



Creators of Leading Neuromodulation Device Increase Quality with Polarion

Polarion is helping us achieve the higher quality we aspire to reach, and saving us money at the same time.

Senior Manager, Systems and Software Engineering



The Situation

Medical device companies face various challenges during the development process to deliver high quality safety-critical products. As project schedules condense and product complexity grows, first-time-through testing, quality, risk, and compliance assurance becomes critical to achieving the project objectives. **A creator of the leading neuromodulation device** recognized that in order to ensure that their products continued to achieve regulatory and customer acceptance they needed to overhaul their product development processes. This included replacing costly legacy silos of IBM® Rational® ClearCase® and ClearQuest® and replacing Microsoft® Word with a more efficient solution for requirements management and traceability. As a result, the company sought a more modern and encompassing product lifecycle solution.



The company wanted a browser based solution for easier access and collaboration with their teams and partners located around the world. They required a more comprehensive solution for product development that included requirements, test cases, and change management with full traceability across all projects and all work items. The company needed a proven solution that could guarantee FDA compliance. At the same time, they were looking for a **cost-effective cloud based or hosted solution.**

The Selection

The company evaluated several vendor solutions over a two year period. In the end, they made the decision to go with Polarion Software for its customer service, willingness to work with them, and many unique solution advantages, the most significant of which were:

- Polarion's 100% browser-based solution is **easy to learn and use**
- **Web 2.0** enterprise application architecture designed for both distributed and centralized project teams
- Polarion is a compliance solution for **CMMI or Agile** environments with out-of-the-box templates for **ISO, IEC, or FDA compliance.**
- Immense **flexibility** allowing the most advanced customizations possible on a project or global basis
- Advanced **workflow automation** which manages work items throughout the product development process
- The option to have either **internally or externally** Hosted **Cloud Computing (SaaS)**

The Solution

Polarion is used quite substantially across the company **organization, for the following disciplines:**

- systems engineering,
- software development,
- firmware development,
- electrical engineering,
- and mechanical engineering.



Environment

International product availability:
~70 countries

Employees:
~570

Patients:
~68,000

Total device implants:
~97,000



Conclusion

"Polarion is helping us achieve the higher quality we aspire to reach, and saving us money at the same time.."

Senior Manager, Systems and Software Engineering

Polarion is used in the following areas at the company:

- Research and Development
- Quality Management
- Clinical Engineering
- Advanced Manufacturing Engineering
- Several company partners around the world

In the near future, the company will expand the use of Polarion to include Marketing and 3rd party component suppliers and partners.

“ Polarion is really helping us develop these safety-critical devices ”

The Benefits

The company confirms that Polarion has delivered these main benefits:

- Polarion has helped create a much more scalable and collaborative product development user base than originally envisioned.
- Polarion provided the company with the ability to replace old and costly tools with a modern hosted solution to save money and provide better support.
- The company is better able to manage an increasingly complex product portfolio with security and flexibility by teams around the world.
- Since Polarion is TUV certified and enables FDA compliance, it serves the company needs to manage thousands of systems, software, electrical, and mechanical assets.
- Polarion enables the company staff to provide solid revision control supporting the development of safety-critical medical device products in an agile way.
- Polarion’s ease of use, and hosted support allows the company to focus resources on products and customers as opposed to IT and Administration.

The Client

The company is considered a leader in medical devices for epilepsy. With its headquarters in the U.S. and international offices the company is dedicated to the continuous development and delivery of life-changing innovation that offers improved Neuromodulation therapy efficacy, more treatment options, greater ease-of-use, and better management of patients with epilepsy.

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 - creators of products that people trust – 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. For more information, visit www.polarion.com.



“Polarion is really helping us increasingly manage a very complex portfolio.”

“Enabling us to work around the world”

“Helps us remain CFR Part 11 compliant”

“A web-centric tool that allows collaboration with partners around the world”

“Unified approach creates more agility”