SIEMENS

SIMATIC IT Unilab 6.7

Concepts Guide - part 1

Concepts Guide

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Guidelines

This manual contains notices intended to protect the products and connected equipment against damage. These notices are graded according to severity by the following texts:

Caution

Indicates that if the proper precautions are not taken, this can result into property damage.

Notice

Draws your attention to particularly important information on handling the product, the product itself or to a particular part of the documentation.

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We have reviewed the contents of this publication to ensure consistency with the hardware and software described. Since variance cannot be precluded entirely, we cannot guarantee full consistency. However, the information in this publication is reviewed regularly and any necessary corrections are included in subsequent editions.

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Preface

Where is this manual valid?

This manual is valid for release 6.7 of SIMATIC IT Unilab.

Basic knowledge required

This guide is intended for SIMATIC IT Unilab users who are responsible for system configuration, such as application managers and system integrators (consultants).

To be able to understand the concepts and examples discussed in this guide, the reader should at least have taken the SIMATIC IT Unilab Basic Training.

Purpose

This Concepts Guide explains all concepts of SIMATIC IT Unilab and includes several scenarios that illustrate how these concepts can be used in specific situations.

Related documentation

The **Unilab Concepts Guide part 2** and **3** contain information related to the content of this Concepts Guide.

These documents are all available online from the SIMATIC IT Unilab Documentation Library**.**

Conventions

The table below describes the specific typographic conventions that are used throughout this manual:

Symbol/Convention	**Indicates...**
E.g.	Where examples are given.
Text in bold	The names of menus, commands, dialog boxes and toolbar buttons and, in general, all strings (e.g. **File** menu; **Save** command).
KEY1+KEY2	Shortcut keys, which permit rapid access to commands (e.g. CTRL+C).
UPPERCASE	The names of keyboard keys (e.g. RETURN key).
Italics	The names of parameters that must be replaced with a specific name or value. E.g. *filename* indicates that the name of the file must be specified; *input* indicates that the corresponding value must be specified.

Symbol/Convention	Indicates...
>	A succession of commands in which the command preceding the symbol must be selected before the command following it.

SIMATIC IT Documentation Library

The SIMATIC IT Unilab Documentation Library provides you with a comprehensive and user-friendly interface to access the overall product documentation where manuals and helps online can be browsed by functionality or by component.

Readme

The installation includes a readme file, which contains information on upgrade procedures and compatibility with previous releases. This file is supplied both in standard text (**Readme.wri**) and in Acrobat PDF (**Readme.pdf**) format.

This file is available in folder \ReleaseNotes of the setup DVD and is available from the SIMATIC IT Unilab Documentation Library.

Acronyms and abbreviations

The table below lists the acronyms and abbreviations that are used throughout this manual:

Acronyms / Abbreviation	Meaning
ad	Address
API	Application Program Interface
ar	Access rights
au	Attribute
ca	Intervention
cf	Custom function
cn	Condition
cs	Condition set
db	Database
DBA	Database Administrator
dd	Data domain
DLL	Dynamic Link Library
eq	Equipment
ev	Event
fa	Functional access
FIFO	First In First Out
freq	Frequency
gk	Group key
GUI	Graphical User Interface
hs	History
ic	Info card
id	Identification
ie	Info field (Configuration)

Acronyms / Abbreviation	Meaning
ii	Info field (Operational)
ip	Info profile
lc	Life cycle (or life cycle model)
LIMS	Laboratory Information Management System
ly	Layout
lo	Storage location
me	Method (Operational)
MES	Manufacturing Execution System
MRP	Materials Requirement Planning
mt	Method (Configuration)
pa	Parameter (Operational)
pg	Parameter group
pp	Parameter profile
pr	Parameter Definition
pref	Preference
pt	protocol
rd	Raw data
RDBMS	Relational Database Management System
rq	Request
rt	Request type
sc	Sample code
sd	study
seq	Sequence (number)
SOP	Standard Operating Procedure
spec	Specification
ss	Status
st	Sample type
tk	Task
tp	Time point
uc	Unique code mask
up	User profile
us	User
ws	Worksheet
Wt	Worksheet type

SIMATIC IT Training Center

Siemens IA AS MES offers a number of training courses to familiarize you with the SIMATIC IT product suite. To successfully achieve this goal, training consists of lessons in both theory and practice.

Courses are held year-round, according to a program that is published well in advance of the first scheduled session.

The material on the basis of which our courses are conducted reflects the result of years of experience in process, LIMS, quality control and production management.

All courses are held by expert personnel that are aware of the developments and innovations in the Siemens IA AS MES product suite.

Courses are held in English at the Siemens IA AS MES Training Centers.

Upon request, training courses can also be organized on the customer's premises.

For more information on the training course calendar, please visit our technical web site (http://www.siemens.com/simatic-it/training).

SIMATIC IT Service & Support

A comprehensive Software Maintenance program is available with SIMATIC IT products. Software Maintenance includes the following services:

- **Software Update Service** (SUS): automatic distribution of upgrades and service packs
- **Technical Support Service** (TSS): support on technical problems with SIMATIC IT software (standard support and other optional services)
- **Online Support**: a technical web site, providing information such as Frequently Asked Questions and technical documentation on SIMATIC IT products

Software Update Service (SUS)

This service provides automatic shipment of new versions and service packs when released. When a new version / service pack is available for shipping, it is typically shipped within one month.

One copy of the installation DVD is shipped for each Server covered by Software Maintenance.

Hot fixes (officially tested and released) are not shipped and must be downloaded from the Technical Support Service web site.

Technical Support Service (TSS)

Siemens provides a dedicated technical support team for SIMATIC IT products.

The following options are available:

Bronze support: 9 hours/day, 5 days/week

Silver support: 24 hours/day, 5 days/week

Gold support: 24 hours/day, 7 days/week

The principal language of the SIMATIC IT hotline is English.

SIMATIC IT partners and customers covered by the Software Maintenance program are entitled to direct access to the TSS.

