



DATATRAK Customer Case Study

DATATRAK: A Success Story of Traceability and Process Transparency

This case study explores how DATATRAK International, Inc., a company offering software solutions and consulting services to simplify clinical research was able to improve its internal processes by implementing codeBeamer. It also looks into the benefits this fully integrated ALM solution has had on the development team's efficiency since the company started using codeBeamer.

As the case study finds, DATATRAK – similar to many other companies in the medical field and other sectors – was utilizing a simple ticketing system and manual tracking tools.

While the approach was successful, traceability and visibility was not optimized. Switching to codeBeamer enabled DATATRAK to use a central platform to manage all artifacts throughout the development lifecycle, and provided the company with complete transparency of processes. This has brought improved processes & efficiency, and simplified overall lifecycle management.

The Customer: DATATRAK in a Nutshell

DATATRAK offers software solutions & services to safely accelerate clinical research. Founded in 1995 and headquartered in Ohio, US, DATATRAK International, Inc. is the longest-standing Electronic Data Capture (EDC) provider in the industry. Driven by key acquisitions coupled with a world-class Software Development team, DATATRAK has evolved to be an all-round clinical research platform provider. Its flagship product is an all-in-one unified dClinical™ solution called DATATRAK ONE UX™ consisting of several products and modules to safely accelerate every drug, every biologic, and every device.

DATATRAK decided to replace a simple ticketing system with a full Application Lifecycle Management (ALM) application in April 2011. Following the thorough evaluation of several products, the company made an initial purchase of a package of codeBeamer licenses in May 2011, and has been expanding the number of users ever since.

While DATATRAK's decision makers were wary of replacing the previous environment with a single ALM platform and the investment (both in terms of costs and time) this entailed, they quickly realized that codeBeamer's affordability, advanced and completely integrated capabilities, user-friendly architecture, and interface aptly addressed these concerns.

The Problem: Process Visibility & Traceability

Prior to starting with codeBeamer, DATATRAK was utilizing a basic ticketing system to track their internal processes. They began looking for a solution that would give them greater visibility, traceability, and efficiency.

As Ben Oberholzer, DATATRAK's Manager of Software Development put it:

“We had no real ability to connect the various collections of information or track actions related to them. We had a simple ticketing system that provided poor traceability and visibility into the process.”

While there were some workflow capabilities in their previous system, they were limited in their functionality. DATATRAK realized they would benefit from the ability to customize processes, fields, and ticket types.

As advancements in technology continued to create new opportunities for DATATRAK, a more comprehensive ticketing system was needed. Since DATATRAK develops software intended to comply with certain specific FDA requirements, validation processes and successful QA audits are of key importance. Consequently, establishing links between all work items (providing complete traceability) and the transparency of processes are vital for the company.

Why codeBeamer?

The company's primary reason to switch to an integrated ALM platform was that DATATRAK needed to have a centralized location for the management of all work items and stages of the lifecycle, from requirements through testing and release.

The company needed a way to maintain complete end-to-end traceability across these elements even with their increasingly sophisticated processes, as well as quality controls that were conveniently auditable.

DATATRAK's requirements, criteria for the evaluation of ALM platforms, and codeBeamer's relevant features can be summarized in the following points:

Integrated, Centralized Solution

In order to be able to bring together and manage all work items in a single platform, DATATRAK was looking for a tool that offered end-to-end functionality. codeBeamer provides just that, relying on a single central repository to store all artifact data, which results in gapless traceability across all work items throughout the entire lifecycle.

DATATRAK is using the advanced tracking feature offered by codeBeamer, simplifying the management of their software upgrades/enhancements.

Flexibility, Customizable Workflows

codeBeamer's flexibility enables DATATRAK to configure all workflows to suit and visually support internal needs & development processes.

However, the system's flexibility doesn't end there: in addition to workflows, DATATRAK's developers have also customized their artifacts (trackers) with additional fields to store relevant data, and applied tailor-made workflows to these updated trackers. For instance, the company's Change Request trackers, used to approve and track all change requests, also include risk and impact analysis data. This ensures that all involved parties have sufficient basis to review change requests, and to be able to make a reasonably informed approval decision.

