MAQSIMALAB

Laboratory Information and Management System

SECURE PLANNING, TESTING, MANUFACTURING

Whitepaper
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maqsima
responsibility management

A COMPANY OF THE TÜV SAARLAND COMPANY GROUP

"Quality begins by placing customer satisfaction at the center of our thinking."

John F. Akers
*Former CEO of IBM.*

CONTENT

The way companies record, store, and evaluate information has been changing fundamentally within recent years. Data storage alone is no longer considered adequate to support the goals of modern companies. This is why old systems need to be replaced by more intelligent information and communication systems on a company-wide level. As information is being recognized more and more as a crucial company resource, information management has emerged as one of the most important tasks in companies today.

Cooperation and information flow between different departments play a major role within a company structure. Certain areas of a company such as quality control have presented great challenges in this field. If you take a closer look at the classic tasks of a quality control laboratory, you will realize very quickly that the use of a data processing system has become absolutely necessary for handling the daily flood of information. Whether you look at tests of incoming raw materials, process control, or quality tests of finished goods, the laboratory represents the control center for information within a company. The production department needs information on the suitability of raw materials or interim reports for relevant processes so that negative trends can be acted upon without any loss of time or money. R&D needs to be informed in a timely fashion about analyses pertaining to developmental projects.

Last but not least, customers also have certain expectations regarding quality certificates. Time and again evaluations are needed which require adequate and high-quality data processing from the lowest to the highest company levels. Furthermore, a smooth integration into a given electronic data processing (EDP) environment should work without glitches as should company-wide communication with other systems. A modern LIM system meets all these requirements.

MAQSIMA LAB offers you all these features. The modular structure of the system enables users to react individually to their own work and business processes. Universal program components support the exchange of information between the laboratory and other departments as well as external communication. The results are short information channels that can be optimized user-specific with numerous mail functions and internet links. Other beneficial results are significant time and cost reductions.
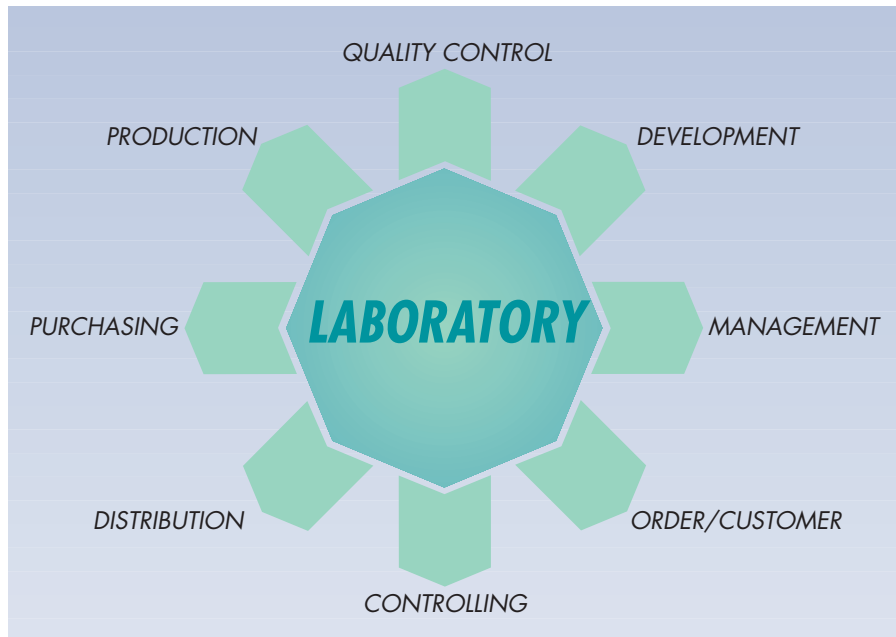
MAQSIMA LAB is not only in use in laboratories of the manufacturing industry; laboratories in the service industry also profit from the high level of flexibility and scalability of this system, which can be installed both as a single-user system or in a client-server version.

