

Customer name: ImunaPharm a.s./Biotechnological Centre of the Slovak Academy of Sciences

Company:

Located in Sarisske Michalany, Slovakia, ImunaPharm a.s. is a research-driven, specialty pharma company with nearly 60 years of experience; focused on research, development, and the manufacture of vaccines, immunomodulatory preparations, allergens, probiotics, and bacteriophages.

Business Challenge:

Analytical method validation and method transfers have always been of key importance for ImunaPharm, because they ensure reliable release testing results for the products they manufacture. In recent years, the company has begun to modernize through financial support from the EU and technical cooperation with the Biotechnological Centre of the Slovak Academy of Sciences. This has created an opportunity for ImunaPharm to expand more rapidly into foreign markets.

ImunaPharm had traditionally relied on Excel worksheets and paper files to monitor method validation in their labs. However, as they expanded, this system became outdated and insufficient to support their growth. Further pressure to find an advanced solution was added due to a greater focus by regulators on compliance and data integrity.

Selection and Initial Implementation

After receiving a demonstration of EffiChem®'s EffiValidation software, ImunaPharm decided that the solution possessed the flexibility the company needed to run method validation studies efficiently and in compliance with the current GMP regulations.

"We chose EffiChem because it could fulfill everything we needed for our method validation and method transfers, but it was also configurable right out of the box. It is a solution we can easily and quickly expand for many years to come as ImunaPharm's validation and compliance needs evolve." - Ondrej Ragac, ImunaPharm

Results

Today, EffiValidation is used to validate all required test methods for raw materials, intermediates, and final products, regardless of whether each method is a titration, chromatographic, or other method. EffiValidation provides ImunaPharm with a centralized platform to manage and report on all of its method validation processes, track the status of validation processes in real time, and identify and analyze issues as they arise.

Specific Results

Better Validation Efficiency

EffiValidation has shortened validation timelines by approximately 50% over ImunaPharm's previous paper and Excel-based system. Users also appreciate the intuitive layout and operational simplicity, which combines the familiarity of Excel with easily available, in-built help screens for every step the user must undertake. Finally, efficiency has further been achieved because of EffiValidation's automatically-created reports which can be used directly in regulatory submissions.

Improved Compliance and Audit Preparedness

By ensuring that all method validation data is logged and reported in a centralized repository, EffiValidation provides a reliable audit trail – whether it be for third-party, regulatory, internal, customer, or supplier audits. EffiValidation has also helped ImunaPharm keep better track of, and evaluate, the way it reports to regulatory agencies.

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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