

A CRO Increases Competitive Advantage by Implementing Empower Chromatography Data System

Client: A&M Stabtest

Technology: Empower Chromatography Data System

BACKGROUND

A&M Stabtest is an independent private Contract Research Organization (CRO) that provides analytical research and development services for the pharmaceutical industry in support of drug development programs. The German-based company has headquarters in Bergheim/Cologne and a branch in Mainz. The company works for nearly all major pharmaceutical organizations with clients located primarily in Germany, Austria, Switzerland, France, and the Benelux countries. The company also supports small biotech startup companies with their services.

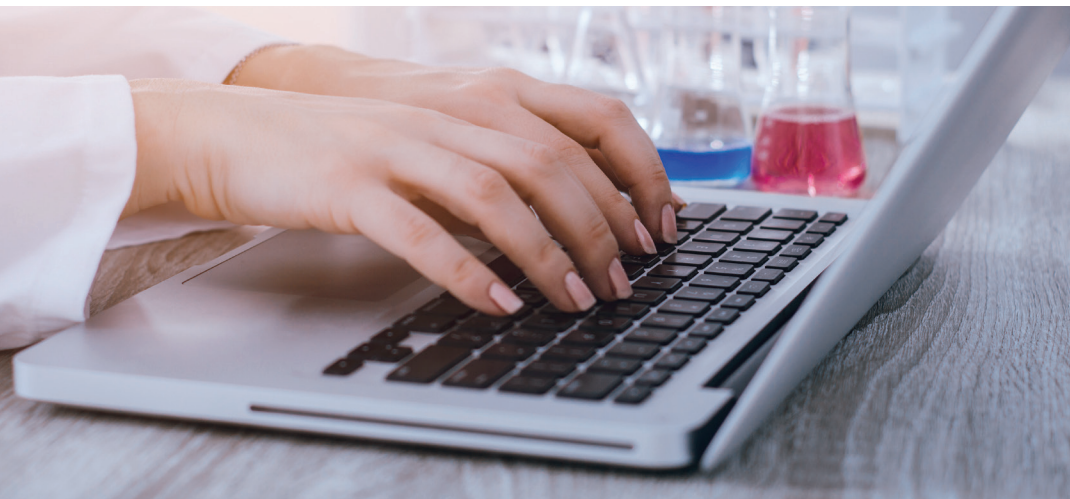
A&M Stabtest specializes in analysis and stability testing of finished pharmaceutical products and active pharmaceutical ingredients (APIs) according to ICH requirements; therefore, the test results and documentation need to demonstrate expected quality. The company also provides development and product release testing, bioanalytical services, and unknowns identification. The tested samples range from small molecule drugs to biopharmaceutical therapies including proteins, peptides, and antibodies. All activities and analyses adhere to GMP/GLP regulations and to demonstrate compliance, the company is routinely audited by customers and regulatory agencies. A&M Stabtest operates in a cost and time sensitive industry, consequently they continuously invest into efficiency increasing strategies like employee training and adopting the latest technologies.

CHALLENGE

The laboratories at both sites employ more than one hundred users and operate approximately 50 HPLC instruments manufactured by Shimadzu. Additional chromatographic equipment includes six gas chromatograph instruments from Agilent and two capillary electrophoresis instruments from Beckman and Agilent.

BUSINESS BENEFITS

- Efficiency gains, such as a time savings of 20% for the result evaluation of a project.
- Enhanced response times during regulatory and customer audits given the ease and speed for which information can be accessed.
- Waste and variability reduction associated with the chromatographic workflow.
- Improved laboratory productivity.
- Lower project costs.
- Increased competitiveness.



The HPLC instruments had been running under the Shimadzu Class-VP software, which was used as a hybrid system. Only data recording was performed with the system. Chromatograms were printed on paper and integrated manually. In order to perform calculations, data was transferred manually into validated Microsoft® Excel® sheets. The different manual activities required extensive double checks for errors and corrections when necessary.

Due to the competitiveness of the industry, A&M Stabtest sought to minimize waste and variability in their laboratory operations by reducing time-consuming and error prone manual steps in the chromatographic testing process.

THE SOLUTION

PLATFORM SELECTION

The decision was made to introduce a modern, state-of-the-art chromatographic data system (CDS). The User's Requirements Specification (URS) document developed by the company identified required functionality, such as Part 11 technical controls, automated calculations, data management, and multi-vendor instrument support. As a result of the URS, two CDS solutions were considered, Waters™ Empower™ CDS and Dionex/Thermo Chromeleon. The company chose Empower because it satisfied their functionality requirements and provided an intuitive/professional user interface, as well as a broad range of multi-vendor instrument drivers (including those for Shimadzu). Interfaces were built through partnerships with the instrument manufacturers to ensure reliability and future upgrade paths. Empower's market leading position, reputation for compliance-ready features, and continuous product improvement solidified the decision.

REGULATORY COMPLIANCE

Because A&M Stabtest must comply with regulatory safeguards and demonstrate this to both customers and government agencies, Empower CDS functionalities that help facilitate regulatory compliance are of tremendous value to the company. The data traceability provided by Empower's audit trails allows staff to easily locate information during routine audits. Because speed of retrieval is so critical, the ability to separate audit trail information by project, method, etc., was considered a key feature.

SYSTEM DEPLOYMENT

Today Empower CDS is implemented in a Citrix environment with a server at each of the two sites to provide greater system performance – analysts can access either Empower server as needed to share information. Advantages of operating under a Citrix environment include easy deployment of Empower clients on PC hardware of differing specifications and streamlined software validation, since only the Empower and Citrix servers require validation.

Empower CDS controls all chromatographic instruments at both sites including data collection, chromatographic peak integration, calculations and evaluations, and results review and approval.

A&M Stabtest opted for the integrated System Suitability Testing option that allows for direct integration of their results into reports – manual interaction is no longer required for these steps. Raw data, reports, and audit trails can easily be accessed within Empower, which is very convenient during routine audits.

Waters assisted A&M Stabtest with the System Validation by performing the Installation and Operation Qualification (IQ/OQ). Performance Qualification was done by A&M Stabtest's staff. Concurrent with the validation efforts, all end users and power users were trained by Waters in a test environment to ensure that they could take full advantage of the Empower production system.

With the validated production system in place and system training for staff completed, A&M Stabtest was able to switch from their legacy system to the new CDS literally overnight.

Waters

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