



## *iStudyReporter product family*



- Regulatory standard based study document generation
- Seamless integration in IT environments
- Fully automated document creation process

### **Efficient solutions for regulatory documentation**

iStudyReporter product family offers regulatory standard-based solutions for automated production of complex study documentation. It is the first off-the-shelf solution to allow for rapid production of complete approval documents, including graphics and statistics.

iStudyReporter has been developed in collaboration with leading pharmaceutical companies with a view to seamless integration with existing IT environments. iStudyReporter provides easy access from any lab data management system such as LIMS, ELN, CDS, ERP (SAP), MES or MS Excel, by a valid data transfer of real time data. The output format (e.g. tables, graphics, statistical charts, trend reports, QC charts) can be tailored to the user's specific needs and thus labor-intensive manual created reports including the tedious data recheck will be eliminated.

The iStudyReporter family of course also offers solutions for overarching presentations of data from various lab IT systems in any given report, even multi-site reports.

### **Advantages for LIMS Projects**

- Off-the-shelf solution for the Life Sciences Industry including user friendly system configuration
- A great many tables and graphics are already available in the standard tool
- Simple and straight forward template management process for the generation of customer-specific reports
- Fully automated document creation workflow
- Interfaces to all commonly used database systems
- MS Excel/ MS Word based lab data management
- Seamless integration with existing IT environments
- Overarching documents, compiled from various systems and sites, based on innovative RemoteCollector technology

## Document generation for LIMS projects

A number of factors are pivotal for a successful roll-out of a complex Lab Information Management System (LIMS). Labs oftentimes expend considerable time and effort on generating process analyses and definitions of requirements, as well as on project organization and management. The representation of main lab results plays only a minor role, since report generation is often implemented toward the end of a LIMS project by making use of given standard tools.

In order to use these reporting tools in a manner that meets lab requirements, the lab has to carry out a programming phase for trend analyses and other complex reports – a phase whose degree of labor-intensity can easily be underestimated. Besides the limitation of classic reporting tools are reached relatively quickly when it comes to the generation of complex tables, graphics, and statistical parameters. As a result study reports are usually produced manually within a tedious, error-prone and time consuming process.

It often happens that on successful completion of a LIMS project, manual data compilation and labor intensive document review persist as the main focus of lab activities.

By introducing iStudyReporter the reporting creation process is elevated to a new level. Multiple functionalities ensure that lab resources will be used in an optimal way. Cross system reports are building the foundation for an efficient interaction of heterogeneous lab systems, delivering data for best practice processing and report treatment for submission documentation.



### Product family

Each member of the iStudyReporter family has been developed in cooperation with leading companies in the Life Science Industry, representing a solution with best practicability build on state of the art technology:

iStudyReporter Stability is the integrated solution for seamless complex submission document generation with any stability LIMS.



iStudyReporter Stability for SAP is the additional solution for advanced preparation of complex stability documents based on SAP/QM.



iStudyReporter Bioanalytic is the efficient solution for creating submission documents on bioanalytical studies based on Thermo Scientific™ Watson LIMS™.



### About up to data

up to data represents an experienced and innovative IT software provider with a strong focus on companies in the Life Sciences, delivering services and products for more than 25 years now.

iStudyReporter has been developed in close cooperation with global pharmaceutical companies based on market-specific requirements.

Thus, many of the leading enterprises around the world rely on the iStudyReporter product family.