MAQSIMA LAB meets all your business demands and, above all as a future-oriented system, it is constantly adapting to the ever changing requirements in today's industry.
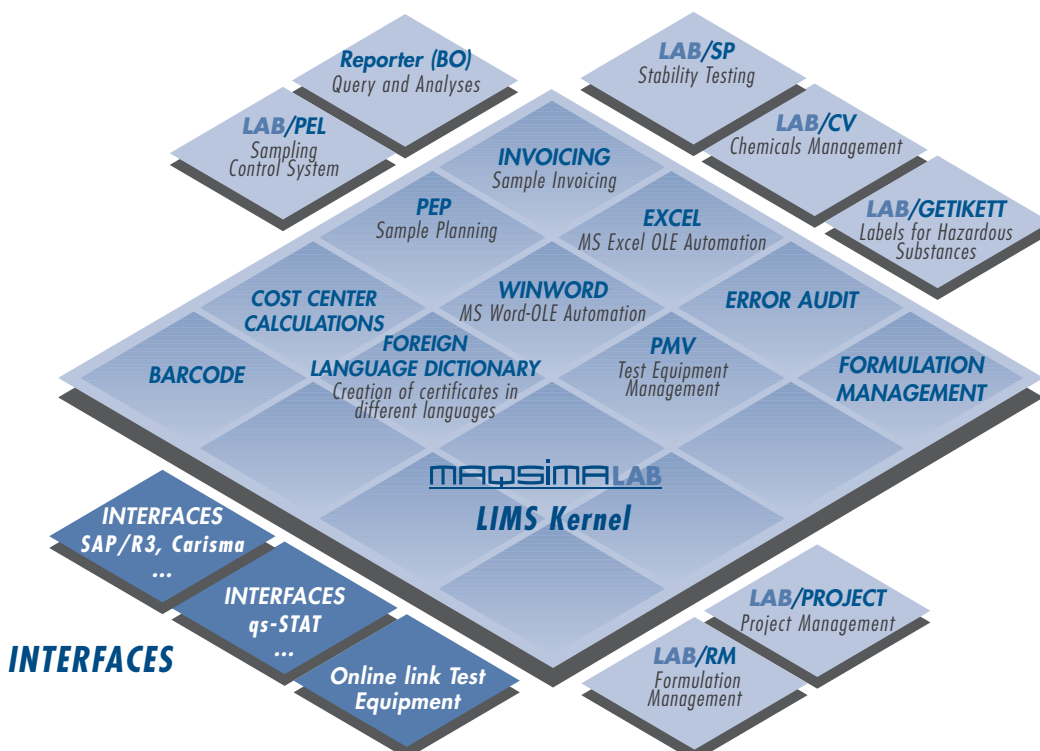
MAQSIMA LAB

- Supports individual laboratory process-oriented configurations with the help of its modular program structure.

- Offers you multiple options ranging from production-supporting routine analyses in your company over analytic work in service laboratories up to the use in Research & Development.

- Has reached a high level of acceptance for more than 10 years through consistent system development in direct and constant contact to the end user.

- Stands out due to its clear and user-friendly structure, which makes it easy to learn.

- Guarantees a comprehensive audit trail through consistent conformance to the GLP/GMP, ISO 9001 / 2000 guidelines, ISO 17025 validation and furthermore in particular to the Guidelines from the US Food and Drug Administration (FDA), e.g. 21 CFR Part 11.

- Offers you stage-oriented access protection up to detailed access code administration on the functional and data level.

- Is parametrized user-specifically and can easily be customized to company-specific terminology in the menu structures and dialog boxes.

- Guarantees smooth communication with other, superordinated systems, such as SAP, CHARISMA/ AS, JBA, through customized interfaces in any desired dimension or extent.

THE MAIN LIMS-FUNCTIONS

MAQSIMA LAB provides you with all functions and features relevant for a state-of-the-art Laboratory Information and Management system today. Individual samples, collective samples, manual samples, or samples created online – none of these will be a problem to **MAQSIMA LAB** ! Samples can be created from the internal order processing, the batch administration, or from sample planning. As a major bonus, **MAQSIMA LAB** can also provide the frequently requested option to integrate data from superordinated systems (WWS, PPS, ERP) into the LIMS. The configuration and realization of most different links resulted, among other things, in a highly developed and certified SAP interface (SAP QM IDI interface).

