Fritz Stephan
Customer Case Study

About Fritz Stephan GmbH

"A finger on the Pulse – Clinical Experience, Technical Competence"

Fritz Stephan is a German medical technology company that develops specialized ventilation, anesthesiology and oxygen supply solutions with a special focus on neonatology and pediatrics. Headquartered in Gackenbach, Westerwald, the family-owned company is now regarded as one of the world leaders in the development of innovative ventilation systems.

The company's founder Mr. Fritz Stephan developed his first reanimator (designed specifically for the ventilation needs of premature infants and newborns) in 1974, and Fritz Stephan GmbH was formally founded in 1978. Following the expansion of the product line to include monitors, and inhalation anaesthetic and respiratory therapy equipment, Fritz Stephan has grown into a successful mid-sized medical technology company with offices and resellers around the world.

Its STEPHANIE neonatal ventilation system is a great example of how clinical experience and technical expertise go hand in hand in the development of high-tech medical devices. Combining the functions of a ventilator, patient gas humidifier, oscillator and monitor, this unit is a result of Fritz Stephan's extensive innovation efforts: the company reinvests approximately 12% of its total earnings in research and development.

To support its strategy of fostering innovation and achieving consistently high product quality, Fritz Stephan has purchased its first codeBeamer ALM licenses in April 2014. As the team started to understand the full potential of this integrated Application Lifecycle Management solution and thanks to codeBeamer's scalability, they gradually moved on to double the number of licenses in use by October 2015.

Development isn't the only department taking advantage: today, codeBeamer ALM supports the work of several Fritz Stephan departments.

> **"All our development employees now use codeBeamer ALM. But we don't just use it for software development: managers, Quality Assurance specialists, and others stakeholders now use codeBeamer ALM for various tasks throughout the whole process of development."**
>
> – Jens Amberg, Vice CTO, Fritz Stephan GmbH

The Problem: Difficulties of Collaboration & Compliance

Fritz Stephan strives to build top-notch medical devices according to the highest quality standards. Not only is the company certified for DIN EN ISO 13485 and DIN EN ISO 9001, but it only works with suppliers certified for those same standards. Their rigorous quality control processes help ensure the reliability of their products and thus, the safety of patients as the ultimate goal.

As a developer of mobile care units used when transporting patients, Fritz Stephan's products are also subject to various medical and aviation standards, for instance, IEC 62304, ISO 13485, and DO-160 – for a full list of regulations that apply to Fritz Stephan's products, see the section titled Specialized Compliance Requirements below.

In such a complex development and regulatory environment, smart tools are needed to ensure transparency and the efficient management of development work throughout the lifecycle. Prior to implementing codeBeamer ALM, Fritz Stephan's developers were relying on Microsoft Word and Excel files to store and manage requirements.

While still a relatively commonly used solution to the question of requirements management, the limitations of MS Office (Word and Excel) in terms of collaborative change management are obvious. More and more companies are realizing that Office documents are insufficient for the collaborative development of high-quality safety-critical products. In the case of Fritz Stephan, the following problems led to an evaluation of an integrated Application Lifecycle Management platform:

Collaboration & Transparency

Traceability

Specialized Compliance Requirements

Collaboration & Transparency

Prior to switching to codeBeamer ALM, Fritz Stephan's development team was using MS Word and Excel files located on the local hard drives of PCs to store and keep track of requirements and test cases. Quite obviously, they quickly understood that this approach made collaboration exceedingly difficult, and implemented a combination of Subversion, LaTeX, and a homegrown issue-tracking system. Using Subversion and LaTeX's reference capability allowed the team to "split" requirements documents, enabling more developers to work on requirements at the same time.

However, it didn't take too long before they realized this solution was unsatisfactory in such highly regulated development projects, where transparency and process control are crucial. Ensuring complete change control on requirements was problematic, and it was difficult to propagate changes to all the artifacts associated with requirements. It was practically impossible to ensure that all developers have access to an up-to-date version of all development artifacts. Therefore, their tool ecosystem hindered, rather than encouraged efficient collaboration.

