

Connecting the Design Control Dots

Biotronik Vascular Intervention's Pursuit of Technical File Integration

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The Company

At BIOTRONIK, patient well-being is our top priority and has been for 60 years. BIOTRONIK is a leading global medical technology company with products and services that save and improve the lives of millions suffering from heart and blood vessel diseases as well as chronic pain. Driven by a purpose to perfectly match technology with the human body, we are dedicated innovators who develop trusted cardiovascular, endovascular and neuromodulation solutions. BIOTRONIK is headquartered in Berlin, Germany, and is represented in over 100 countries.

The business unit Vascular Intervention offers a broad range of products to restore blood flow in arteries of the heart (coronary) and body (peripheral, excluding carotid and brain) that are narrowed or blocked. We produce a full range of scaffolds, stent systems, balloon catheters, multifunctional and speciality catheters for treating patients with coronary and peripheral artery diseases.

The Challenge

Establishing medical device technical files for a global market posed a considerable amount of documentation work for the Biotronik Vascular Intervention development team. The use of several, separate, non-integrated software tools, accompanied by the management of Word reports containing redundant information made the compilation of the necessary documentation to satisfy regulations and standards such as ISO 13485, ISO 14971 and FDA QSR 820 a dreary affair.



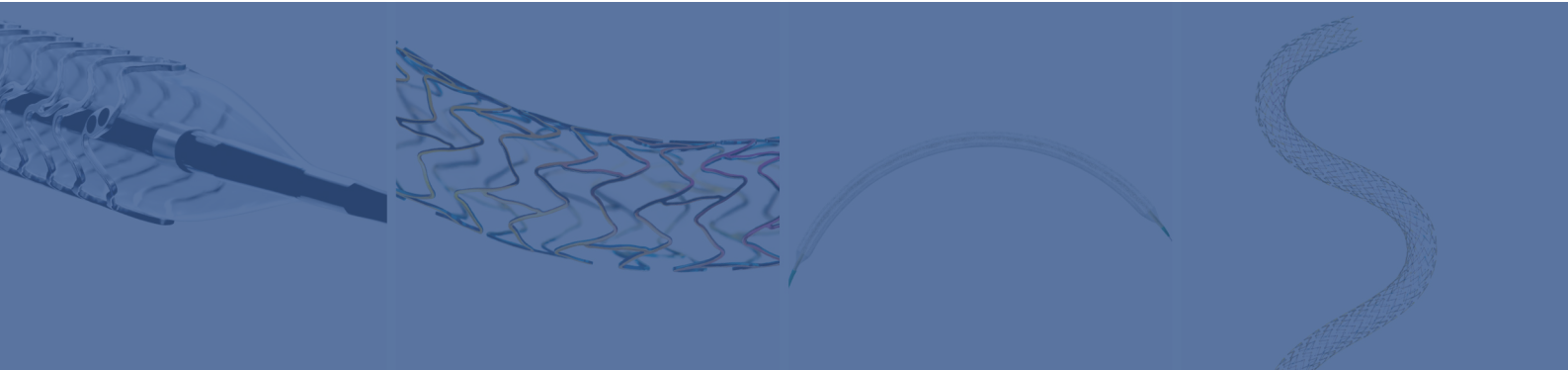
"...That was the major reason we chose Aligned...."

The disconnected system landscape resulted in a lack of communication between the tools, leading to potential data inconsistencies. The resulting manual tracking to avoid inconsistencies and implementation of changes at various locations further exacerbated the challenge, resulting in a cumbersome manual process, occupying valuable team-members with menial tasks. The challenge was taken on by several key departments within the organization. The risk management team needed to invest great efforts for maintaining traceability and consistency across documents and projects. Similar, the design control and requirements engineering department within the business unit Vascular Intervention was mainly occupied in ensuring that design specifications and requirements were accurate and up-to-date.

Addressing these challenges became critical as the tool users expressed dissatisfaction and consistently raised concerns about the existing workflow.

Recognizing the need for a more streamlined and integrated approach, it became imperative to find a comprehensive solution that would enhance efficiency, reduce redundancies, and ultimately contribute to the comfortable production of high-quality technical files for Biotronik's Vascular Intervention life-saving medical devices.

The Solution



When analysing their needs, it became obvious that the unconnected tools and manual interventions led to redundancies and additional and repetitive work.

Biotronik Vascular Intervention business unit searched for a software tool that could support their technical file documentation process by spanning all design control and risk management aspects and support the entire development life cycle. However, it was equally important to have a system flexible enough to allow the necessary adaptations to Biotronik's Vascular Intervention process requirements and design control workflows.

After a carefully executed evaluation process, Aligned Elements emerged as the best choice, being highly configurable, explicitly designed to solve the high regulated industry's technical documentation problems. For Biotronik Vascular Intervention this resulted in a configuration addressing several parts of the design control structure including design, test and risk management.

"The configuration possibilities offered true benefit. We have a very large freedom in configuring Aligned Elements according to our processes. Once our team understood the underlying concepts of Aligned Elements, this opened doors to even more powerful and interlinked usage of process data.", said Sebastian Reiter, Manager Risk Management and Usability Engineering at Biotronik Vascular Intervention.

The Experience

"In our team, the Aligned Elements user interface was perceived as very easy to use. New users are up and running extremely fast and the learning curve is minimal for the core functionality.", states Sebastian Reiter. "It is great to have requirements, risks and tests within the same integrated system with no gaps. A single data source removes a lot of redundancies previously present in the disconnected systems." Adds Sascha Miskovic, Senior Principal Design Control Engineer

at Biotronik Vascular Intervention. "We now leverage Aligned Elements linked-projects to achieve significant re-use of data."

The Biotronik Vascular Intervention team started transferring existing project data into Aligned Elements by applying Aligned Elements extraction and parsing tools to efficiently import legacy data.

"Effectiveness is achieved through consistency and re-use of data for the entire product life cycle. With the single data source, high data integrity with integrated, automated change control and a complete and consistent audit record of all our actions" states Mr. Miskovic.



**"New users are up
and running extremely
fast..."**

Conclusion

Biotronik Vascular Intervention faced challenges due to disconnected tools and manual work, causing extra effort. They were looking for a flexible and integrative software tool and chose Aligned Elements after evaluating their best options.

Aligned Elements convinced Biotronik Vascular Intervention with its user-friendly interface and seamless transition for new users. In the end, Aligned Elements improved Biotronik's Vascular Intervention documentation processes, offering a single data source, high data integrity, automated change control, and a consistent audit record—boosting efficiency across the product life cycle.