Access to TSS

To be able to access TSS, the customer needs to register as a user on the Technical Support web site: http://www.siemens.com/mes-simaticit and follow the **Technical Support Service** link

The registration form must be completed with:

- Personal data
- The required company and plant information
- The Contract Number provided by Siemens Back Office when the contract is agreed.

Online Support

A customer who is a registered TSS user, can access the Technical Support web site (http://www.siemens.com/mes-simaticit/tss), which contains technical information such as:

- Service conditions (Phone numbers, Working hours, Reaction times,…)
- SIMATIC IT knowledge base: a technical support database that includes practical service solutions from Technical Support or the SIMATIC IT community
- SIMATIC IT software (e.g. hot fixes, software examples) and release notes that can be downloaded
- SIMATIC IT cross-industry libraries that can be downloaded (limited access to SIMATIC IT certified partners)
- SIMATIC IT product documentation that can be downloaded
- Frequently Asked Questions and useful tips.

Table of Contents

1 General Description of LIMS

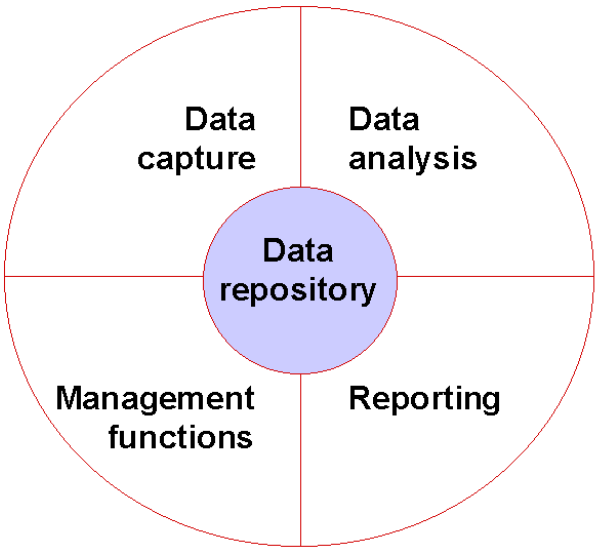
This chapter introduces the definition of a Laboratory Information Management System (LIMS) and points out the benefits of using a LIMS for both the laboratory and the company as a whole. History and future of LIMS are explained briefly. Particular attention is given to the integration of LIMS with other software packages used in the company, such as MES and ERP systems, with a view to integrated quality.

1.1 About LIMS

1.1.1 Definition of a LIMS

Different authors have proposed their definition of a LIMS. Dr Robert McDowell, an authority on LIMS and the 1997 LIMS award winner, defines a LIMS as an integrated computer-based system combining data capture, data analysis, reporting and management functions, linked by a common data repository, to meet the needs of a laboratory environment. In addition, Dr McDowell points out that a system that does not meet these minimum functional requirements may help to automate the laboratory, but is not a LIMS.

The picture below presents the LIMS model of Dr Robert McDowell.



1.1.2 Advantages of a LIMS

Both analysts and lab managers benefit from the implementation of a LIMS in the laboratory. The benefits of a LIMS can even be extended to the corporate level.

1.1.2.1 For the Analysts

Analysts benefit from the implementation of a LIMS in two ways:

- They can perform their tasks more efficiently
- The data entered and processed are much more reliable.

1.1.3 Increased Efficiency

The implementation of a LIMS allows analysts to perform their tasks much more efficiently. Efficiency may increase up to 30 % because of several reasons.

First, a LIMS provides global guidance through the workflow. Well-defined tests or analyses have to be performed on each sample according to well-described methods. Each analyst receives a worklist that indicates all the analyses he/she has to perform. If the analyst is not acquainted with the analyses, a full description of the analytical method and procedure is available on line. When entered into the LIMS, the analytical result is automatically compared with the previously entered specifications. If the result lies within the specifications, a report can be generated automatically, if not, a warning is displayed. The result will then have to be evaluated by the lab manager before a report can be issued.

Secondly, the turnaround time on the analysis of a sample is considerably reduced by the following LIMS functions:

- Automatic data acquisition through the integration of automated devices
- Indication of errors when incorrect data is entered
- Automatic calculations
- Automatic validation of data
- Automated generation of reports.

Finally, a LIMS speeds up the storage and retrieval of data. Time-consuming information searches are reduced drastically because all laboratory-related data is stored in one central database. The data can be accessed in a fast and user-friendly manner.

Increased reliability

One of the most important advantages offered by a LIMS is the reduction of the number of data entry errors. Plausibility checks are performed at different levels to prevent users from entering useless or incorrect data. A simple but elementary example is the restriction of the pH value to the 0–14 range.

Data entry errors are reduced even more by the possibility of integrating measuring instruments. Connecting equipment directly with the LIMS eliminates manual data entry, thereby resulting in fewer typing errors.

For the lab manager

For lab managers, the benefits of a LIMS concern the areas of improved lab management and better availability of information.

Improved lab management and control

A LIMS provides information regarding the efficient use of resources. At any time, the lab manager can obtain information on the actual workload, the distribution of the workload, cost and time of the analyses, and the number of analyses performed per day, shift, week, etc. Personnel, investments, consumables, etc. can be planned by the lab manager in accordance with the actual requirements.

Moreover, a LIMS provides the necessary tools for a more flexible day-to-day management of the laboratory. It allows the lab manager to allocate resources such as personnel and/or equipment. Immediate feedback on the progress and on the status of the work being carried out can be obtained at any moment. The workload per analyst, the workload per equipment, the number of samples processed in the lab, etc. can be consulted instantly. If required, resources can be re-allocated to eliminate bottlenecks and/or delays.

Improved data retrieval

Laboratory data is easily retrieved from the centralized LIMS database. The data can be used for Statistical Quality Control (SQC), Statistical Process Control (SPC) or proof of regulatory compliance.

