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SOFTWARE



# Gedeon Richter Customer Success Story

Gedeon Richter chose codeBeamer ALM to test, document, and validate its pharma process control & automation systems



### GEDEON RICHTER

This Hungarian multinational pharmaceutical and biotechnology company selected codeBeamer ALM to manage the testing, documentation, and validation of its computerized pharma manufacturing process control & automation systems.

#### Problems & Challenges

Founded in 1901, Gedeon Richter (GR) successfully weathered the changes of the 20th century and became one of the largest pharmaceutical and biotechnology companies in the CEE region. With over 12,000 employees and a revenue of US\$ 1.57 billion in 2018, GR is today a multinational company with operations in three Hungarian manufacturing plants and numerous locations worldwide. This success story focuses on the adoption of codeBeamer ALM for a project at GR's biopharmaceutical plant in Debrecen, Hungary.

Before switching to codeBeamer ALM, Gedeon Richter relied on a paper-based system in their validation efforts for computerized manufacturing automation and process control systems. Due to paper-based tracking and sign-offs, paper trails ran to thousands of pages of documentation. Handling that volume of documentation alone was a challenge, not to mention the process of sharing, reviewing, approving, and signing off documents in a way that complied with industry regulations.

Searching for and collaboratively editing documentation was often problematic, and version control relied on error-prone manual processes. GR needed a system to define clear and enforceable workflows, with granular insights into responsibilities, deliverables, and work progress along the way.

## Solution

Gedeon Richter made the transition to digital systems validation using codeBeamer ALM in 2018. The company evaluated other alternatives for this purpose (including a popular issue tracking tool that GR had already used for work tracking) but ended up choosing codeBeamer ALM for its better applicability to pharmaceutical processes and regulations.

The switch brought about a much-appreciated change in culture: with the help of codeBeamer ALM testing, documentation, and validation processes are accurately defined, enforced without deviations, and full transparency is ensured every step of the way. codeBeamer ALM is used to manage functional specifications, as well as IQ (Installation Qualification) and OQ (Operation Qualification) before a validation report is generated in the system.

GR was able to loop in suppliers, conducting communication and collaboration with 3rd parties in a shared platform. codeBeamer ALM also helped the company map Good Automated Manufacturing Practice (GAMP), 21CFR11, and Annex 11 compliance requirements in the system, and adhere to those requirements.

## Benefits

Overall, Gedeon Richter values transparency in workflows and improved team collaboration as the primary benefits of using codeBeamer ALM. All operations around systems validation are clear and controlled, with real-time monitoring on tasks and responsibilities. Traceability and complete change control are ensured throughout all validations processes, and a full audit trail is logged to accelerate compliance audits.

Efficient work management has the additional benefit of easily discovering bottlenecks, leading to reduced cycle times on various processes. Documents managed in codeBeamer ALM are always up to date and easy to collaborate on, with a complete item history (including comments) facilitating teamwork.

Today, 70% of Gedeon Richter's automation team in Debrecen uses codeBeamer ALM, as well as additional team members from the QA and operations teams. Due to the success of the system, the company is currently architecting a central codeBeamer infrastructure for the Debrecen plant, planning to move all operation technology processes to the platform.

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