

# LAB+ | The LIMS

By experts for professionals. Simply safe.

## **MAQSIMA**

#### Security from the experts.

Responsibility for material, quality and safety and the management of these tasks come naturally to MAQSIMA. For more than 15 years, we have been developing customized standard software solutions which meet all the quality requirements in the sensitive fields of laboratory and technical management – ensuring that company liability risks are kept to a minimum.

The basis for this is the ideal combination of technical industry knowledge and IT know-how in mapping laboratory processes in a user-friendly way. Because, the success of a software program is inherently linked to its usability.

The team of laboratory experts, consultants and programmers combines the experience gained from various LIMS launches, quality control laboratories, development laboratories and other companies. As diverse as the projects may be: The MAQSIMA LAB+ team always assists with the secure management of

Since 2003, MAQSIMA has been continuously certified according to the applicable versions of the

laboratory data.

DIN EN ISO 9001 quality standard.











Management

### LAB+ | The LIMS

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The crucial issues in a modern laboratory information and management system (LIMS) are as follows:

- Does it meet the main requirements in day-today laboratory life?
- Does it map the laboratory processes realistically?
- Does it guarantee the security of the collected data?
- Can it be operated intuitively and is it user-friendly?
- · Does it make laboratory work efficient and rational?

For more than 15 years, MAQSIMA has developed a new standard for LIMS, based on the experience gained in many customer projects: MAQSIMA LAB+.

On a highest technological level, MAQSIMA LAB+ combines the convenience and userfriendliness of classic Office programs with the know-how and process-orientation of dayto-day laboratory life. All this, with the guarantee of meeting the strict provisions of GLP/GMP, ISO 9001 and ISO 17025. This combination results in a high level of acceptance from employees, customers and vendors and contributes to efficient working in laboratories.

Standard modules in the basic system and useroriented additional modules as well as customization to the requirements of individual work stations make MAQSIMA LAB+ extremely flexible. Access protection and complex rights assignment secures the system and the data and at the same time acts as a basis for seamless communication – also with customers and suppliers.

#### Overview of the benefits of LAB+:

- Established in many branches
- Modular structure
- Intuitive user interface
- Rights and access assignment can be controlled on detail level
- Standardized interfaces (SAP, other ERP systems, device connection and much more) allow for integration into different system landscapes

- Releasability, despite individual requirements
- Full scalability
- Sophisticated technology
- Diverse and flexible reports and analyses
- Test types that support work flows (e.g. pharmacopoeia)
- Individual configuration options (system options, free fields, mandatory fields, mandatory reasoning and more)

Classified as a configurable product according to GAMP 5 software category 4.

# **MAQSIMA LAB+** The basis for your suitable modules.

Management and monitoring of calibration and maintenance schedules including e-mail notification for due dates and status changes. Hierarchical visualization of test devices and systems (object structure).

Supports users in the control of chemicals and reagents with regard to quality, shelf life, consumption and storage.

Central **LIMS functions** from LAB+

Definition of completed or ongoing sample plans which can be executed by quantity or time. The test scope can be varied per test point. Applications: e.g. hygiene monitoring, in-process controls.

> Development, release and documentation of formulations and production of mixtures and batches. Amounts used are automatically booked out of the raw materials warehouse.

Key figures and complex reports can be generated flexibly and easily, even without knowledge of databases, by both in-house laboratory staff and staff without direct contact to the laboratory software.

Automated actions

LAB+ |

Barcode

(e.g. pharmacopoeia)

Test equipment management

LAB+ | PMV

Chemical and Standard management

LAB+ | CSV

Stability test

**Master data** administration

> **Batch** management

LAB+ | PEP

Sample planning

Formulation and raw material management

LAB+ | RV

LAB+ | Bill Billing

Reporter (BO) Evaluation system LAB+ | EDI

Framework-Interface

**Detailed** 

audit trail

LAB+ | QRK

Quality control chart

LAB+

customer portal

Browser-based

**Customer Portal** 

LAB+|

LAB+ | OOS

Out Of Specification . Management

**Special** LAB+ | PAV test methods Test order management

> Release of work flows

Sample

**Rights** administration

Report generator

> LAB+ | IZ International

certificates

LAB+| Mobile MVR

Mobile measurement value recording

Tolerance violations (OOS), trend violations (OOT) as well as expectation violations (OOE) are documented systematically and in full.

