

Customer name: Health Institute Usti (Czech Republic)

Industry: Government

Company Overview

“Health Institute Usti” is the largest state-owned laboratory organization in the Czech Republic, with more than 540 employees spread over 45 sites, with labs in Prague, Pilsen, Ceske Budejovice, Usti nad Labem, Hradec Kralove, Pardubice, and others. The Institute provides comprehensive laboratory testing services for companies, municipalities, practitioners, and citizens in accordance with ISO 17025 and/or GMP regulations for the pharmaceutical industry. These services include the laboratory testing of pharmaceuticals, drinking and waste water, food, beverages, environment, and waste.

Business Challenge:

As the largest state laboratory organization operating under ISO 17025 and GMP regulations in the Czech Republic, the Institute must ensure a reliable and systematic approach to analytical method validation and the estimation of uncertainties in test results. Because the Institute has dozens of sites/labs, alignment and harmonization between facilities is key to regulatory compliance and operational efficiency.

The Institute traditionally relied on in-house developed Excel sheets and paper systems, created by each individual lab. However, in 2015, it was determined that with multiple locations and scattered systems, it was impossible to ensure the same quality and regulatory compliance throughout all labs if all of them used self-created tools. Moreover, there was growing pressure from new requirements, most notably the software validation and data integrity requirements in the GMP laboratories. This was a driving force to implement a centralized system, compliant with all current pharmaceutical regulations.

Selection and Initial Implementation

After receiving a demonstration of the EffiValidation software from EffiChem, the lab in Hradec Kralove – which performs GMP testing - determined that EffiChem’s software had the right functionalities and efficiencies necessary to meet current and future growth. While the system was initially selected for only one GMP lab, the decision was made to roll out the system to the other 15 locations, because EffiValidation was the best option for the ISO 17025 accredited labs as well.

The system is fully operational in the institute’s pharmaceutical labs, and implementation and training continue in 2016 for the remaining labs.

“We selected EffiChem because the EffiValidation software meets all method validation and GMP requirements, including software validation, data integrity, and reporting. Moreover, the company was able to provide us with the application support and documentation that we needed for more general use, namely for risk management and general GMP compliance. It was a solution and documents that we could implement quickly and easily, becoming a backbone of our GMP compliance system.” - Rudolf Stransky, Head of the GMP control laboratory - Hradec Kralove.

Results

EffiValidation is deployed in the GMP control lab in Hradec Kralove. 15 more ISO 17025 accredited labs will follow. This solution provides the Institute with a centralized platform to manage its method validation processes, enables the definition of individualized acceptance criteria, and simplifies, and automates reporting.

The documentation, guidance on risk management, and the general GMP compliance components of EffiChem became a foundation for the Institute's entire quality system, which created increased confidence and preparedness for regulatory inspections and customer audits.

Specific Results

Better Validation Practices and Higher Efficiency:

EffiChem doubled speed at which method validation data could be evaluated. The lab also found that EffiChem includes many configurability options and always allows the systematic and logical assessment of validation parameters in the desired way, both numerically and graphically.

Better Risk Management and Audit Preparedness:

Because of EffiChem's guidance on risk management and general GMP compliance, the entire quality and documentation system at the Institute became more robust. This gives the Institute a higher confidence to successfully pass regulatory inspections and/or customer audits at any time.

EffiChem, an industry leading provider of computerized quality and laboratory management solutions, enables businesses to safely and efficiently deliver their products and services to the market. Headquartered in Brno and with distributors across Europe, Americas and Asia, EffiChem maintains an extensive user base in the pharmaceutical, food, and petrochemical industry, as well as in ISO 17025 accredited testing laboratories.

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