

UCB

ALM/Quality Center supports non-IT equipment verification for end-to-end traceability in new biotechnology manufacturing plant.



Who is UCB?

UCB is a global biopharmaceutical company, focusing on neurology and immunology. It aims to transform the lives of people living with severe diseases. With more than 7,600 people around the globe, total revenue in 2020 was €5.3 billion.

ALM/Quality Center Extends Beyond Supporting Software Testing

When the organization introduced SAP into the business, it realized it needed a robust software testing solution to support the global roll-out and ongoing maintenance. After a thorough market evaluation, OpenText™ ALM/Quality Center was chosen. This governs test

management activities to improve quality and meet business and compliance goals by implementing rigorous processes. Emmanuel Devos, IT Lead Testing Centre of Excellence at UCB, picks up the story: "Our SAP roll-out was very extensive, covering finance, manufacturing, supply chain, HR, etc., and took quite a few years. ALM/Quality Center grew with the project and was used to run standard testing for all our sites. Each country has its own legal entity, and the SAP implementation needs to conform to both local and central standards, so ALM/Quality Center gave us the flexibility and visibility to achieve this fully."

Encouraged by the success of deploying ALM/Quality Center for the global SAP implementation, Mr. Devos expanded its use across the IT organization, with ALM/Quality Center leveraged for the strict testing requirements for pharmaceutical applications to support clinical development and market authorization, including mobile apps and web-enabled applications for patient interaction. The IT organization had largely moved from paper-based processes to more automation and electronic support. However, the manufacturing side of the business was still run in a traditional, paper-led manner. This changed when the decision was taken to build a new biotechnology manufacturing plant in Belgium.

"We will have substantial efficiency and compliance gains through end-to-end traceability with ALM/Quality Center which means no shortcuts can be made when it comes to the thorough testing of our manufacturing equipment."

EMMANUEL DEVOS

IT Lead Testing Centre of Excellence
UCB



At a Glance

■ Industry

Biotechnology

■ Location

Belgium

■ Challenge

Adopt a proven IT software testing solution to support non-IT equipment verification for a new biotechnology manufacturing plant

■ Products and Services

ALM/Quality Center

■ Success Highlights

- + Central source of truth for full visibility and traceability
- + Data consistency and automated reporting supports audit requirements
- + Increased testing robustness for improved overall quality
- + Standardization and reuse deliver operational efficiency and compliance gains

Automating Equipment Verification Processes in Non-IT Environment

The new facility supports the company's growth and prepares it for the launch and long-term supply of future medicines currently under worldwide market authorization reviews. It represents an investment of several hundred million euros over the coming years and is expected to be operational in 2024. The biotechnology plant will be the largest and most modern at UCB.

During this time, a mindset transformation was taking place within the company. Mathieu Marrot, Quality Lead for the new plant at UCB, noticed the advances in IT and came to Mr. Devos with an interesting question: "I wanted to understand if ALM/Quality Center could be deployed in a non-IT environment. The new facility will be supported by hundreds of equipment provided by dozens of different vendors. The equipment must be tested at the vendor sites and at our UCB site. This question came from a lesson learnt from our colleagues in Switzerland who managed a similar project a few years ago. The two main outcomes were that the absence of standardization, due to the involvement of different vendors, led to difficulties during project execution, and that paper-based protocols required a strong and complex archiving process. We figured there must be a better way to document verification activities electronically, so we were interested in the experience IT had built with ALM/Quality Center."

Central Source of Truth with Full Data Integrity, Leveraging e-Signatures

With up to 100 people involved in the project, including many contractors and vendors, this is a mission-critical project for UCB. "We had some convincing to do internally," says Mr. Devos. "We knew ALM/Quality Center could really streamline and enhance the processes by automating equipment verification but having worked with paper-based processes for so many years, this

required a real culture change. It helps that we work in a highly regulated industry and have a recognized need to track and trace everything, with full data integrity. We could showcase that ALM/Quality Center could increase the efficiency in the delivery of all audit-related deliverables and facilitate a digital approval process with its electronic signature capability. A central source of the truth gives us visibility and easy access for all stakeholders. We were delighted to work with our business partners in making this happen." The native ALM/Quality Center e-signature solution also ensures repeatable validation and testing processes and optimizes reviews and approvals across the UCB organization with full traceability.

