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Medtronic

Medtronic Customer Case Study

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This case study explores how the Neuromodulation department of Medtronic, a global leader in medical technology, has implemented codeBeamer ALM to overcome issues that their previous software ecosystem wasn't able to efficiently address.The organization set out to make the transition from legacy systems to state of the art solutions and processes. codeBeamer ALM has efficiently assisted the department in realizing their vision of scaling Agile while building processes to support compliance in this highly regulated industry.In effect, Medtronic's Neuromodulation department has completely re-shaped their processes, and has used codeBeamer ALM to drive this change.

About Medtronic

Medtronic is the world's largest standalone medical technology company headquartered in Dublin, Ireland, with its operational headquarters in Fridley, Minnesota, US. The company founded in 1949 was among the first to use electrical stimulation to treat irregular heart rates, and has since evolved to develop and manufacture high-tech devices and therapies for several chronic diseases such as Parkinson's disease, heart failure, Down's syndrome, obesity, chronic pain, and diabetes among others.

Operating in more than 155 countries and employing over 85,000 people worldwide, Medtronic is a global healthcare solutions company with a revenue of over $20 billion in 2015. Aligned by the company mission of "Alleviating pain, restoring health, and extending life", Medtronic is composed of several business units. Neuromodulation is the second-oldest and third-largest Medtronic unit, accounting for $1.9 billion, or 11% of Medtronic's revenues in 2014.

In a tool evaluation, selection and purchase process, Medtronic Neuromodulation has implemented codeBeamer ALM in April 2015 with 50 reviewer users and 200 ALM users, which they have shortly expanded to include all 250 of the department's developers as well as 50 reviewer users. In his role as Director of Patient Care Software at Medtronic Neuromodulation, Sarb Singh-Kaur is responsible for the development of all Health Software Products, R&D, Innovation and Mobile, Cloud and Data Sciences Infrastructure development.

His vision that codeBeamer ALM helps accomplish, however, is greater than the sum of these activities:

> **"I am transitioning the organization from legacy embedded software systems to state of the art mobile and cloud software medical systems and processes."**

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Led by a visionary software executive, Medtronic's Neuromodulation department has developed a framework that combines the use of scaled Agile processes and the advanced capabilities of a cutting-edge Application Lifecycle Management solution, codeBeamer ALM, to help the world's largest medical technology company stay ahead of its competition in terms of Agility, velocity of software innovation & development, and product quality.

> **We needed to capture customer needs and trace them down to product requirements, down to design, tests, and source code. codeBeamer ALM was the only tool that allowed us to do that in a smooth way.**

ALM to Alleviate Development Pains

Before implementing codeBeamer ALM, Medtronic Neuromodulation was relying on an elaborate software ecosystem to manage their ALM and Agile needs. JIRA, VersionOne, PTC Integrity, SharePoint, IBM Rational RequisitePro & ClearCase, GitHub, and several ingrown tools were all in use.

While the team was happy with the functionality that the combination of these software platforms provided, integrating this plethora of standalone solutions was a difficult task. Using isolated and manually integrated tools inhibited transparency. Ensuring the traceability of requirements all the way down to source code, and exporting comprehensive documentation that needed to be submitted to FDA for compliance audits were problematic.

Therefore, the Medtronic team started looking for a tool that could help them implement integrated Application Lifecycle Management and Agile software development at the same time, all in a scaled environment to allow the collaboration of all 250 developers as well as other stakeholders.

Diagnosing Pain Points

The traceability of requirements down to source code was one of the most critical issues the team was facing. But it wasn't the only one. Below is a list of the essential problems Medtronic's Neuromodulation team had to overcome, and how codeBeamer ALM addresses those issues.

Associations & relations

Due to the number of individual software tools in use, the association of several types of work items along the lifecycle, and many-to-many-relations were difficult to deal with.

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codeBeamer's fully integrated, single repository architecture allows the referencing of all work items even across projects throughout the entire product lifecycle. codeBeamer's configuration database allows custom data models and many-to-many referencing.

Traceability

With referencing work items being a crucial issue, ensuring and demonstrating traceability required strenuous manual effort & careful monitoring.

codebeamer

In addition to allowing the referencing of all types of work items, codeBeamer ALM also offers a comprehensive, filterable, exportable overview of these associations via the Traceability Browser.

Process management and transparency

Managing processes potentially spanning several tools, and ensuring process visibility and transparency throughout the lifecycle were overwhelming tasks. Medtronic Neuromodulation needed "single pane of glass" process management and monitoring.

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Using codeBeamer's workflow engine with Business Process Management capabilities, process management and complete visibility are guaranteed. Workflows may be flexibly configured even across projects and tools, and processes are automatically visualized providing complete lifecycle transparency.

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Document management

With no shared repository between tools, managing documents was a painful task. Storing documents in a way that supports collaboration, ensuring version control, and tracking all changes was barely possible.