At corporate level

The implementation of a LIMS provides multiple advantages at the corporate level:

- Enables better management of the lab data.
- Improved data accessibility.
- Data can be used as input for decision-making processes.
- Contributes substantially to overall quality assurance.
- Ensures greater productivity.

Management of data

In recent years, there has been an explosion in quality assurance data. This is due to:

- Increased government regulations that impose strict requirements with regard to laboratory practices and procedures
- Progress in automated instrumentation, which allows faster data collection
- Higher quality-control standards in the laboratory, which have increased the required amount of testing
- Increased demand for statistical quality control (SQC) and statistical process control (SPC) and, consequently, increased demand for data collection, storage, retrieval, analysis, reporting and archiving.

A LIMS helps to organize and store lab data, contributes to the laboratory quality-assurance practices, interfaces to laboratory instrumentation, interfaces to other departments within the company, provides data import and export capability with other software packages and helps to produce reports and graphs.

Quality assurance

Modern-day companies face greater challenges and conflicting demands such as reducing costs while increasing customer satisfaction and maintaining a high level of product quality and compliance with governmental or other regulatory agencies. A LIMS enhances the companies' quality assurance practices by organizing and storing production-related data in one central database. This allows improved quality control for products and the production process.

The documentation needed to provide evidence that a quality system is in place could be classified in two categories: plans and records:

- Plans are policies, objectives, procedures, specifications, methods and instructions. They specify what the company does or intends to do.
- Records prove that the plans have been implemented and that the work has been performed in accordance with the plans.

Documentation in support of both plans and records is kept in the LIMS database.

Greater productivity

The implementation of a LIMS drastically improves laboratory efficiency, due to faster turnaround times on samples and optimization of lab activities.

It is clear that corporations benefit from faster turnaround times on samples, both in the short and long term. For example, in a manufacturing environment, a batch out of specification is discovered earlier in the process and the necessary actions can be taken at once. This means less scrap and repairs at the end of the production, so less additional costs. Quality-assurance strategies have evolved in the same way: from quality assurance based on the inspection of end products towards quality systems used to detect and prevent defects during the production process (and even throughout the entire organization).

In a service laboratory, long-term benefits of faster turnaround times are reduced testing costs.

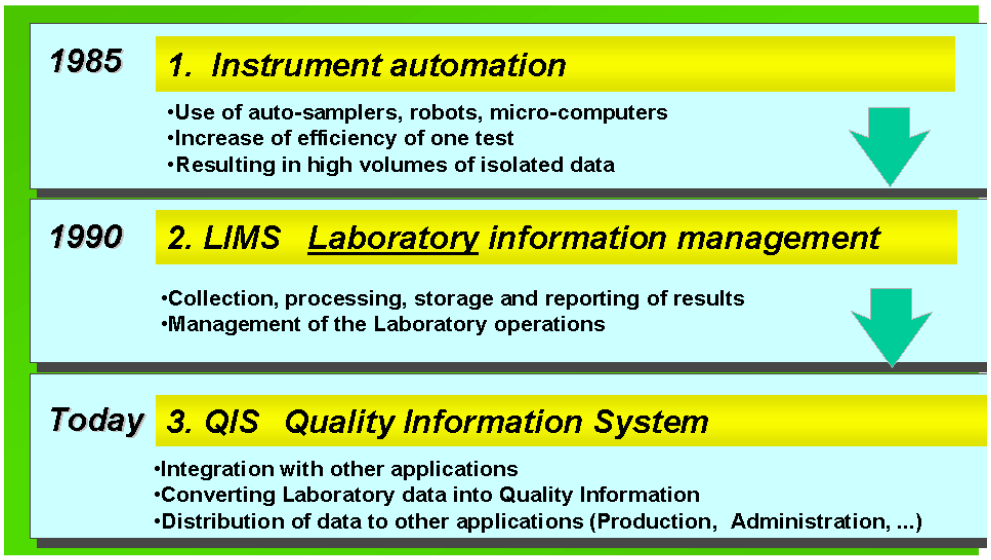
Not all software tools are LIMS

From what has already been discussed in the previous sections, it follows that not all software tools used in the laboratory can be considered as full functional LIMS. A spreadsheet, for instance, is not a substitute for a LIMS: it is not a data management system. Data entered into a spreadsheet is not secure, mistakes can be easily made during data entry, data retrieval is not easy to accomplish and a spreadsheet can be accidentally saved in a transitional state.

1.2 MES Context

1.2.1 From LIMS to QIS

The figure below illustrates the stages in laboratory automation.



LIMS development was a logical step in the laboratory automation process, which started with instrument automation in the middle of the eighties. Instruments such as a Gas Chromatograph (GC) or a Nuclear Magnetic Resonance (NMR) were able to provide large volumes of data in an electronic format. This substantially increased the efficiency of the tests. However, each instrument acted as a system on its own, which resulted in large volumes of isolated data.

The need was felt for a system that centralized all this data. This led to the introduction of LIMS in laboratories at the beginning of the nineties. In addition to collecting all lab data and storing it centrally, a LIMS was able to process this data and report the results. It turned out to be the perfect tool to organize the daily work in the laboratory and manage the laboratory operations. LIM systems enabled lab managers to optimize the laboratory's activities and to increase the laboratory's efficiency.

The demands for lab data has increased over the years. LIMS data has become important source material when it comes to managing and proving the quality of materials and finished products. This trend will persist in today's global market which focuses on increasingly complex products of high quality.

In addition, increasingly demanding government regulations impose strict requirements with respect to the practices and procedures used in laboratories as well as the liability of produced goods. Evidence in support of regulatory compliance, data used for declarative labeling of produced goods – it can all be retrieved from a LIMS database.