For sample management purposes which represent the core element of a LIM system, **MAQSIMA LAB** does not only focus on the classic quality control functions for incoming products, raw materials, and finished goods, but offers in addition consistent process control with the help of predefined sampling strategies. Also, serial tests or storage tests in form of collective samples are possible without any problem. Thanks to the high level of flexibility the system allows for fast and easy handling of Research and Development samples, which only rarely show predefined testing structures.

Samples can be created in product-oriented, order-oriented, and customer-oriented ways and labeled with a variety of secondary information which serves as a basis to optimize data interpretation.

Recording of analytical results is almost as versatile and user-friendly as the sample registration. In particular, you can easily import samples and results from Excel® data sheets. In this way, **MAQSIMA LAB** supports communication with external labs. For the entry of test values **MAQSIMA LAB** offers easy-to-use features that allow you to select between individual and multiple measurements as well as using selections from predefined drop-down menus. Another nice feature is that you can integrate test values as calculating fields on the basis of individually defined formulas. The bidirectional transfer between LIMS and Microsoft Excel tables goes even further as all functions of the table calculation system are supported for the test value calculation. As soon as specified limits are exceeded and Out-of-specification incidents occur, **MAQSIMA LAB** will alert you.

The high performance and flexibility of the system can also be witnessed within the direct sample editing and test result calculation: The testing scope, for example, can be enlarged or redu-ced at any time; research samples or customer requirements can be rearranged and individually changed. Comfortable copying features duplicate samples so that rapid sample generation can be carried out even after individual adjustments to test requirements.

The actual sample editing ends with the completion of the sample, either automatically after all test results have been entered or manually if the test needs to be closed out early. Additional release or lockout mechanisms allow the laboratory – or other departments such as production and sales – to get a fast overview on the current sample status. Possible difficulties can be identified faster and, as a result, reaction times can be reduced substantially.

An essential element of a state-of-the-art LIM system is a comprehensive audit trail. In addition to details on the data entry clerk and test personnel you also find a log of all entries and all data belonging to one specific sample. In other words, each individual change to existing test results must be logged in with the exact date and time of change; you can also enter reasons for each change. From this log you receive a complete history for each sample, which, in addition to the performed operations, documents the testing schedule along with the test methods in exactly the condition they were in at the time of sample registration.

Additional functions supporting the audit trail are offered by a revision-controlled administration of the testing schedules, specifications, and test methods which meets the stringent requirements of the pharmaceutical industry in particular. All core functions are being supplemented by individually retrievable work lists, sample labels, storage life statistics, administration of retain samples, and others.

Test group	Test	Unit	Obl	Specified value	Tested value	Ok			Tested value	Test
purity	temperature	℃	☑		22	☑ Info	gh		23	temperature
	residue	mg	☐	10 <= ... <= 20		☐ Info		F	19	residue
	pH-value		☑	6,1 <= ... <= 7,8	6,8	☑ Info	gh	X	6,5	pH-value
	turbidity		☑	clear	clear	☑ Info	gh	X	clear	turbidity
content	Vitamin D	mg	☑	20 <= ... <= 30		☐ Info		Y M	23,00	Vitamin D
	iron	mg	☑	<= 25		☐ Info			23	iron
appearance	color		☑	4,00000 <= ... <= 5,00000		☐ Info			4,00000	color
	dissolution		☑	completely		☐ Info			completely	dissolution
microbiology	entero.bact.		☑	1000 ± 10 %		☐ Info			1000	entero.bact.

PARAMETRIZATION

The basis of any LIM system is the master data. These are key for the future success of a company. **MAQSIMA LAB** offers a variety of master data tables, which can mimic any company-specific structures or business practices.

MAQSIMA LAB is particularly flexible in the individual setup of the work environment. For instance, the user can very easily adjust menu names and masks to the terminology he is accustomed to. With these user-friendly features it is very easy to identify yourself with the system. A global switch to other languages such as English, French, and Italian can also be accomplished without effort.

SECURITY ASPECTS

The security concept realized in **MAQSIMA LAB** is guaranteed by the audit trail mentioned earlier which is consistently following the guidelines of Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) as well as ISO 9001:2000, ISO 17025 and 21 CFR Part 11 (FDA). Furthermore, there are comprehensive security functions for the protection of the system. User-specific codes prevent unauthorized access. The individual allocation of access rules allows for each employee to have access to functionalities he or she is authorized for. These access rules can be allocated all the way down to the data level. Above and beyond that convenient options for data storage and long-term archiving mechanisms offer a high degree of security.