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codeBeamer's Document Management capabilities took much of the burden off of the Medtronic Neuromodulation team's shoulders. Documents are stored in a shared repository, accessible to all users with a permission. A full audit trail is recorded, providing complete version control.

Wiki

Sharing knowledge and how-tos with documents was a highly inconvenient process. The team needed an efficient way to set up a central knowledge base and share how-tos internally.

codebeamer

Further enhancing collaboration, codeBeamer's Wiki functionality has allowed the Medtronic team to create a shared and versioned Knowledge Base, as well as interactive dashboards with plugins and widgets

Baselining

Due to the rigorous industry standards that apply to medical software development, comprehensive baselining is a fundamental requirement. Creating baselines spanning each and every tool used in the development lifecycle was a highly impractical and frustrating process.

codebeamer

Thanks to its central repository and fully integrated nature, baselining in codeBeamer ALM takes no more than a few seconds, saving a great deal of time and effort for the Neuromodulation team.

Test management

Medtronic's Neuromodulation team uses test-driven development. The ability to develop and execute test cases, perform unit testing as well as system-level verification tests, and trace testing activities to software code is fundamental.

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codeBeamer's capabilities around test management allow the Medtronic team to manage testing from business goals to release by helping them plan, manage and execute manual or automated testing. Test results (with the appropriate statistics) are managed and reported on using codeBeamer.

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Reporting & documentation

Before implementing codeBeamer, reporting on processes, traceability and access control, and compiling thorough and transparent documentation across tools for audit purposes was a complicated task.

codebeamer

Relying on codeBeamer's complete process transparency, automatic documentation and customizable reports, the time and effort costs of reporting and documentation have significantly decreased.

Integrations and DevOps

The integration (data transfer) between standalone legacy tools was insufficient, hindering the implementation of DevOps at Medtronic's Neuromodulation department.

codebeamer

The team chose to extend codeBeamer's built-in DevOps functionality with some of their preexisting tools. The ease of extraction and relation of data via APIs helped integrate their ALM solution and DevOps strategy.

FDA Title 21 CFT Part 11 compliance

Products developed by Medtronic's Neuromodulation team are subject to a number of regulations, amongst which FDA Part 11 governs the use of electronic signatures. In their legacy environment with several software solutions, adequate process and access control were difficult to achieve.

codebeamer

codeBeamer's advanced capabilities allow the granular management of access and process control. FDA Title 21 CFT Part 11-compliant e-signatures may be configured to be required at any point in the lifecycle, and a preconfigured IEC 62304 Medical Template is available to support compliance with other standards. The Neuromodulation team chose to create custom workflows to tailor their ALM system's capabilities to their internal process needs.

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Medical Compliance Requirements

As a medical device developer, Medtronic Neuromodulation's products are subject to various standards and regulations. Therefore, achieving compliance is a critical requirement. Medtronic factored in this aspect when evaluating ALM solutions, and found that codeBeamer ALM adequately supported compliance either through its out of the box functionality, or due to its highly adaptable nature that enables the use of custom configurations.

Among the standards relevant for Medtronic Neuromodulation are:

- **IEC 62304:** Medical Device Software – Life Cycle Processes
- **IEC 82304:** Health Software
- **ANSI/AAMI HE75:** Human Factor
- **AAMI TIR45:** Guidance on the use of Agile practices in the development of medical device software
- **IEC 60601-1:** Medical electrical equipment
- **ISO 13485:** Medical devices – Quality management systems
- **ISO 14971:** Medical devices – Application of risk management to medical devices
- **FDA Title 21 CFT Part 11**, and other **FDA regulations**

Achieving compliance with the above regulations requires flexibly configurable custom workflows that allow the execution and monitoring of fully controlled processes, complete traceability, and comprehensive documentation. The evaluation found that all of these requirements are aptly fulfilled by the features and capabilities of codeBeamer ALM.

While Intland's preconfigured Medical IEC 62304 Template supports compliance with various healthcare software standards, like most other users, the Neuromodulation team have tailored ALM workflows to their needs, taking advantage of codeBeamer's process control features with Business Process Management capabilities, its risk management and quality assurance & testing features, as well as its FDA-compliant e-signatures.

Thus, Medtronic's team was able to fully configure codeBeamer ALM to support their specific compliance needs. The effort required to prove compliance at validation audits has significantly decreased thanks to codeBeamer's automatic documentation and custom-configurable reporting functionalities. Pulling reports in codeBeamer about the development processes used is convenient and efficient.

Quite naturally, compliance accounted for only a fraction of aspects and criteria considered during the search for, and evaluation of ALM solutions at Medtronic Neuromodulation.

ALM Evaluation Criteria

Medtronic Neuromodulation initiated the tool evaluation process in September 2014. In order to be able to support Sarb Singh-Kaur's vision of transitioning Medtronic Neuromodulation from legacy to cutting edge development processes, the team needed a fully integrated, robust yet flexible cloud-hosted ALM solution. The hunt for a suitable software platform started with establishing the criteria for evaluation.