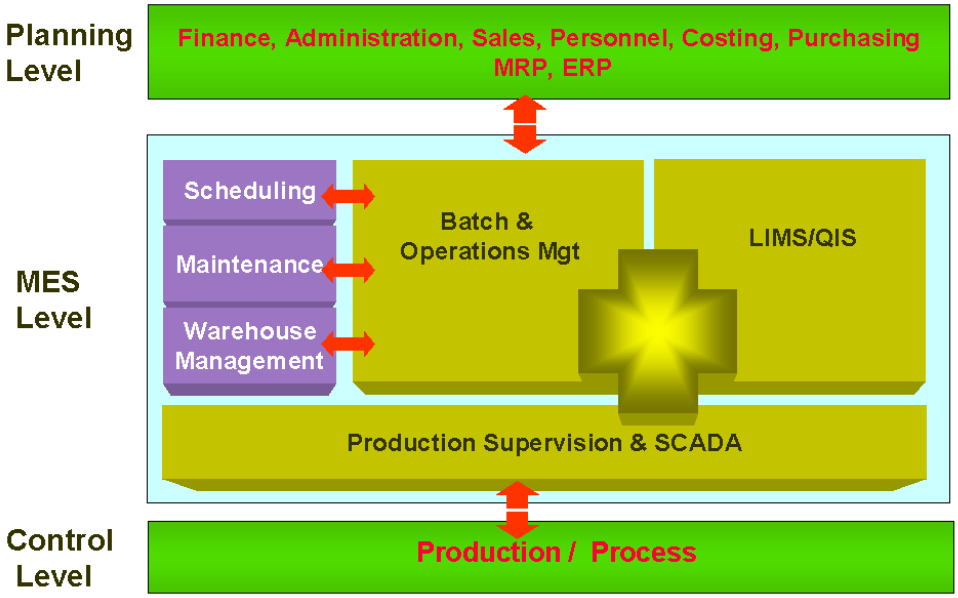
The LIMS database has therefore become an essential source of quality information. The LIMS has become a Quality Information System, a QIS.

But the laboratory is not the only source of quality information in the enterprise. Other departments, such as the production department or the sales department, keep evidence records of the quality of processes or products. However, quality procedures are often ad-hoc solutions developed to deal with specific departmental problems. They focus on the internal departmental goals. As a result of this fragmented approach to quality management, multiple software packages cover the quality management spectrum. Quality records kept in these isolated packages are often hard to reconcile. In response to this fragmented approach, efforts are currently under way to integrate the different software packages used for quality management at the enterprise level. Although having integrated the different parts of information within the laboratory, the LIMS has continued to be an island between the different systems used at the enterprise level.

1.2.2 The LIMS in the MES Environment

Software solutions are provided for each of the three quality management levels within a production environment.

The figure below shows the software solutions in the production environment.



At the lowest level, on the production floor, Open Control Systems (OCS) control the execution of the actual production processes. The OCS systems are tailored to real-time quality control, testing and inspection. They are often well integrated with the production supervision systems at the MES level.

At the Manufacturing Execution Systems (MES) level, systems are grouped to take care of manufacturing processes. They ensure that the production process is executed according to specific quality standards.

At the planning level, Enterprise Resource Planning (ERP) systems manage the customer-oriented manufacturing. The ERP systems track customer, supply performance and manage quality information related to expenses and material.

Over the years, the LIMS has acquired a unique and central position amongst the other software solutions used in an organization. It contains data originating from a wide range of analyses:

- Analyses in support of quality management during the manufacturing process
- Analyses in support of quality management of materials
- Analyses unrelated to production runs (environment, calibration of equipment, reference samples, etc.).

This explains why the LIMS has continued to be independent from other systems. Lately, considerable efforts have been made to interface LIMS with MES and ERP systems to improve the co-ordination between tests and production.

At the MES level, the LIMS plays a crucial role in quality management during the manufacturing process. Quality management systems, such as those based on the ISO 9000 standards, usually require well-defined processes with built-in quality assessments rather than inspection afterwards. Consequently, quality control should be considered as an integral part of the production process itself. In order to maintain overall responsiveness of the manufacturing process and avoid bottlenecks and delays, the results of the analyses performed on the intermediate manufacturing products should be available to the manufacturing supervisors on a real-time basis. Therefore, the focus is shifted from off-line testing to at-line testing or even in-line testing. To put this into practice, the LIMS is interfaced with other systems at the MES level – in particular, those used for batch and operations management. The systems referred to can even perform a variety of LIMS operations remotely, such as logging in samples, scheduling laboratory analyses or entering sample information in the LIMS. Depending on the analysis results returned by the LIMS, the execution of the subsequent manufacturing processes could be adjusted, if necessary.