> **"From our point of view, it's not just difficult to keep all documents up-to-date and linked together using Word and Excel: it's impossible. It's never going to work out."**

– Jens Amberg, Vice CTO, Fritz Stephan GmbH

Traceability

Being able to establish links between requirements, tasks, test cases, issues, bug fixes, and other work items is not just beneficial in terms of ensuring transparency. In fact, it's an explicit requirement of several standards that regulate the development of medical devices. Thus, Fritz Stephan's developers needed an ability to interlink all work items, and to export simple reports that help auditors overview these relations.

Using codeBeamer ALM, the team can easily propagate changes (for example upon changing a requirement) to all affected artifacts. Considering their elaborate compliance needs, it's no surprise that Fritz Stephan's development team highly values codeBeamer's ability to associate bug tracking with the SVN database. Being able to connect bug fixing tasks to source code changes, the team can easily check up on issue numbers, and trace back how specific issues were solved.

Naturally, auditors also love this feature, as it makes bug fixing (and the whole process of development) completely transparent and fully traceable. Fritz Stephan's manufacturing and electronics departments have since adopted the use of codeBeamer ALM to enhance traceability.

> **"We store everything in codeBeamer. All our specifications, technical summaries, documents, and all other information about our medical devices is saved here, and their relations are maintained. codeBeamer helps us make sure that every member of the team has an overview of, and access to a single shared database where all our artifacts are linked together."**
>
> – Jens Amberg, Vice CTO, Fritz Stephan GmbH

Specialized Compliance Requirements

Since the company builds complex, innovative devices for a highly regulated medical industry, compliance with medical standards is a crucial point for Fritz Stephan, as it is for any other global medical device developer.

But that's not all: since their products are used in emergencies, during patient transport (for instance, with helicopters), and in hospital environments alike, the company's product development team has to juggle compliance with a variety of standards applying to both medical devices and avionics products.

Its *EVE* mobile ventilation system is a great example of Fritz Stephan's compliance challenges: offering complete patient care from emergency site to intensive care unit, EVE_{TR} units are used in emergencies and during transport, while EVE_{IN} is an intensive care respirator used in hospital environments. The multipurpose use of these products means that compliance needs to be achieved with all relevant regulations, including RTCA DO-160 and medical standards.

Risk management is another important process covered by stringent regulations including ISO 14971. Using Intland's Medical IEC 62304 Template, Fritz Stephan no longer needs to worry about adhering to standards: they simply use the template's risk management trackers and features out of the box. Having added usability indicators to codeBeamer ALM, Fritz Stephan's development team is able to set up direct links between requirements and risks. Traceability between all work items is ensured, thorough risk management activities are carried out, and complete audit trails are automatically recorded by codeBeamer on all development work.

Overall, since making the transition to codeBeamer ALM, adhering to rigorous medical and avionics standards no longer poses a problem to Fritz Stephan. In fact, the development team has been able to put into place a process of continuous compliance.

Using mature processes, they don't have to sacrifice valuable work hours on ensuring and proving adherence to the requirements of all these regulations as a final stage of development. Instead, they are in a state of automatic and continuous compliance. Thus, Fritz Stephan has been able to eliminate the burden of needing to prepare for audits: they can simply export comprehensive reports any time. When it's time for their yearly compliance audit, they simply log in to codeBeamer and let the auditor check through all the processes and data therein.

Having set up the lifecycle in a way that fits the requirements of the latest regulations, the development team has also managed to future-proof their processes. With new EU MDR regulations coming into effect soon in Europe, Fritz Stephan developers sleep well knowing they are prepared for regulatory changes.

