlier solution, traceability and predictability were exceedingly hard to achieve.

Now, with Polarion, project managers are able to report on interim results and deliver concise real-time status updates on the topics such as:

- Which requirements have been implemented
- Which test objects are related to which requirements
- Which change requests have influenced what project results

The full traceability Ottobock has gained from Polarion is especially valued because of the tightly regulated environment it operates in as a maker of medical devices.

Enhanced Collaboration

Ottobock has found it easier for development and test teams to collaborate through use of Polarion's LiveDocs $^{\text{\tiny TM}}$ central repository. LiveDocs supports a document centric view, so users can easily view text that provides detailed information about the tests, guidelines, background, or feature sets.

The company's earlier solution was a slow, decentralized process involving various desktop applications. With LiveDocs, developers, testers, and project managers enjoy an always up-to-date online environment.

The real-time information available in the new system makes it possible to accelerate work processes and significantly improves communication and collaboration between different teams.

Improved Visibility Boosts Quality

The implementation of Polarion has helped provide requirements transparency for all project teams. Ottobock credits this improved visibility into requirements with boosting quality for the company's already high-quality products.

In addition to boosting quality, the visibility increases team morale. Each team member can easily recognize their own contribution to the overall project, as well as gain insight into the reasons for any tasks and omissions, resulting in much higher employee motivation.

Ottobock believes that Polarion's ability to provide greater transparency also helps employees strengthen their identification with the product and the company.

Tighter Security

Ottobock believes the overall security of its product development has been enhanced since deployment of Polarion. The company credits Polarion's unique traceability and its unified approach with providing a high level of security, since automated testing and routine loops ensure that nothing is forgotten or overlooked.

Change & Configuration Management

Reuse & Branch Management

Collaboration Traceability Workflow

Test & Quality Management

Issue & Risk Management

Issue & Risk Management

Agile / Hybrid Project Management

Planning & Resource Management

Audits & Metrics, Reports

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About Polarion

Polarion Software is a leading provider of a 100% browser-based and unified platform for Requirements-, Quality- and Application-Lifecycle-Management (ALM). The company helps global organizations in a wide range of industries from automotive to medical device and aerospace achieve agility, traceability and compliance for their complex products. More than 2.5 million users worldwide rely on Polarion to fuel collaboration; integrate ALM and Product Lifecycle Management (PLM); and more efficiently bring their high-quality products to market while pleasing the regulators. For more information, visit: www.polarion.com