In close collaboration with OpenText™ R&D and a local implementation partner, the team assessed the current paper-based processes that are required to comply with regulations or quality standards. They then mapped the process entities to ALM/Quality Center modules to create mockups and define the level of configurations to meet the full requirements. The final designs were tested against real data scenarios and validated. A lot of time was spent on standardizing processes so that they can easily be reused. To achieve an end-to-end view from requirements definition to testing execution, the project team also implemented the ALM/Quality Center Requirements module, which hadn't been extensively used by IT previously.

Previously, each vendor would have their own template and tests which made it complicated for the UCB project team to review. For this project, non-equipment-specific tests (e.g., slope check, material certificate check) were written by the UCB team in ALM/Quality Center and imposed on all vendors to standardize the content. Tests which were specific to an equipment were written by vendors or UCB in an Excel file and imported in ALM/Quality Center by using a standardized template. "The flexibility within ALM/Quality Center is one of the main

benefits for us," comments Mr. Devos. "Our data access has to be strictly segregated by role or by vendor. With so many people accessing the system, it is fantastic that we can open it up with ALM/Quality Center's role-based access control without violating anyone's privacy or access rights and while respecting equipment's intellectual property."

Real-Time Test Status and Meaningful Management Reporting

With over 14,000 entries logged in the ALM/Quality Center Requirements module and the estimate of at least 50,000 test executions over the course of the facility's completion, the increased visibility is already proving very useful, as Mr. Marrot comments: "With such a big project and testing activities happening all around Europe, at vendors' sites and at our UCB site, it can be difficult to have full status visibility. With ALM/Quality Center, I can simply log into the system and view the test status in real-time. It gives me relevant information and by customizing KPIs and generic reports, I can generate useful report data for senior project management."

Portable test execution on-site is done with tablets which connect to the UCB network and feed their test results directly into ALM/Quality Center. The end-to-end traceability is a real operational benefit to UCB. At any point in time the team can see how requirements and tests are linked. ALM/Quality Center automatically populates a traceability matrix through this linking. Project managers can check how many tests or defects are in progress, whether they are major or minor, and what their status is. Clear reporting against established KPIs gives an increased level of reliability about the project's progress.

A full audit trail keeps track of any field changes and logs information about who makes changes and when, comparing old and new values. The

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MATHIEU MARROT

Quality Lead—New Biotechnological Plant
UCB

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e-signature feature within ALM/Quality Center is integrated in the approval workflow and manages a digital approval process. ALM/Quality Center also tracks interdependencies between different roles and links versioning to the different stages of the approval workflow. "Electronic end-to-end records will be a great help. Now, we can just log onto ALM/Quality Center and see all the test evidence on the screen. It will be a change for our regulators too, but I believe a very welcome one," says Mr. Marrot.

Achieve More in the Same Timeframe: Improving Quality and Efficiency

"This is an innovative approach in the manufacturing and pharmaceutical market for Belgium, so we're educating our stakeholders as we go," says Mr. Devos. "Everything we do now will help us improve our equipment lifecycle management and ensure that new projects won't need

to reinvent the wheel but can benefit from our experience. We will have substantial efficiency and compliance gains through end-to-end traceability with ALM/Quality Center which means no shortcuts can be made when it comes to the thorough testing of our equipment."

He concludes: "ALM/Quality Center has enabled us to do more in the same timeframe, increasing our testing robustness, traceability, and efficiency. To reach the same quality levels with our previous manual processes would take a huge number of resources. Instead, we have better quality and data integrity which increases our confidence and reduces our business risk. We enjoy the partnership we have built with Micro Focus (now part of OpenText™). They listened carefully to our requirements and worked closely with us to meet our needs on this critical project."

Learn more at

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ALM/Quality Center user community

- 250 IT users
- 800 business users, including manufacturing user