Traceability & Process Visibility

As mentioned in previous sections, DATATRAK greatly benefits from codeBeamer's centralized architecture. Much like DATATRAK's own unified platform, codeBeamer's single repository is used to store data as well as relationships between all work items (which may be derived from each other). This guarantees gapless end-to-end traceability throughout the entire chain of work items, from user stories and requirements all the way to testing and release.

codeBeamer's Traceability Browser provides DATATRAK with a simple, efficient, and easily filterable way to overview the relationships between all work items.

To ensure the coverage of all requirements with test cases, a convenient Test Coverage Browser is available.

Our entire release approval process is done through these trackers, and we use codeBeamer's workflow process as our signoff functionality.

Document Management

Instead of relying on codeBeamer's built-in document management functionality, DATATRAK customized codeBeamer to fit their needs. Document Management was tailored to the unique needs the company requires to satisfy applicable industry standards. The development team has improved their efficiency by implementing codeBeamer's flexible Document Management. This allows the company to apply custom reviewer and approval workflows. As a consequence, the development team is able to use this tracker to process all system document signatures. This has greatly facilitated and accelerated the approval process.

Facilitate QA Audits & Compliance

DATATRAK's software solution is designed to comply with certain FDA rules and regulations. Therefore, the development and QA teams really appreciate codeBeamer's advanced capabilities around audits.

“The ability to perform full traceability, track the process and signatures/signoffs through the various reporting methods provided in codeBeamer allows us to clearly demonstrate and visualize our quality SOPs as it relates to our software development and related validation. The most positive value we got out of the software was the ability to clearly show process support and traceability.”

For QA audits on software development projects, deep (distributed) version control integration is a must. Otherwise, information silos would isolate SCM and ALM. As is the case with DATATRAK, integration of the SCM is key for traceability of code reviews and other development artifacts – which is why the company really values codeBeamer's Mercurial integration over the functionality offered by other products. DATATRAK also relies on codeBeamer's built-in Traceability Browser, Test Coverage Browser, its many custom Wiki plugins, and custom workflows to enforce processes, prove process quality, and to facilitate compliance audits.

Affordability, Total Cost of Ownership

codeBeamer is affordable, easy to roll out, and simple to learn. When compared to competing solutions over the course of 5 years, DATATRAK realized that the value, as well as total cost of ownership, made codeBeamer a better choice than all the other tools under evaluation. What's more, codeBeamer's friendly learning curve meant that the company was able to realize value with this platform from day 1.

“The staff was able to be immediately effective. Value was almost immediately realized with better visibility into the process, clear approvals of everything in the process, and simple, straightforward change control management and validation.”

While configuration took some time for the team back when they started with codeBeamer 7.2, they really valued the recent updates that simplify the rollout process. Version 7.6 greatly reduced the time needed to configure changes, making the rollout process simple and convenient.

Benefits

codeBeamer's advanced features, affordability, great value, and simple rollout & use have all contributed to DATATRAK's decision. Right from the first day of using codeBeamer, the company was able to use this ALM system to streamline multiple internal processes, including:

- Requirement tracking and approvals, and linking to development activities
- Test case review and approval tracking
- User Acceptance Testing
- Software-based tracking and approvals of incident reports, system change control, and document approvals/signoffs
- Support of all internal COTS (commercial off-the-shelf) systems

DATATRAK highly values the fact that all processes are completely traceable in codeBeamer, pinpointing this as the most important feature for medical development companies.

Overall, the benefits gained in higher visibility of processes and enhanced quality have been supported by improvements in DATATRAK's internal processes. codeBeamer has helped the development team improve its original incident report management processes, functional and user requirement management, and the company has also gained a better general understanding of quality and traceability.

In addition to these, DATATRAK has also realized that due to the system's inherent flexibility, codeBeamer is able to support further processes. The company has been growing the number of licenses in order to be able to increase the system's user base (Operations, QA, System Owners), as the team found that codeBeamer can be configured to respond to more and more needs within the organization.

Wondering how you could reap similar benefits?

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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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