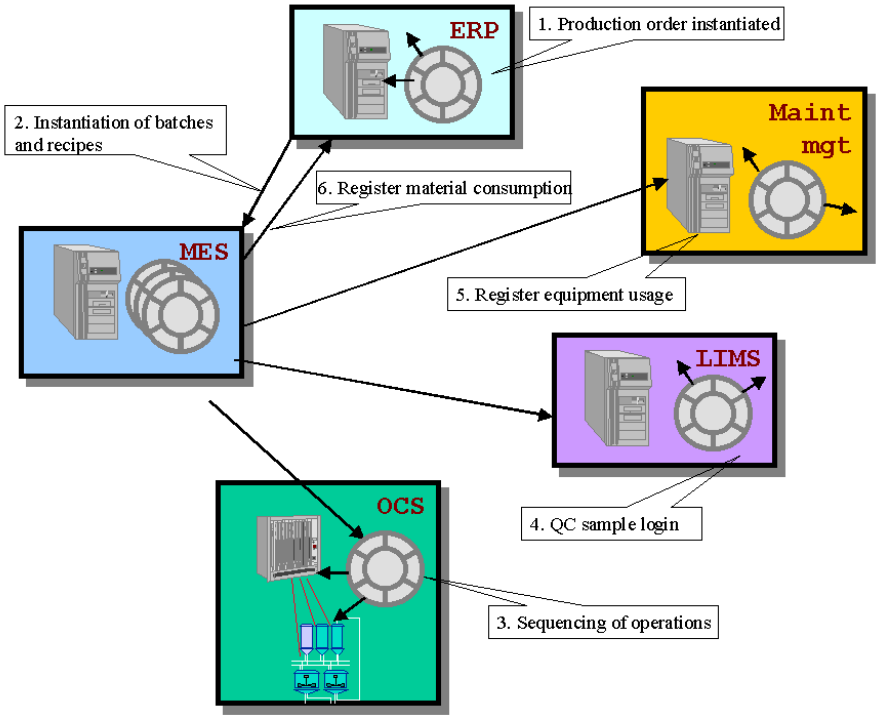
1.2.3 Integrated Quality Management

The integration of the enterprise's different software solutions goes beyond the MES level. The ERP systems need the analysis results to make decisions with regard to purchases, material, financial means, production and distribution. Hence, interfacing between solutions at the MES level and solutions at the ERP level is the logical way to proceed. At most manufacturing sites, ERP systems are used in combination with a LIMS to manage laboratory-based sampling processes, standards for testing, and administration of records. The combination aims at:

- Approving a batch of materials for use in production processes (on the basis of test results)
- Approving a product lot for distribution to customers (on the basis of product tests).

To an integrated Quality Management System

The final goal is an integrated quality management system. The figure below illustrates an example of such a system.



MES and LIMS applications are the core of integrated quality management.

Incoming customer orders are processed at the ERP level. This information includes the product type, the product quantity and the specifications. The ERP system triggers the MES system to instantiate the recipes as batches. The MES system manages the configuration and the production of the batch or lot and includes the test and specification details as part of the detailed work order or batch.

Once the production process is started, the MES system manages the manufacturing execution. The sequencing of the operations is sent to the OCS systems, which are in charge of the real-time control. The MES system provides a near real-time step-by-step tracking of the production order or batch recipe execution. Significant events are recorded and used to trigger new operations and material movements. Exception events are triggered when the batch performance does not comply with the standards or specifications; they may initiate activities such as the login of Quality Control samples, tests, inspections or calibrations in the LIMS. The MES system also provides feedback details, such as material usage and control measurement from execution steps to external systems for maintenance management and ERP.

The electronic batch record at the end of the MES batch execution can be a master record. It is passed back to ERP inventory records for distribution processes. It will be integrated with quality records from tests performed on raw materials, received from the LIMS, and stored within the ERP systems for product records and certificates of analysis. For traceability purposes, all the results are stored together with the specific customer order that initiated the production batch.

Benefits of Integrated Quality Management

Benefits of an integrated quality management system are:

- Improved monitoring of the production process
- Improved traceability
- Improved decision process at the business level
- Documented quality procedures.

Improved Monitoring of the Production Process

By coordinating the laboratory tests for intermediate manufacturing products and the execution of the subsequent production steps in the manufacturing process, bottlenecks and delays in the manufacturing throughput can be eliminated and the overall manufacturing responsiveness can be improved.

The improved monitoring of the production process substantially reduces manufacturing expenses. Waste and repair costs resulting from defective batches are lowered drastically by the improvement of the overall manufacturing responsiveness.

Improved Traceability

The integration of different software solutions leads to simpler audit trails in case problems occur. This is because links are established between quality records stored in the different databases and double records are eliminated. Consequently, problem-solving is performed more quickly and customer service improves.

Improved Decision Process at Business Level

The linking of data from different levels improves the decision process with respect to the deployment of resources at the business level. In the long term, this leads to a more cost-effective way of working at the enterprise level.

Evidence on Quality Procedures

The linking of data from different levels makes validation for regulatory compliance much easier.

1.3 Application Areas

The configuration of a LIMS largely depends on the type of laboratory in which it will be used. Each type of laboratory is organized in a different way, deals with specific customer demands and has a different workflow. Unilab is especially designed for Quality Control labs and service labs. However, it must be noted that most laboratories are not pure QC or service labs. In reality, the requirements of a lab may be similar to those discussed, completely different, or a hybrid of the different lab types.

1.3.1 Quality Control Laboratories

A Quality Control lab is primarily concerned with product quality and is therefore closely related with the manufacturing process. From the delivery of raw materials to shipping finished goods, product quality and variation must be monitored and effectively reported in order to determine when process-corrective actions need to be taken and to verify that these actions were successful.

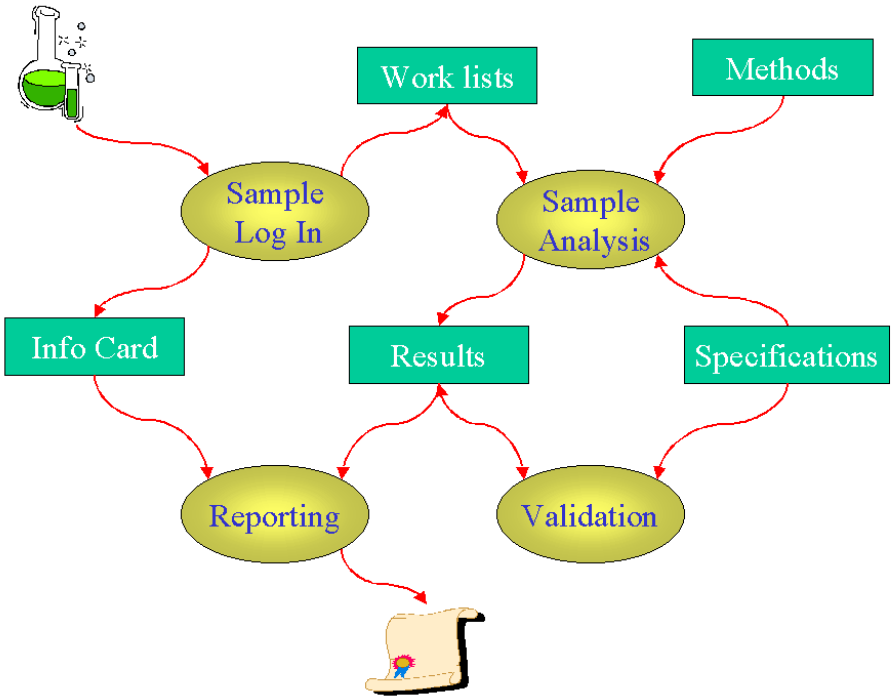
Unilab allows the user to classify products into different groups (for example, Raw Materials, In Process Products, Finished Goods, etc.). In addition, groups can be configured for suppliers and customers. For each group of products or sample type, the application manager can define which analyses need to be performed, how frequently they need to be performed, and which specifications apply for each parameter.