REPORTING

Normally the completion of a sample is not the end of the laboratory technician's work. Typically, he also has to generate a test report and official certificates for customers. Such tasks can be carried out fast and easy with the help of an interface to MS Word. An unlimited number of templates for different certificate types a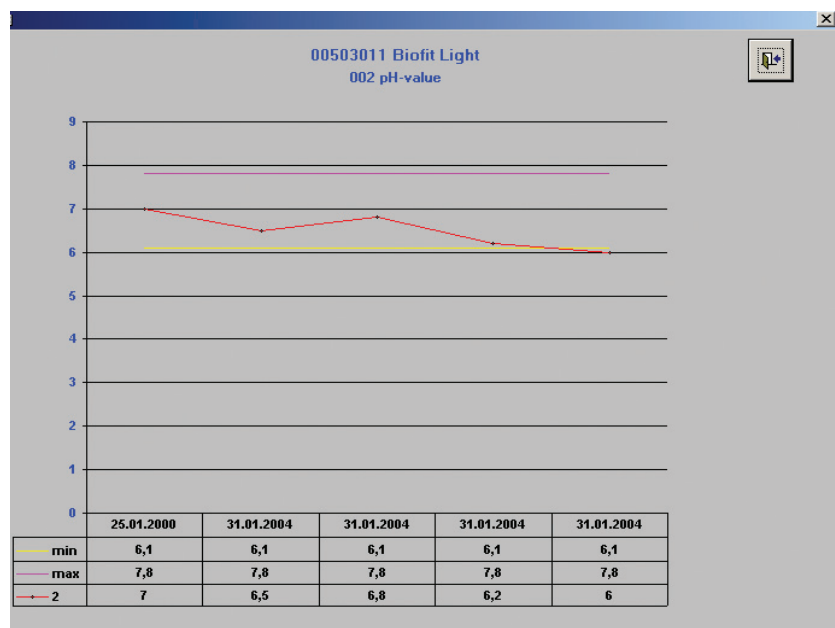nd layouts can be defined. On demand such certificates and reports can also be directly transferred to a network printer or mail server. As mentioned earlier, these documents can also be created in different languages.

You can also take advantage of the functionalities of the module Reporter (BO) when high reporting standards are important.

EVALUATION AND STATISTICS

MAQSIMA LAB offers comprehensive reporting structures that can be customized for the entire database. For example, you can select all samples of a certain batch within the last 24 hours; or MAQSIMA LAB searches for a raw material with a density that exceeds a certain value. Comparison views of preceding samples can be easily created as can tabular result lists (e.g. for storage tests). Result trends can be directly retrieved as graphical illustrations upon entering an analysis. Thus, tendencies in production can be recognized instantaneously. Next to a variety of standard statistical tools you can use an interface to Microsoft Excel®. With the help of special macros this interface facilitates comprehensive and very specific evaluations that connect special calculations or graphical illustrations directly to the data transfer.

00503011 Biofit Light
002 pH-value

	25.01.2000	31.01.2004	31.01.2004	31.01.2004	31.01.2004
min	6,1	6,1	6,1	6,1	6,1
max	7,8	7,8	7,8	7,8	7,8
2	7	6,5	6,8	6,2	6

ERROR AUDIT

The error audit represents a special evaluation procedure. Analyses in which Out-of-specification values occur are being automatically logged and can be displayed in lists if desired. In addition, you have the option to enter comments such as error descriptions, root causes, and possible corrective actions to be taken. The error audit therefore plays an important role within the supplier assessment; incorrect deliveries can be called up online including a root cause analysis.

BARCODE

MAQSIMA LAB supports the use of barcode systems in the field of sample registration and searches. Sample labels are provided with bar codes additionally to uncoded text. With regard to mobile data collection the tester, testing equipment and parameters can be identified via barcode.