Overview of standards applicable to Fritz Stephan's development activities:

IEC 62304: Medical Device Software – Life Cycle Processes

ISO 13485: Medical devices – Quality management systems

ISO 14971: Medical devices – Application of risk management to medical devices

ISO 80601-2-12: Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators

DIN EN 794-3: Lung ventilators – Part 3: Particular requirements for emergency and transport ventilators

RTCA DO-160: Environmental Conditions and Test Procedures for Airborne Equipment

"Auditors were astonished to learn about this feature, and to see how simply we were able to trace bugs down to source code and verification. It is a source of great pride for us. Also, the development department no longer has to prepare for audits – using codeBeamer ALM, we are automatically compliant, all the time."

– Jens Amberg, Vice CTO, Fritz Stephan GmbH

The solution: Evaluating ALM Tools

Having realized that they could no longer live with the limitations of their MS Office-based requirements management and testing tools and processes, Fritz Stephan's development team began looking for an integrated ALM solution in April 2013, and ended up purchasing their first codeBeamer ALM licenses in January 2014.

While they were aware that some of the company's external suppliers were using Application Lifecycle Management tools, the concept of integrated ALM was new to the team. One of Fritz Stephan's external engineering partners had been using Visure, making that the first ALM tool the team had ever seen.

In an evaluation project led by Mr. Jens Amberg, Fritz Stephan's developers then started researching ALM tools, and identified Visure, Polarion, add4Q plugin for Enterprise Architect, IBM DOORS, Qware® Riskmanager, and Intland Software's codeBeamer ALM as potential candidates. They visited the booths of several ALM vendors at trade shows and conferences, and continued the evaluation and selection phase online.

Jens Amberg, Dipl.-Ing. (FH) is Fritz Stephan's Vice CTO with 15 years of experience in hardware and software development. Mr. Amberg has had a key role in the ALM evaluation process that led to the company's purchase of codeBeamer ALM.

Visure and IBM DOORS were deemed to be too expensive for their value, while the add4Q plugin simply didn't offer the functionality that was required by the Fritz Stephan development team. They thought that Polarion ALM was too document-centered, and didn't offer as wide a range of features as the more comprehensive codeBeamer ALM.

According to Mr. Amberg's account of the purchase decision, another major reason behind Fritz Stephan's choice of codeBeamer ALM was the tool's seamless integration. As codeBeamer uses a single repository to store all development data, development is not being done in an environment stitched together from various standalone modules. Instead, Fritz Stephan is taking advantage of the ALM platform's holistic integration: in codeBeamer, everything is connected from requirements through tasks, test cases, test sets, test runs, and issue tracking all the way to release and operations.

> **"We chose codeBeamer ALM because with this tool, it finally feels like we're really working together. As the tool's modules are organically integrated, all our requirements, testing, issue tracking activities, and artifacts are connected, traceable, and accessible to every member of our team."**
>
> – Jens Amberg, Vice CTO, Fritz Stephan GmbH

codeBeamer ALM Rollout &
Process Optimization

When making the transition to codeBeamer, Fritz Stephan's development team took a swift approach. They switched to integrated ALM in the middle of an ongoing project, for which the specification of requirements was already completed. They didn't purchase any extra training or consulting services, and figured out how the tool works on the fly. While this approach doesn't help to make the transition process smoother, it does force the team to get up to speed with their new tool as fast as possible, making it a somewhat difficult but rewarding way of implementing integrated Application Lifecycle Management.

As a feature-rich tool that supports the management of immensely complex development lifecycles, codeBeamer ALM can have a manageable but challenging learning curve. With just a day's training from Intland Software, it took the Fritz Stephan team one year to fully understand all the tool's features and capabilities, and to be able to fully use it in the management of complex projects (i.e. ventilator development). Based on feedback form several codeBeamer users, Intland's Medical IEC 62304 Template has been built since Fritz Stephan implemented the tool. This preconfigured template, along with other materials and services, help our users get up and running with the system in no time. As Mr. Amberg says:

> **"We started with codeBeamer ALM in the middle of a project, with all the requirements already specified and approved. After migrating to the tool, it took us one year to really get up to speed and realize the full potential of our new ALM platform. There are so just many features in codeBeamer, and we were trying to learn all of them under high pressure. Things have since gotten much better: Intland's Medical IEC 62304 Template is really helpful and easy to use. That said, at the end of the day, I'm convinced that it was a good decision for us to migrate to codeBeamer ALM as early as possible, and start realizing the benefits right away."**

– Jens Amberg, Vice CTO, Fritz Stephan GmbH

codeBeamer ALM Value Highlights:

Collaboration   Transparency   Better change management   Traceability   Compliance

Possible limitations of codeBeamer ALM

When asked about any feature enhancements Fritz Stephan would like to see in codeBeamer ALM, Mr. Amberg said he'd like to be able to use Gantt charts as seen in MS Project. This has since been resolved, as Gantt charts have been available in codeBeamer ALM since release 7.9.

Mr. Amberg's request to facilitate the management of exporting (using custom Word templates to export reports, for instance, for CE Marking in other countries) has also been responded to, with a solution coming in codeBeamer's next release 8.2.

Finally, due to the large number of requirements used by Fritz Stephan's developers, they noted that prior to version 8.0, they felt that codeBeamer should have been faster. However, as Mr. Amberg noted, this issue has been resolved with the recent release of codeBeamer ALM 8.0.

Follow-up: Process optimization with codeBeamer ALM

Since rolling out codeBeamer ALM, the development team at Fritz Stephan have radically changed their workflows, and the way they collaborate with other departments. Prior to implementing integrated ALM, data was stored locally and information shared via e-mail and live meetings.

Using codeBeamer's advanced workflows to guide and automate processes, the team is now able to enforce the use of mature processes throughout development. For instance, their robust deployment management processes built with codeBeamer ALM let them link bugfixes to issues and to test runs. With clearance documents storing all this information, Fritz Stephan's developers can easily work together with the quality department, making it easier for them to write release notes.

What's more, their technical writing department now also makes use of codeBeamer ALM's versioned document management features. These allow the team to share a folder offering automated revision control, which facilitates collaboration, while developers are able to trace the IDs of all documents in order to ensure complete transparency. The writing department has access to the usability engineering file, based on which they can determine the intended use of the product, helping them formulate user instructions and packaging details.

> **"With codeBeamer ALM, we are now able to control workflows, and to ensure a consistent chain of product information across all departments. The flow of information has made collaboration significantly more efficient, both internally and externally. The team loves codeBeamer ALM."**
>
> – Jens Amberg, Vice CTO, Fritz Stephan GmbH

Bottom-line value

And it's no wonder that the team has grown so fond of their ALM tool: since the initial deployment and process optimization work was done, Fritz Stephan was able to achieve significant time savings using codeBeamer ALM. In a competitive and fast-paced market environment where compliance is key, developers are under a lot of pressure to maintain the high quality of their products while reducing time to market. Reaching these seemingly contradictory goals without the right tools is a real challenge.

Offering access to up-to-date and consistent information for all stakeholders, codeBeamer ALM has helped Fritz Stephan enhance collaboration both internally and with external partners. The team can now automate and optimize mature processes, and the tool automatically records a history of all work items and their relations, thus significantly reducing the burden of administration and preparation for compliance audits. All that translates to huge costs savings, and a competitive advantage for Fritz Stephan on the market.

> **"From a business point of view the most important benefit codeBeamer ALM has brought us is that it saves us a great deal of time when generating documents to register our products in markets across the world. Not having to sacrifice valuable development time to prepare for compliance audits is a blessing. Using codeBeamer ALM, we are automatically compliant, all the time."**

– Jens Amberg, Vice CTO, Fritz Stephan GmbH

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About Codebeamer

Codebeamer is an Application Lifecycle Management (ALM) platform with unique configurability and product line configuration capabilities.

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

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