



pro **LISA**
"Stability Testing"

Functions

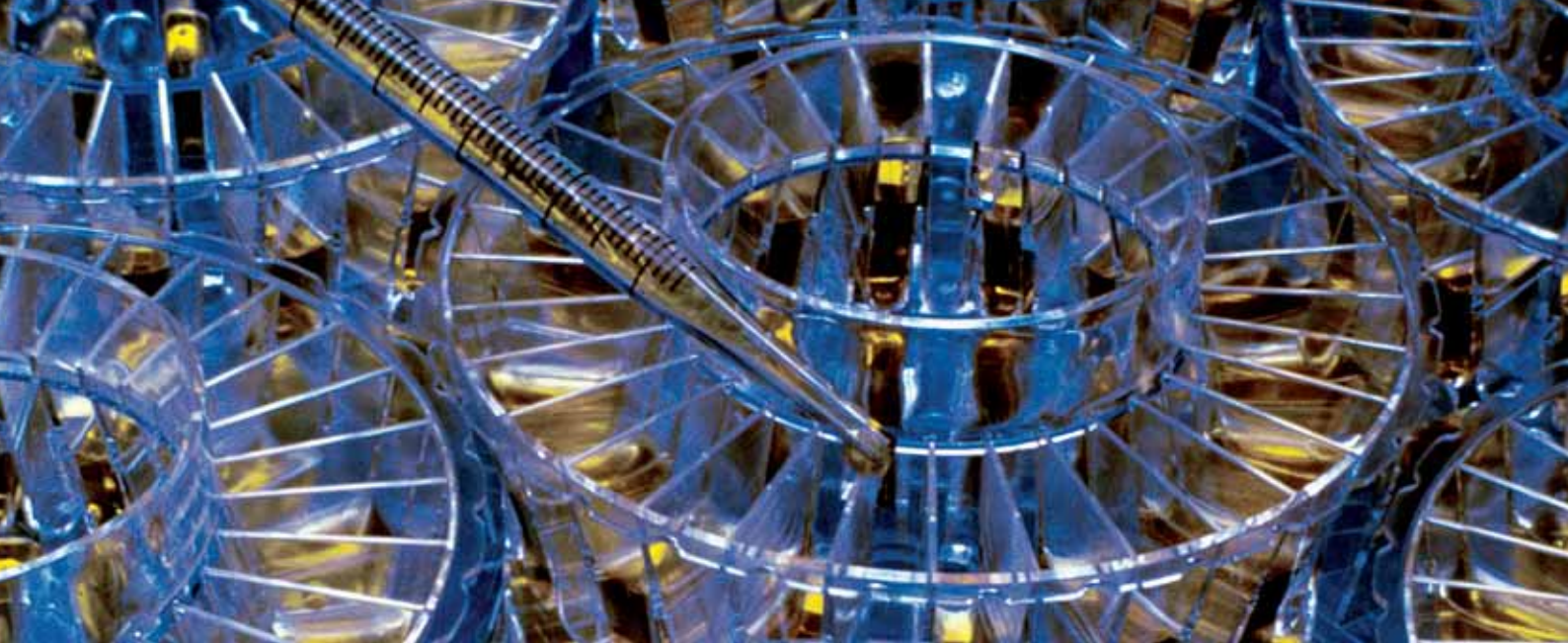
Applications

System Integration



LISA the lims

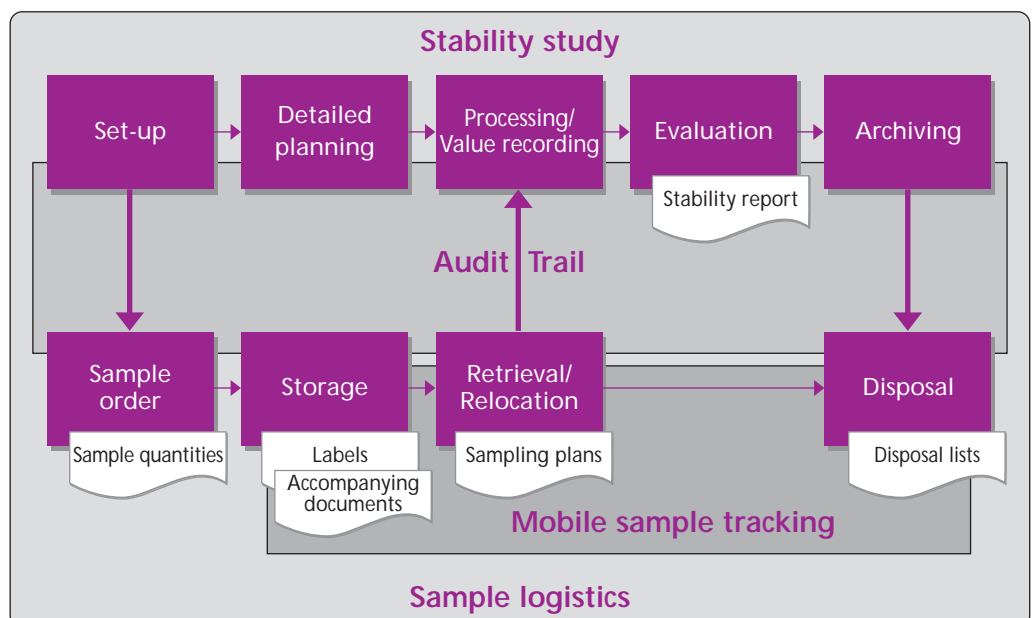




“Stability Testing” with **LISA**: dynamic, precise, transparent

Quality, quantity and documentation requirements for stability testing and studies are increasing all the time, while pressures are growing on laboratories and logistics services to cut costs and streamline processes. The only way to cope is to seek extensive electronic support. The **LISA** “Stability Testing” module offers specific, integrated solutions to meet these requirements. The International Conference on Harmonization (ICH) guidelines for stability tests and the even more stringent requirements for such tests in “regulated” environments (GxP, FDA) greatly influenced the architecture and the functionality of the module in many ways: from rough planning for the set-up of a study and detailed planning with discrete scheduling of tests, the wide-ranging functionality of storage and logistics processes, and the documentation of storage conditions, up to standardized reporting and evaluation. Because of its high degree of flexibility the **LISA** “Stability Testing” module is found in all relevant areas of application: pharmaceutical, cosmetic, food, chemical and automotive technology.

Optimized
sample logistics





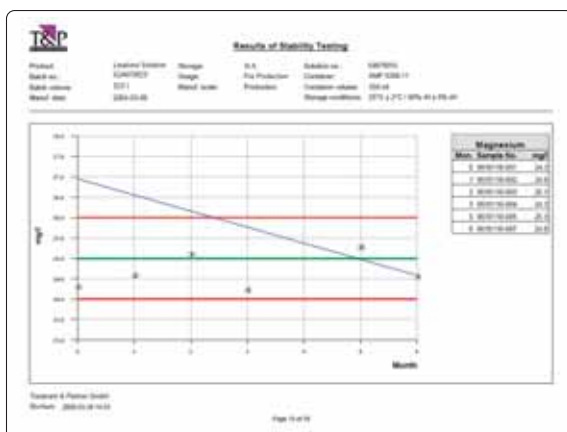
Stability planning and sample logistics

Matrixing, bracketing

When a study is started manually the module provides cyclical and discrete scheduling options for planning the types of samples and quantities necessary, organizing capacities, and scheduling the respective tests. Manual changes to scheduling, scope of testing, and storage location are possible at any time with all actions being recorded in the audit trail. Especially the logistics processes with functions for storage, retrieval, and relocation of samples, sample orders covering several batches and packaging according to ICH guideline Q1D, calculation of quantities and documentation of disposal, as well as the integrated administration of storage locations and conditions create the necessary transparency and minimize the workload associated with the corresponding documentation. Storage labels, documents accompanying samples during transport, sampling plans, and disposal lists for residual samples are all part of the functions supporting logistics activities. The consistent use of mobile data recording terminals and identification systems (bar code, data matrix code, RFID) optimizes the process.