PEP– SAMPLE PLANNING

Very often, tests and analyses are carried out according to certain schedules, which define testing intervals and testing scope. This applies particularly to production-supporting controls of ongoing processes. Sample planning supports the sample organization, which supplements the classic form of quality control described up to now. Sampling orders are marked with schedules consisting of the starting and end point of tests as well as the test intervals. You can also apply quantity-oriented strategies for monitoring the batch and order production. Typical examples for use include the sampling of a ground water test station in biweekly intervals and sampling in 500 kg intervals from a batch with a total production volume of 15 tons. No matter which of the schedules is being selected, this creates a vast number of specified test dates, the scope of which can vary tremendoulsy. All tests are not required for each ground water sample. Instead, there are weekly, monthly, and quarterly testing variants. The major task of sample planning consists in the on-time sampling and entry of the sample into the system. With the sample planning module of MAQSIMA LAB it is virtually impossible to miss sampling dates.

LAB/PEL – SAMPLING CONTROL SYSTEM

Samples are often not taken directly by the laboratory staff. The module Sampling Control System offers the possibility to have a closer look at a certain set of relevant data without having to use the complete LIM system. The Sampling Control System is an independent solution, limited to the display of upcoming test dates. The display of specified test dates can also be customized for specific user groups. Consequently, one function of the sampling control system is the registration of routine samples (planned samples) in the laboratory. Upon request, you can have labels printed with the hazard symbol including the sample number. In addition to the planned test dates the sampling control system allows for the registration of special samples in MAQSIMA LAB.

COST CENTER CALCULATIONS

The laboratory often plays the role of an internal service unit within your own company. Therefore, cost control is of utmost importance. All companies focusing on internal cost allocation have found a solution with MAQSIMA LAB Cost Center Calculations, which allows different calculations ranging from the cumulation of the costs over individual cost analyses up to a complete cost center calculation. Various calculations for different intervals can be carried out; the laboratory keeps control over the complete volume of samples and analyses as well as of the total expenditure. A monthly export of the calculations into a super-ordinated company-wide calculation system can be accomplished via a link.

INVOICING

In an oder-oriented laboratory cost center-oriented calculation procedures are usually not adequate. The module "Invoicing" has been developed particularly for the needs and requirements of service laboratories. With the help of rate models you can pre-define fixed prices, price ranges and rebate structures in the system. This can be applied either for individual analyses or for entire sets of analyses. On the basis of customer-specific details, all analytical costs are automatically transferred into the invoicing module. Certain items on the invoice can be corrected and supplemented. Individual or collective invoices, with **MAQSIMA LAB** you can produce invoices fast, correct and easy. Upon request, special control functions provide information about the current invoicing status. Special attention has also been given to allow print-outs of bank transfer forms or the integration of laboratory invoices into super-ordinated company-wide systems. The modules "Cost Center Calculations" and "Invoicing" can also be customized in the respective local currency.

TEST EQUIPMENT MANAGEMENT

Test equipment management has become a central issue for quality control labs. Reagents, solutions, and analytical instruments have to be maintained at regular intervals to guarantee the accuracy of test results. Which test equipment is suitable for a requested analysis? Is the necessary test equipment available?
MAQSIMA LAB has an answer to all these questions: the "Test Equipment Management" module. This module manages all relevant test equipment and combines it with supervising strategies and the respective control plans. These strategies can be either time- or user-oriented; a direct link to the result recording automatically registers the number of uses. For the control of test equipment you can carry out calibrations and control samples and also register relevant results in **MAQSIMA LAB**.

Furthermore, there is the possibility to supervise other maintenance and control functions. If there are limits and specified values defined in the system, you receive warnings when Out-of-specification incidents occur. An internal mail system issues advance notice for upcoming control activities. The Test Equipment Management does not only support your company within the organization of various controlling and supervising functions, but it also provides a thorough history for each test equipment. Through the registration of check-ups that have been carried out and the display of the respective check-up status, you can easily find out for each taken sample or test in which status and condition the used test equipment was precisely in at the time of the test.

LAB/PROJECT – PROJECT MANAGEMENT SYSTEM

A further sector in which a laboratory has to cooperate closely with other departments consists in the completion and organization of comprehensive projects. Two main examples include the development of new products and the continuous improvement of existing products. With a multitude of different departments being involved, a key challenge is to provide each user with correct and relevant information at any time. The complexity of such projects arises from the challenge that very different tasks and a variety of different types of data often need to be dealt with and processed by several different departments simultaneously. This challenge led to the development of LAB/PROJECT as a standard solution, which can tackle these problems and organize complete projects. Embedded in MS Office LAB/PROJECT is an effective tool to concentrate all actions and information around your projects in one central point in the company. The high flexibility, configurability, and adaptability of LAB/PROJECT allows for a company- and user-specific management and organization of projects tightly adhering to the business structures within your company.