As soon as a sample is logged in, specific information such as the sampling location, sampling time, batch reference or lot number can be entered. This information is stored in the sample information card.

For each sample, parameters or analyses can be determined using different analysis methods. Related analyses (such as chemical or microbiological analyses) are grouped in parameter groups. The analysis method can be defined as a series of steps that have to be performed before the final result is calculated automatically.

As soon as the parameter result is known, it is checked against the specifications. If a result is out of specifications, the application manager can make several decisions: he/she may request that an additional analysis or re-analysis be performed, that the product be rejected, etc. Generally, the results that comply with the specifications are validated automatically, which enables the lab manager to focus on the exceptions (and leave the day-to-day routine to the system).

The figure below shows the workflow for a quality control lab.



As soon as all parameter results are known for a specific sample, a certificate or approval report can be generated and distributed automatically. The same data can be classified in reports by product type, by supplier name, or by another selection key chosen by the user.

1.3.2 Service Laboratories

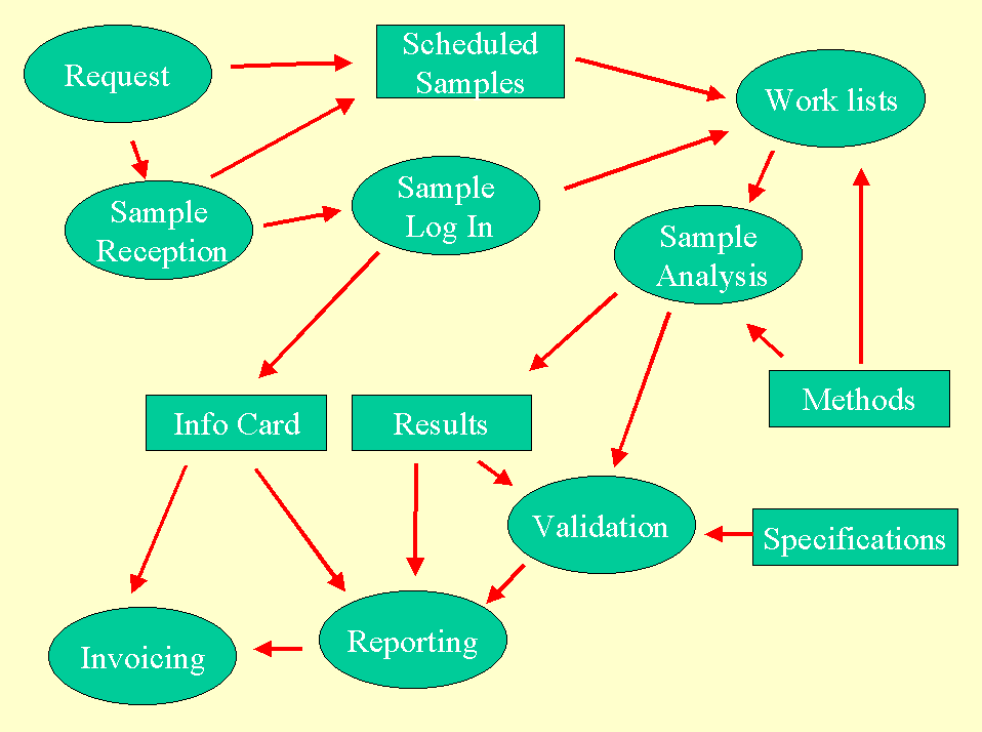
The day-to-day operation of service labs differs in various respects from that of Quality Control labs. Service labs typically provide services to customers on a commercial basis, or provide technical support to QC labs that belong to the same organization. They often perform tasks for the latter, such as supplier evaluation, product related R&D, complex or expensive analyses, etc.

Generally, analyses are carried out upon request. The request consists of a sample or a group of samples on which a set of analyses must be performed. When the samples are received, the required analyses are immediately assigned. Requests and/or samples can be scheduled according to the time when they are received, or priority, or turnaround time. The workload in this type of lab is variable.

Service labs apply a wide variety of test methods. Often, these methods must be compliant with regulatory rules such as GLP, EN45001, FDA and ISO.

When a parameter result is calculated or measured, the result is reviewed by an authorized person. If necessary, a re-analysis or an additional measurement is scheduled. Sample results that pass the validation obtain the Approved state. The approved results of a sample are reported to the client. If necessary, an invoice is issued for the work that was done.

The figure below shows the workflow for a service lab.



Cost control is often a major concern for service labs because they work on a competitive basis. The system only provides the basic data needed to make the invoice. Invoicing itself is not considered to be an essential part of the LIMS.

1.4 Types of Users

Actually, there are only a few types of users, but they perform several tasks during the day. Therefore, the identification of the different types of users should be considered from the perspective of the task(s) they perform in the LIMS.

The users are divided into five groups:

- People working in the lab and using the system
- People from the IS department (mainly for setup and technical configuration)
- People from production or other departments using (and providing) some of the information in the LIMS
- Information users, i.e. people who only request information from the system
- Instrument connections; these are not real users, but additional connections to the database that might be required.

Each user type is discussed in greater detail below.

1.4.1 Users Working in the Laboratory

Application Manager

The application manager is responsible for Unilab configuration when the LIMS implementation project is started and for maintenance of Unilab thereafter. His/her tasks include:

- The definition of all configuration objects (e.g. sample types, methods, etc.). Writing custom functions to enhance functionality (e.g. to implement specific calculations) may be required as well
- The setup of all user-related issues (definition of new users and user profiles, configuration of user applications).