Ongoing stability testing

A study may also be started and conducted automatically. Depending on certain events and conditions – such as a [batch release](#) – the system can automatically generate the related stability tests and initiate the storage and retrieval measures. After the tests have been repeated by a preset number of times, the study will be concluded. Irregular sequences are achieved by setting several interval periods with different starting times. The scope of testing itself can be varied according to material, packaging, event, schedule, storage conditions, results of previous testing, etc.



Except from stability study

Flexibility and transparency

The “Stability Testing” module is fully integrated into **LISA**. This means that all of the **LISA** functions can be used – from capacity planning and online connectivity, value recording and dynamic automation of testing, up to archiving and statistical or graphical evaluations. In connection with the related detailed information, special tabular summaries of results from ongoing studies can provide the clear picture needed for making executive decisions and discovering potential risks. Test results can be called up for evaluation and visualization purposes at any time and they can be documented in summaries. Stability reports satisfy the requirements of ICH guideline M4Q and those of M2 for preparing electronic Common Technical Documents (eCTD). The export function enables easy integration of external systems such as graphics and forecasting tools.

**Differentiated
reports and
statistics**





Module- overarching functionality

Integration in the workflow

All the stability planning functions are integrated into **LISA** workflows and into the business functions in particular, providing a full spectrum of cost accounting functions for step-by-step or final invoicing of services and stability testing.

LISA „Stability Testing“ – Facts & features

- ▼ Easy stability planning in accordance with ICH guidelines
- ▼ Optimized logistics and storage processes
- ▼ Precise processing adjustments thanks to flexible configuration
- ▼ High degree of automation
- ▼ Transparency of all testing procedures
- ▼ Full integration into **LISA**'s many functions

in time

in quality

in budget



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