LAB/PROJECT coordinates and organizes time-related processes and monitors the status of these projects at the same time.

Using this workflow it is possible for each authorized person at any point of time to retrieve the status of any project, including a detailed cost monitoring. A core function of LAB/PROJECT lies in the concentration of all relevant project information at one central point independent of where these pieces of information can be found physically within the network. This information can consist of reports, Excel® calculations, graphics, and scanned images as well as laboratory data and formulations from the LIMS. As an example, this would enable a sales and distribution representative not only to retrieve the status of a customer project but also to transfer intermediate reports and test results directly without any problem. With the concentration of all this information and data in the relational database of LAB/PROJECT you also have a most effective spectrum of research features.

LAB/CV – CHEMICALS MANAGEMENT

Often the use of different chemicals is necessary to guarantee a trouble-free test process in the laboratory. One essential subject matter in this area lies in the storage control of chemicals. How do you find out fast and easy when a chemical is running out and where it is stored? Legal regulations furthermore require the administration of safety-relevant data and information. These requirements are being met by LAB/CV, the module for chemicals management of **MAQSIMA LAB**. LAB/CV is a module that can be applied independently from the system; it provides a strict and efficient organization of the storage of chemicals. No matter whether you take a look at the current stock of a specific item or you want to have a printout of a list of hazardous substances, LAB/CV provides you with the desired information fast and easy.

For each chemical you can keep information such as minimum stock requirements, specified stock, main supplier, and price. Furthermore, for each data record LAB/CV manages the individual risk and safety labels. Safety data guidelines in form of external documents can be integrated. Storage classes define which chemicals can be stored together without any restriction or which chemicals must be kept strictly separate. If an inventory falls below the minimum stock requirements, LAB/CV generates a report and simultaneously produces an entry into the list of proposed orders.

LAB/RM – FORMULATION MANAGEMENT

Within the development of new products or the improvement of existing products the main focus normally lies on the development of formulations: This is an evolutionary process. Development formulations become gradually refined until they can be released for production. Over time, such developments, which do not always follow a linear trend, produce a huge database to be managed. Particularly the search for established formulations or the search for certain components have proven to be almost impossible without the use of data processing. LAB Formulation Management provides laboratories with a comprehensive management system to tackle these tasks. The relationship between different formulations is documented and a "tree" of a certain formulation generated. Each formulation is subject to strict revision control up to the release by authorized personnel. Clear access rules define the authorized access to formulations.

Next to providing a wealth of header information you can also calculate the total cost of a formulation for a given base amount. A link to existing OLE documents can be created very easily with LAB Formulation Management. The list of components for a formulation is directly linked to the respective mixing instructions, which include all steps necessary to produce a certain formulation. As components do not always consist of individual raw materials LAB Formulation Management can integrate intermediates or masterbatches, such as color variants and additive mixtures, without redundancy. LAB Formulation Management records for each item in the bill of materials and other components whether it goes into a formulation in absolute amounts or in percentages. LAB Formulation Management independently carries out conversions into the base unit as well as control calculations to verify a 100% total amount. Important is also a direct calculation of critical parameters in case modifications to a mixture are implemented.

LAB/SP– STABILITY TESTING

The module "Stability Testing" has been developed in strict accordance with the requirements of the pharmaceutical industry. According to ICH guidelines, Stability Testing gives your company the tool to realize a comprehensive processing of stability tests through predefined storage periods. Relevant information on batches and environmental storage conditions can be pulled up and evaluated by the user at any time. On the basis of a time scheme "Stability Testing" establishes specified dates on which stability tests are due. Like in the LIM system this module creates a detailed audit trail for all transactions, data records, and analytical results. Completion of all required testing leads to the release or blocking of a given batch – either manually or automatically. The responsible management in your company can see where difficulties or problems arise. Additional module features include action- or time-oriented searches as well as a multitude of statistic evaluations. Standard features also include storage and sample management as well as printing of sample labels, recording sheets, and test protocols.

