



UCB opted for iStudyReporter on Labware LIMS as stability reporting solution

Customer Reference Story

"When you use iStudyReporter, you've got to think outside the box relative to conventional approaches to reporting. We're not talking any more about individual reports, but rather complete approval documents that we'd otherwise never be able to generate so quickly. The solution provides us with turnkey stability documents that can be commented on individually and also meets all data integrity requirements."

*Eric De Maesschalk, UCB Pharma GmbH
Head Global e-Analytics, Corporate Analytical Sciences*

"iStudyReporter allow my team to only focus on scientific and added values sections when issuing a report and totally remove all activities related to the edition of the document itself (data table, trend chart, ...)."

*François Delcroix, UCB Pharma GmbH
Stability & Critical Materials Manager / Corporate QC Support*



Challenge

UCB is running its stability operations QA using a LabWare LIMS with great success. Scientists compiled the stability documents manually, shelf-life evaluation had to be done by statisticians and every report was manually validated.

As UCB consistently grew and expanded over the years, the need for a system for creating, validating and approving reports of stability studies became apparent. An internal project to implement an automated CMC stability reporting facility was initiated. But due to the complexity in data setup, the complexity of the stability process and the underlying regulatory requirements this project delivered a partial solution only.

To provide a complete solution to this challenge, UCB decided to drop the custom development and use iStudyReporter, a flagship solution created by up to data. The software is an open and readily configurable off-the-shelf solution that allows for the elaboration of eCTD-conformant stability reports using data from any LIMS or other data source.

Solution

By design, iStudyReporter eliminates time-consuming steps in creating submission documents for pharmaceutical studies from almost any study data system. Report elements such as graphs, statistical calculations, and trend analyses – up to and including full-fledged annual product reports – are predefined and are fully integrated into the solution.

An initial Proof-of-concept was the first step to a proper understanding of UCB's requirements and the types of reports generated during stability studies. Once that was evaluated, iStudyReporter Stability (Version 3.5) was installed and configured with a formal ICH compliant Stability Report.

Based on this, a customer specific data interface was configured to match the particular processes and requirements on usage of country specifications for regulatory reporting purposes. Furthermore, the standard shelf-life calculation and plotting functionality was configured to be used as part of the default reporting to create a comprehensive documentation. This step vastly eliminated the need for external statistical evaluation. After the necessary system qualification and validation, UCB began using iStudyReporter Stability as their stability reporting solution. All this was done within a six months period.

Results

Instantly, iStudyReporter added value to the reporting process for stability studies thereby speeding up the medicine creation process and allowing UCB fulfill their promise of quality medicine to patients faster.

Ultimately, iStudyReporter will allow UCB to reduce the time spent reporting stability studies and consequently create more time for research and innovation.

UCB was impressed with the speed of implementation and their expectations were fulfilled by iStudyReporter.

About UCB

UCB is a global biopharmaceutical company, focused on severe diseases in the therapeutic areas of neurology and immunology. With a global revenue of € 4.5 billion in 2017, operating in approximately 40 countries and over 7500 staff, UCB is a world leader in the biopharmaceutical industry.

The ambition to transform the lives of people living with severe diseases particularly neurology and immunology disorders motivates UCB to continuously research, innovate and create value through cutting-edge science, innovative drugs, and practical solutions.