The application manager assists other users faced with problems while using the system. He/she should have a thorough knowledge of the system's functionality, as well as a basic knowledge of the hardware and software at the system administration level.

The application manager acts as an intermediary between the LIMS software supplier and the laboratory staff. In most cases, the application manager also has a specific function in the lab (e.g. lab manager, first analyst, etc.).

From a technical point of view, the application manager should be able to access all applications and all data to carry out maintenance. Therefore, it isadvisable to use this user definition only when performing configuration and maintenance tasks, not when performing daily tasks in the lab.

Important

Other users will only be able to see the data they are allowed to view . Their access to the data is implemented by means of access rights configuration.

Lab Manager

The lab manager is responsible for the short- and long-term management of the laboratory and bears responsibility for the lab results. He/she defines the sample workflow and procedures in close collaboration with the QA manager. The lab manager makes the major decisions with respect to the configuration and use of the system. He/she should have a clear understanding of the concepts and the global functionality of the LIMS.

On the other hand, the lab manager only uses the system for:

- The validation of certain results and the release of samples (level 3)
- The viewing of results in the database. To achieve this, he/she will use reporting (mainly, survey reports and custom overviews) and launch ad-hoc queries.

For frequently-used reports, the lab manager may rely on reports generated by the analysts (on paper or in electronic form).

First Analyst

In large laboratories, often a first analyst is assigned to assist the lab manager with daily management. They offer operational management to the lab and staff:

- Work assignment and follow-up
- Decisions with respect to methods or instruments to be used
- Management of the analysts' capabilities
- Instrument maintenance
- Management of the configuration
- Validation of results and samples (level 2). Writing conclusions for a sample or for the analysis request may be required as well
- Distribution (and sometimes validation) of predefined reports (e.g. certificates).

The first analyst should be very familiar with the operational part of the LIMS. This knowledge will allow him/her to successfully perform his/her duties and assist analysts whenever needed.

Analysts

The analysts are responsible for:

- Sample login (and sometimes sample taking)
- Entry of analysis results (including level-1 validation). This may include the entry of information on info cards and remarks on the actual analysis
- Entry of calibration results and information
- Predefined reporting (e.g. printing of certificates).

Analysts who are allowed to use the system must have a clear understanding of the Microsoft Windows concept and the normal workflow procedures within the laboratory. They should also be trained to use those Unilab modules that are relevant to their tasks (including configuration-specific parts, if necessary).

Secretary

The secretary can provide administrative support to the laboratory by performing the following tasks:

- Login of samples and analysis requests that arrive at the desk. Most probably, the secretary will decide which sample type is to be used, provide the required information on the info card(s) and enter the parameters to be determined (if not predefined on sample type level). The first analyst will then have to detail the latter to specify which methods are to be used, and by whom
- Predefined reporting (mainly, printing and distributing the reports)
- Browsing through results (e.g. when an applicant calls to inquire after the status of his request, the secretary should be able to provide the requested information and perhaps send out a preliminary report)
- Invoicing or using other cost-calculation reports
- Entering parameter results received from external parties (e.g. from suppliers, external labs, etc.)
- Maintaining the address books of customers, suppliers, external labs, distribution lists, etc.

Secretaries who are allowed to use the system must have a clear understanding of the Microsoft Windows concept and of the normal workflow procedures within the laboratory. They should also be trained to use Unilab modules that are relevant for their tasks.

1.4.2 Information Services Department

System Manager

The system manager is responsible for the computer system and its software. He/she may be faced with hardware and software related requests such as:

- Adding or removing client personal computers, printers or other network equipment
- Installing additional software (word processors, spreadsheets, etc.) on the PCs

The system manager is also responsible for backup and archiving.

Generally, the system manager has an average knowledge of the LIMS functionality. If he/she is appointed to integrate the LIMS with other packages (e.g. ERP), this knowledge may be of use to him/her.

Database Administrator

The database administrator is the “owner” of the Unilab database. He/she is responsible for the different users' access rights to the database. The database administrator gives assistance during installation of the Unilab database, and provides maintenance in the following areas:

- Management of users
- Storage conditions of the database (e.g. optimal distribution across disks, avoid chaining, etc.)
- Archiving and backup procedures.

These tasks involve a close collaboration with the application manager and the system manager.

1.4.3 Other Departments

People from other departments, such as a quality-assurance manager or a production supervisor, may be interested in sample-related data. Generally, users of this type only have access to the validated results. The application manager can alter these access rights if necessary. Besides, some users from other departments will have to enter data in the LIMS in order to support the production process (e.g. entry of samples from quality checks on production material).

QA Manager

The QA manager will use the LIMS information to support QA management. He/she will therefore be able to:

- View results in the database by using reporting (mainly, survey reports and custom overviews) and by launching ad-hoc queries
- Browse through results of analysis requests and samples in read-only mode
- Manage sampling rules and sampling plans
- Approve the product release.

The QA manager bears full responsibility for the LIMS configuration data, together with the lab manager. Therefore, all changes concerning the configuration of the LIMS (such as adding new methods, parameter profiles, etc.) will have to be approved by this person formally or automatically. In addition, the QA manager consults the audit trails on all data stored by the LIMS when performing quality audits.

The QA manager should have a substantial knowledge of the concepts and the global functionality of the LIMS.

Production Supervisor

The production supervisor may be an important user of lab results. Typically, he/she wants to examine these results as soon as possible. The production supervisor should be able to:

- Browse through production-related sample data (preferably using production-related access keys, such as batch numbers or production lines)
- Run some (predefined) reports on available data.

The production supervisor should have a clear understanding of the data that he/she is using. Some training may be useful to facilitate browsing. An alternative approach consists of allowing him/her to consult the required information in another package (such as the production supervision system).

Production Operator

As more and more actual testing is performed in-line, people from the production floor frequently enter a number of results. Production operators should have a dedicated user interface at their disposal, which enables them to do exactly what they are allowed to do and performs the necessary checks on the data entered.