LAB/GETIKETT – PRINTING OF LABELS FOR HAZARDOUS SUBSTANCES

As a completely independent system LAB/GETIKETT supports the printing of labels for hazardous substances with the required risk and safety statements.

Linked to **MAQSIMA LAB** this system is particularly useful for sample planning.

REPORTER (BO)

The module "Reporter (BO)" provides you with a comprehensive evaluation system which supports individual queries, report generation, and data analyses. Its use is intuitive and its evaluation features are very diverse. With this module you can either generate or update standard reports or generate customized reports.

In addition, you have the possibility to generate reports in a time- or event-related fashion and send the reports to selected users. These features give you the tools to organize your reporting processes intelligently and with a maximum level of automation.

INTERFACES

MAQSIMA LAB can be integrated smoothly into the IT world of a company. This does not only imply the integration of the most commonly used Office environment, but with increasing importance the exchange of information with company-wide systems, e.g. ERP. **MAQSIMA LAB** guarantees this way of communication by providing appropriate interfaces to super-ordinated systems. Through many years of professional experience, systems like SAP, CHARISMA/AS, JBA, etc. have been linked successfully and efficiently to MAQSIMA LAB.

DATABASE

The LIM system **MAQSIMA LAB** and all accompanying modules have a common central database. You can use this together with the database models Microsoft Access, Microsoft SQL Server, and Oracle. The choice of an appropriate database is often based on the number of users which need simultaneous access to the database and the data volume. In smaller laboratories, **MAQSIMA LAB** can come into use as an Access version in a single user version or multiuser environment. **MAQSIMA LAB** can be used particularly successful in big companies as it has been designed originally as a client-server-solution based on Microsoft SQL Server or Oracle. Besides using them together with **MAQSIMA LAB** you can also use the modules LAB/PROJECT (Project Management System), LAB/CV (Chemicals Management), and LAB/GETIKETT as completely independent system solutions.

When employing the LIM system **MAQSIMA LAB** simultaneously in different locations within your company, we highly recommend the use of Citrix servers to guarantee that only one central database has to be maintained.

Since hardware requirements depend strongly on the choice of the database, we will be happy to help you over the phone with your individual questions.

MODULE:

- *Error Audit*
- *Bar Code*
- *Formulation Management*
- *PEP Sample Planning*
- *LAB/PEL Sampling Control System*
- *Cost Center Calculations*
- *Invoicing*
- *PMV Test Equipment Management*
- *LAB/PROJECT Project Management System*
- *LAB/CV Chemicals Management*
- *LAB/RM Formulation Management*
- *LAB/SP Stability Testing*
- *LAB/GETIKETT Printing of Labels for Hazardous Substances*
- *REPORTER (BO) Reporting, Query and Analyses*

TECHNICAL SPECIFICATION:

- **Database:** MS Access, Oracle, SQL Server

SYSTEM REQUIREMENTS

- **CPU:** Pentium or equivalent
- **Graphics:** Resolution 1024 x 768
- **Operating Systems:** MS Windows NT4.0/ 2000/XP
- **Terminal Server Version:** Citrix Metaframe on MS terminal server

We are here for you to provide support for the use of MAQSIMA LAB.

OUR SERVICE INCLUDES:

- *Individual consultation*
- *Hands-on training*
- *Customer-specific installation*
- *Company-specific data modelling*
- *Individual program customizing*
- *Maintenance agreements (Hotline, Receipt of future program versions free of charge)*

MAQSIMALAW
responsibility management system

is a development of *MAQSIMA GmbH* in cooperation with the TÜV Saarland

MAQSIMALAB
LaborInformations- und ManagementSystem

is the upgrade of the Laboratory Information and Management System LABORA

MAQSIMAECO
Energie- und StoffstromControlling

is the upgrade of the Energy and Electricity Controlling System E-BILANZ

MAQSIMAIPS
InstandhaltungsPlanungs- und SteuerungsSystem

is the upgrade of the Maintenance, Planning and Controlling System ALWIN

For further information please contact us. We will send you a test version or arrange for an on-site presentation.

www.maqsima.de

maqsima
responsibility management

A company of the TÜV Saarland Company Group

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