



Extremely rapid implementation of regulatory bioanalytical reports

Customer Reference Story

„We have never implemented a software project that was as competently managed as the project we did with up to data (...).

We were able to implement the target process so quickly because many of our specifications were already met by the “out of the box” application.”

Dr. Martina Wein, LIMS project manager, Boehringer Ingelheim



Challenge

Boehringer Ingelheim decided to implement the Watson LIMS from Thermo Fisher Scientific as part of the replacement project for its proprietary bioanalytical laboratory LIMS. During the implementation phase it was unveiled that the new solution did not provide an adequate automated procedure for generating the required regulatory bioanalytical reports.

Additionally, the customer wanted to implement the new automated solution as quickly as possible in order to avoid undermining the efficiency of the replacement project as a whole.

Solution

up to data's iStudyReporter Bioanalytics application provides an open, configurable solution for generation of eCTD-compliant bioanalytical reports retrieving data from Thermo Scientific™ Watson LIMS™.

iStudyReporter's virtually complete coverage of bioanalytical report elements (e.g. preformatted texts, tables and statistics) allowed the customer to implement a solution that meets Boehringer Ingelheim's requirements very well.

Advantages

- Efficient generation of bioanalytical reports
- Validated interface with the Watson LIMS
- Rapid, simple and secure procedures
- Full “out of the box” coverage of all bioanalytical report elements
- User-configurable report templates
- Rapid implementation

A configurable solution versus individual programming

Bioanalytical reports intended for regulatory submission are complex documents that are subject to various requirements in respect to authorities, internal SOPs and corporate policy. What's more, the need for a completely secure data transfer process makes bioanalytical report generation a labor-intensive task that often has to be performed by a number of specialists. Boehringer Ingelheim decided in favor of up to data's iStudyReporter Bioanalytics solution because it allows for efficient use of the customer's existing Watson LIMS.

Due to the seamless integration of iStudyReporter with the Watson LIMS and the numerous standard options offered, almost all of Boehringer Ingelheim's specifications could be met simply and easily by configuring tables and templates and without additional programming.

An efficient Implementation plan

Thanks to up to data's efficient and transparent project plan, Boehringer Ingelheim's solution could be rolled out rapidly. In order to indicate the exact costs of the solution up front, up to data held a special workshop with the customer based on typical study data and current report templates. The workshop provided all participants with clear information regarding the project's implementation, customization, and validation costs. up to data's precisely structured project supported the defined schedule and allowed for accurate planning and deployment of project resources.



The iterative approach used by up to data facilitated testing of previously implemented functions via defined cycles - which in turn made it possible to verify that the solution met the customer's needs in his environment. During this process, key users received the requisite intensive training, and thus were efficiently integrated into the roll-out process, thereby ensuring the implementation of the customer's specifications at all times.

Dr. Martina Wein, LIMS project manager was extremely pleased with the highly successful outcome of the implementation: „We were able to implement the project very quickly. What's more, we obtained an intelligent solution that meets our requirements, but that still leaves room for change.“

The up to data solution was integrated seamlessly in the customer's IT environment, enabling automated and validated workflows, from study planning to report management.

Executive Summary

The iStudyReporter Bioanalytics project was implemented from October 2009 to February 2010 and was integrated into Boehringer Ingelheim's software environment. This allowed Boehringer Ingelheim to benefit from an extremely expeditious roll-out phase, as well as very low validation effort.

However, the measure of the success of up to data's Boehringer Ingelheim solution only becomes clear when the process-oriented approach enabled by iStudyReporter is compared with the labor-intensive report generation procedure the customer was using previously. The outstanding efficiency of the iStudyReporter process makes generation of complex reports far less labor-intensive, while at the same time allowing for totally secure data transfer.

For further information regarding the iStudyReporter Bioanalytics solution visit www.istudyreporter.com.