

## End-to-End Management of SAP Stability Data

### THE CHALLENGE

As one of the world's leading specialists in immunology and hematology, Biotest AG, a listed biotech company headquartered in Dreieich, Germany, uses SAP QM to document lab data. Particularly important for the company in this regard is its use of the integrated SAP stability module for monitoring and documentation of investigations concerning the stability of active ingredients.

In practice it has not always been possible to fully leverage the advantages of this module due to the lack of availability of an affordable alternative to labor-intensive manual compiling of regulatory CMC reports. However, in order to streamline work processes, reduce working time, and minimize data transfer risk, it is essential to implement an end-to-end reporting solution.

*“One of Biotest’s overarching goals is process optimization that expedites our development processes and keeps us out ahead of the competition. Against this backdrop, iStudyReporter Stability is an invaluable tool that enables us to fully leverage the options of our SAP system in the lab and allows for genuine end-to-end management of our stability data.”*

Biotest Stability-Study Manager Dr. Christoph Apel

### THE SOLUTION

Against this backdrop, up to data's iStudyReporter Stability software turned out to be just the right solution – an out-of-the-box tool that generates a nearly complete gamut of eCTD-conformant, regulatory stability reports and is also easy to configure, without labor-intensive coding. Thanks to iStudyReporter Stability's various modules for graphics, statistics, and protected tables, specific requirements such as CoAs, trending reports, and even complete product quality reviews can be elaborated in a manner that allows for fully automated and valid data importing from SAP QM or any other LIMS. Hence for Biotest, iStudyReporter Stability is an invaluable and essential tool that cuts down on approval time and gives the company a competitive edge.

### ADVANTAGES

- Efficient stability-report elaboration
- Configurable report templates (CoA, trending reports, PQR/APR)
- Quicker and simpler reporting process
- Intuitive – and thus extremely user-friendly – software
- Automated rather than manual data transfers, thus minimizing the risk of transfer errors
- Valid interface with SAP QM
- Short implementation time

#### REFERENCE CUSTOMER:

BIOTEST AG, DREIEICH



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## AN OPTIMAL SAP-BASED PROCESS FOR EFFICIENT STABILITY REPORTING

The gold standard in compliance with, and monitoring of, regulatory standards is IT-supported quality management. This applies in particular to highly sensitive blood plasma preparation by companies such as Biotest, for which quality is a key parameter when it comes to successful manufacturing in the context of international competition. But as implementing new software in this sector is normally both cost and labor-intensive, it is all the more important to leverage all the available potential of an IT solution with a view to optimizing the relevant processes and at the same time ensure their reliability.

To this end, Biotest decided to extend its successfully rolled-out SAP system by implementing iStudyReporter Stability – a solution the company selected for more reasons than meet the eye. For iStudyReporter Stability allows for automated preparation of regulatory stability reports out of the box, thus obviating the need for an oftentimes time-consuming process involving application customization or additional programming. iStudyReporter Stability is far more versatile than conventional reporting tools, is easy to configure, automatically extracts all necessary data from the SAP QM system, and compiles reports according to the relevant regulatory rules via a smooth-running overarching process and end-to-end stability-data management. iStudyReporter Stability also integrates as standard features tools that support indispensable tasks such as data processing and statistical assessments.

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## REGULATORY SAP STABILITY REPORTS

Implementation and customization of iStudyReporter Stability, which was realized in close cooperation with Biotest, went very quickly, and the BAPI (business application programming interface) to the SAP system was customized following realization of a feasibility study. In the interest of presenting the customer early on with an optimally tailor-made solution as a basis for development, up to data opted for an iterative project methodology that enabled the company to supply the customer with the relevant standard reports within the initial iteration test. Following realization of a configuration analysis (including definition of possible deviations from the desired report format), the interface and report templates were customized in accordance with Biotest's specifications within the next iteration.

The validation process went equally smoothly, thanks in large measure to iStudyReporter's included vendor qualification, which enables the customer to incorporate the relevant documentation from up to data and validate the solution in accordance with GAMP 5 guidelines with minimal effort. Having opted for this procedure, all Biotest needed to do was document the attendant business cycle tests; and this in turned saved the company a huge amount of time and effort relative to a complete validation.

This proved, for Biotest IT consulting manager Matthias Schott, that the company had definitely opted for the right solution: *"iStudyReporter Stability is easy to configure and roll out, and thus relatively inexpensive – which means that opting for an out-of-the-box solution such as iStudyReporter Stability was the right decision. This is particularly evident all the way down the line when you compare iStudyReporter Stability with the labor-intensive process of a customized solution."*

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## CONCLUSIONS

The main benefit Biotest derives from iStudyReporter Stability is that the solution meets all requirements for rapid implementation as an off-the-shelf solution. When rolled out using up to data's iterative project methodology, iStudyReporter Stability allows for streamlined workflows and high-quality project realization.

Particularly noteworthy is the ease with which iStudyReporter Stability can be adapted to specific business processes, and the fact that it obviates the need for the specific customizations and time-consuming validation process entailed by individual SAP-based applications. In a production environment, iStudyReporter Stability's end-to-end processes and reliable data transfers are extremely impressive. Thanks to up to data's extensive and detailed knowledge of current regulatory requirements and versatile LIM-Systems, iStudyReporter Stability delivers an impressive set of functionalities off-the-shelf.

For further information on iStudyReporter Stability and up to data visit [www.uptodata.de](http://www.uptodata.de).

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