



LIMS Application at B. Braun

Melsungen AG

Analyzes, integrates, validates!

B. Braun Melsungen AG uses LISA.lims to differentiate and map its stability tests is highly automated, standards-compliant, and validated. The system is based on powerful LIMS software that supports both the integration of all the relevant testing and registration processes and the general customizing of system functions for specific customers and locations.

The “Good Manufacturing Practices” (GMP) code defined by the American Food and Drug Administration (FDA) has an equivalent validation basis in Europe in the GAMP standards. GMP sets extraordinarily high standards for the traceability of samples and analytical data. Under these regulations, it must be possible within a tolerably short period to trace every sample and find out where, when, who, and what testing procedure was performed.

From climate chamber to raw data archive

The processes involved in automated “Stability Management” must be fully documented. At B. Braun, a leading manufacturer of infusion solutions, the documentation range from climate chambers all the way to archiving the raw data. Included are the process of transferring samples from chambers to the laboratories, the integration of the analytical procedures, including all equipment and test-relevant reagents and chemicals, the entry and evaluation of results, and the storage of these results in the raw data archive. This complex sequence is nothing new in itself, although it used to involve “a lot of

people, a lot of paper and, as everyone knows, somewhat ‘conservative’ clarity,” Dr. Volker



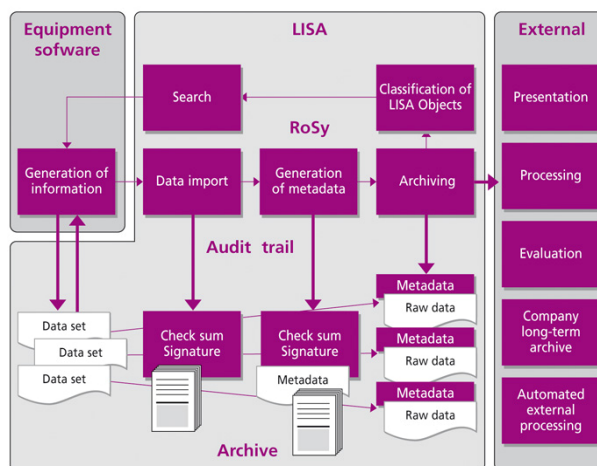
Labmanager Dr. Volker Krüger and project manager Mr. Martin Wenzel accompany this process at B.Braun Melsungen AG

Krüger. Krüger developed a stability group with the ambitious intention of integrating all the process steps of stability management into a largely paperless workflow in a LIMS. The globalization of B. Braun had led to a sharp increase in the number of samples arriving for testing, and this situation convinced the central development site in Melsungen that a powerful system solution was needed for both economical and organizational reasons.

All equipment integrated

The route to full, paperless process integration also involved networking the entire spectrum of laboratory analysis equipment, from sample preparation systems to chromatography and spectroscopy equipment—around 100 systems in all. The task of testing and validating every single equipment connection included the detailed test documentation, data preparation, mapping of functionality across interfaces and proof that the equipment in question met the specifications. All tasks had to be complete in accordance with GMP standards. This procedure proved to be considerably more complicated than those usually found in environmental analysis, for example. The system itself, as designed by B. Braun in consultation with Bochum LIMS specialists T&P, is fully capable of functioning without paper based record keeping. FDA-compliant software has been procured for all analytical equipment—where available from the manufacturer. The only obstacle to a completely paperless workflow is the range of old equipment still in use, which churns out conventional paper reports rather than digital data. However, these reports are now scanned in at the central scanning station and transferred to digital originals in PDF format.

All the processes described also involve interlinked testing and archiving sequences. Their data can be used simultaneously by B. Braun employees at other site through the internet thanks to one of the particular program features of LISA LIMS – a localized language translator user interface.



A dynamic system

To guarantee the consistently high quality of stability tests, FDA/GAMP rules specify that the software used must be regularly re-validated, a process that is mapped in a dynamic “software

lifecycle model.” Such a model was developed for B. Braun in consultation with the service provider, and it ensures that the validation and production systems throughout the software lifecycle meet the specifications—including the integration of new modules.

So what makes for system quality in the opinion of a highly critical user? Dr. Volker Krüger differentiates between the convenient and reliable core functionalities offered by some LIMS and the individually customized solution developed by him and his team in close cooperation with software provider T&P. “I would emphasize above all the smooth way in which the project developed and that it ended in joint validation under FDA and GAMP rules within the specified time frame. The same goes for the trouble-free system acceptance in an audit performed by independent third parties. Completely aside from the system’s technical qualities, these factors are indicative of successful project cooperation.”

Further Information Contact:

Victor Taruch
Account Manager
Systat Software Inc
408-715-7083
vtaruch@systat.com