First and foremost, the Neuromodulation team was looking for an easy to use solution that offered complete clarity of visualization, as well as convenient navigation of requirements. Traceability and flexible configuration options to support compliance were as important as strong core capabilities (requirements management, source code control, quality assurance & testing features). Document management features were also highly valued criteria.

Finally, there was of course the consideration of costs: codeBeamer's Total Cost of Ownership (TCO) was deemed reasonable. Our ALM solution's integrated nature enables advanced functionality right out of the box, sparing the costs and frustration of installing and maintaining additional plugins or other software. The Neuromodulation team found that the basic training offered by Intland Sofware was affordable, sufficient and thoroughly educational, but they expressed a need for more advanced training options.

Alternative ALM Solutions Considered

Among the software solutions the Neuromodulation team has chosen to evaluate were: Atlassian JIRA, Jama, Polarion ALM, PTC Integrity, VersionOne, Rally, and codeBeamer ALM.

Generally, competitors fell short in their Agile capabilities: VersionOne was the only tool deemed satisfactory at Agile, but it needed additional tools to adequately perform requirements management. Their inherent lack of complete integration, and the need to install plugins or other additional elements ruled out the use of JIRA, Jama, and Rally. Besides the lack of real Agile support, PTC was considered too heavy-weight by the Neuromodulation team, with a poor user interface and the need for extensive customization. Polarion's shortcoming was its document-centric view, leaving Medtronic's team wondering if it was "optimized for those who like to view the world as a Word Document".

codeBeamer's complex asset management capabilities, complete traceability, advanced testing features, and best practices offered around application lifecycle management and compliance were its most highly valued features. Being able to configure custom trackers for different object types, and to create relationships between all work items are codeBeamer features that the Neuromodulation team simply can't imagine living without. The ability to show these relationships via the Traceability Browser, and to export documents and reports greatly facilitate compliance and were therefore considered key assets when Medtronic's evaluation ended with the decision to purchase codeBeamer ALM.

Deployment & Rollout Process

Once the purchase decision was made in April 2015, Medtronic's Neuromodulation team deployed codeBeamer ALM in less than two weeks. A pair of Intland Software engineers flew over to the Medtronic headquarters for an intensive week of technical rollout (configuration and training the trainers), helping the team get up to speed with codeBeamer's features right away.

The Neuromodulation team migrated data from their previous tools using APIs and codeBeamer's import capabilities, staging their new ALM software on a test server to perform the migration. After the Primary Tool Validation was done in four weeks, the entire team started using codeBeamer ALM, and were surprised to see how user-friendly it was.

> **"The solutions is easy to learn and use. New employees find their way around in less than 2 weeks. They are able to do tracker configuration within 2-4 weeks."**

Benefits and Value Realized with codeBeamer

Medtronic's Neuromodulation team has configured trackers, projects, roles and workflows to establish their new internal processes – process change and codeBeamer went hand in had.Essentially, codeBeamer ALM has helped them transition a department of the world's largest medical technology company from legacy solutions to state of the art processes, greatly facilitating the efficient production of innovative mobile and cloud software medical systems.

> **"Here are the things we have been able to accomplish: We have completely re-shaped our processes and have used codeBeamer as the instrument to drive that change. We were up and running in less than 30 days. We have over 250 active users already. Intland Software has implemented specific features to satisfy our needs."**

Calculating the ROI on complex tool investments is a difficult task. At the end of the day, it's all about the capabilities and process improvements that the new solution brings to the organization. When asked about the bottom-line value that codeBeamer ALM delivers, Medtronic's Neuromodulation team has quoted the following:

- Predictability and well-traced adherence to establishedsoftware development process
- Software Portfolio Management
- Compliance with regulatory requirements
- Complete transparency
- Better Project Management

Overall, Sarb Singh-Kaur's ambitious and forward-thinking goals of replacing legacy processes with leading edge ones to create a powerhouse of innovation and improve value creation were aptly supported by the robust capabilities of codeBeamer ALM. Medtonic's Neuromodulation team was able to start quickly, and realize value almost immediately after implementing their new ALM solution. codeBeamer ALM has helped them address issues faced by many, if not all medical device and embedded software development teams globally – and has helped resolve these problems in a matter of weeks.

Soon after the initial 200 ALM licenses were deployed, Medtronic Neuromodulation purchased an extra 50 licenses, and as of March 2016 are investigating how other Medtronic departments could benefit from using codeBeamer ALM.

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About Intland Software & our solutions

Intland Software offers industry-leading software tools to simplify complex product and software engineering at scale. Our enterprise-grade platforms help accelerate the development of technology products and simplify regulatory compliance.

Intland's solutions are used by leading companies including top automotive, medical, pharma, and life sciences developers worldwide to manage their innovative, compliant product engineering processes.

codebeamer is an Engineering and Application Lifecycle Management (EALM) platform with unique configurability and product line configuration capabilities.

codebeamer X is an integrated platform Engineering Lifecycle Management (ELM) platform for life sciences companies with regulatory process & compliance support.

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