> Structured mapping of the relationship between project and order, organization of orders according to specified work flow. The responsibilities and rights are clearly defined by the client, contractor and person executing the order.

> Monitors trends, controls processes and reports differences in the capture of measured values.

Quick and easy automated translation of reports and certificates using stored language dictionaries.

#### **MAQSIMA LAB+**

Ideal process mapping.

Testing and documentation requirements for laboratories are on the increase – for both contract laboratories and industrial laboratories. In addition, strict quality guidelines apply such as GLP/GMP, FDA, ISO 9001, ISO 14001 or ISO 17025. Laboratories must take on these responsibilities, regardless of their structures and working methods.

One of the fundamental requirements for an LIMS is the flexible adaptation to individual structures and needs. Good, when you can fall back on a laboratory information and management system that knows the fundamental processes in a laboratory and maps these as a basis, and has the flexibility for individual adjustments and changes: MAQSIMA LAB+.

MAQSIMA LAB+ optimally maps your laboratory processes. Building on a basic system, multiple options and additional modules are available. Of course, with user and access rights, which can be managed down to the smallest detail. All according to your requirements.

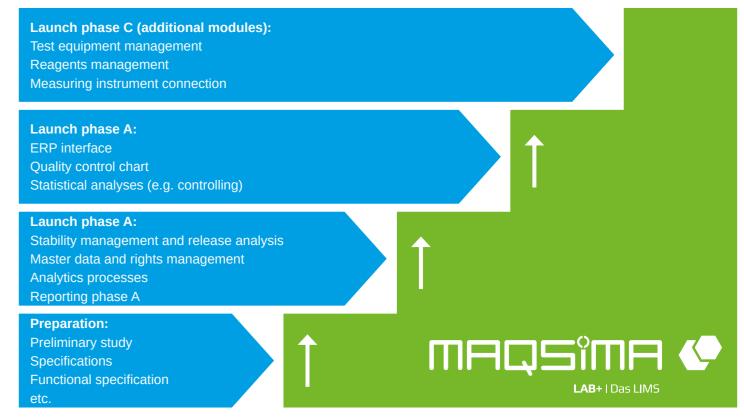
With MAQSIMA LAB+ laboratories consistently work in compliance with GMP and GLP, as it meets all documentation and protocol requirements. And this in combination with short, transparent and target-oriented information channels.

#### User and access rights Create samples/ Administration Recording of Release Reporting orders of samples analyses Generated from an Assessment, Single/multiple Batch tracing Opening samples interface or manrelease stage. measurement/s Value charts Change/deactivate additional texts ually Transfer of samples Test protocols Order creation measurement Control Additional tests Analysis certificates values Batch/sample Approval Sample search/ • Labels Process-controlled creation Release stored search Analyses tests Assignment of test Standard filters Statistics Variables and plans formulas Change to test plan Analyses not Copying of performed samples Filing of documents **GxP-compliant logging**

#### **MAQSIMA LAB+**

Systematically approaching success.

#### **Example of a process:**



An established laboratory information and management system saves resources, adds security and allows for lean communication. To achieve these objectives from the start, a professional system implementation is required.

Following diverse projects, MAQSIMA has developed a proven implementation routine which ensures an optimal transition to MAQSIMA LAB+.

The basis is always the holistic view of the situation and the laboratory processes. Which particularities need to be observed? Which standards must be observed? How are the individual process regulated in detail?

The implementation is performed in stages. The project team and the customer jointly specify the required steps.

The requirements and processes are recorded in detail in a preliminary study. If no specifications are available yet, on request, MAQSIMA assists in the creation thereof.

The functional specifications (FS) describe in detail which program functionalities will cover the individual requirements. The go-live phase can also be performed in steps, in order to optimally support the daily operation and to save staff costs. This ensures a smooth takeover of the documentation and the test reports into MAQSIMA LAB+.

In a regulated environment, validation requirements can be made available, supporting your validation. In addition to consulting and implementation in the launch phase, we offer our customers professional support for the ongoing operation of the system.



www.maqsima-lab.de



Head of Sales:
Stefanie Kirchner
kirchner@maqsima.de

#### **MAQSIMA GmbH**

Am TÜV 1 D-66280 Sulzbach Tel.: +49 6897 506 41

Fax: +49 6897 506 491 E-Mail: info@maqsima.de



Head of Consulting:
Eveline Thielen
thielen@maqsima.de