Reception of Goods

At the reception desk of raw materials, samples taken from raw materials are logged in immediately. The reception desk people will:

- Use sampling rules to determine the number (and amount) of samples to be taken
- Log in samples, enter the available information into info cards and print labels for the samples (later on, the analyses are often assigned automatically according to a previously-defined frequency).

1.4.4 Instrument Connections

Several instruments or other software packages may interact with the system in an automatic manner. Such interaction is implemented using client or database API functions or some batch programs processing ASCII files. These connections may perform tasks that are identical to those performed by other users and will thus require the full functionality of the system – although without user interface. For instance, they may change specifications, log in samples, enter parameter or method results, extract data, etc.

2 Main Functionality of SIMATIC IT Unilab

This chapter describes the scope and the main functionality of SIMATIC IT Unilab.

2.1 Scope of SIMATIC IT Unilab

SIMATIC IT Unilab aims at:

- Centralizing all available lab data
- Managing the sample workflow in the laboratory
- Performing reporting on the available information.

2.1.1 Centralizing Data

By centralizing all available lab data, Unilab is able to support:

- Information retrieval on samples and analysis requests
- Day-to-day task organization (by means of worklists)
- Management of standard operating procedures (SOPs)
- Management of quality records and audit trails
- Retrieval of historical data
- Management of specifications and use of a product repository
- Reporting.

Samples and analysis requests

Unilab provides information on the samples and analysis requests that have been logged in. At any time, information can be retrieved concerning the status of samples in the laboratory and the number of analyses that still have to be performed on these samples.

Worklists

When a sample is logged in, the analyses to be performed on that sample are automatically distributed to the appropriate worklists.

Unilab provides the necessary tools for a more flexible, day-to-day management of the laboratory. It allows the lab manager to allocate resources such as personnel and/or equipment. At any time, the lab manager can obtain the latest information on progress and status of the work performed. The workload per analyst or per equipment as well as the number of samples processed in the lab can be instantly consulted. If required, resources can be relocated to eliminate bottlenecks and delays in the laboratory workflow.

Standard operating procedures

Quality regulations such as ISO 9001 require the presence of a documented system of procedures and instructions and an effective implementation of such procedures. GLP requires the same, but applies the concept of Standard Operating Procedures (SOPs).

Unilab satisfies these requirements in two ways:

- It permits the automation of routine procedures
- It provides an easily-accessible link to documents, which describe the procedures and operating instructions.

The documents describing how to execute a procedure can be made accessible on-line within Unilab. The documents themselves, files edited by means of a word processor or text editor, are stored on a file server. They are available on-line in electronic format and can be consulted by the analysts whenever needed. New document versions can instantly be made accessible to all personnel by replacing the old version with the new one on the file server.

Unilab does even more. Routine laboratory procedures can be automated by customizing the life cycle of the appropriate object. For example, the formal procedure to handle samples of a specific sample type is defined by means of a specific life cycle. The same principle applies to method handling. The system guides the analyst through the procedure. Unless all previous steps have been carried out successfully, the analyst cannot perform the next step. When this approach is used, all steps in the procedure are necessarily performed in the correct order. No step can be skipped. The input of mandatory data can be guaranteed by using electronic forms for data or result entry. The input is checked by automatic validation functions.

Quality records and audit trails

The audit trail allows tracking of all changes to the database. An audit trail is necessary for good quality-assurance practices, as regulatory and quality standards require that any laboratory maintain audit trails for automated systems. These standards specify what information must be kept for all data changes:

- The nature of the changes (what)
- Date and time of the modification or timestamp (when)
- Identification of the individual who modified the data (who)
- Reason why the changes were introduced (why).

Historical data

The Unilab database of is a valuable source of historical data because it keeps track of all analyses performed in the laboratory. Historical data may be available on-line, or it may have to be retrieved from archived files.

Specifications and product repository

An important step in the validation of lab results is the check against the parameter specifications. In a QC laboratory, this check is performed to ensure that the manufactured products have the required properties or that the manufacturing process is still running within the specified limits.

Which application defines the specifications largely depends on the MES context. In service laboratories, the specifications are often managed by the LIMS; in large manufacturing organizations, by the MES or ERP systems. The latter use a product repository, i.e. a central database in which all specifications for the different products are kept.

Reporting

In the laboratory, both routine reports and ad-hoc reports are created.

Routine reports include reports for both external use, such as COA (certificates of analysis) and reports for internal use such as reports on the workload. For the generation of routine reports, such as analysis certificates, the lab manager defines a number of standard reports that are used by the analysts. The standard reports are stored in a central repository. The analyst simply retrieves the desired report from the repository and refreshes it for the required information.

Ad-hoc reports are custom reports that answer specific information requests. A user can retrieve the required information from the database at any time to find an answer to specific questions.

2.1.2 Managing the Workflow

Since all laboratory information is centrally stored, Unilab can be used to manage the workflow in the laboratory.

Unilab manages the different steps in the workflow by means of the life cycle concept. For each step in the life cycle, the lab manager can specify who is authorized to execute that step. Automatic actions can be triggered upon specific life cycle transitions.

2.1.3 Interfacing with Other (Sub)systems

Invoicing is not considered to be a prime function of a LIMS. Although a LIMS can keep information on cost, effort and duration of certain analyses, the invoicing itself is often managed by ERP systems, which have been interfaced with the LIMS. The cost related information kept in the database of a LIMS is primarily used as input for flexible day-to-day management of the laboratory.

The inventory of all chemicals used in the laboratory and the evolution of the stock of consumables are managed by specialized systems.

Human resources information, such as personnel scheduling, training records, holiday management, etc. is managed by specialized systems at the enterprise level.

These (sub)systems may be integrated with Unilab through different interfaces.

The following interfaces are available:

- A database interface. External systems can access a Unilab database, select views or call any database function.
- An XML interface. No connection is needed; systems exchange XML files with each other.
- A certified SAP/QM interface.
- A COM interface.

- A Web service.

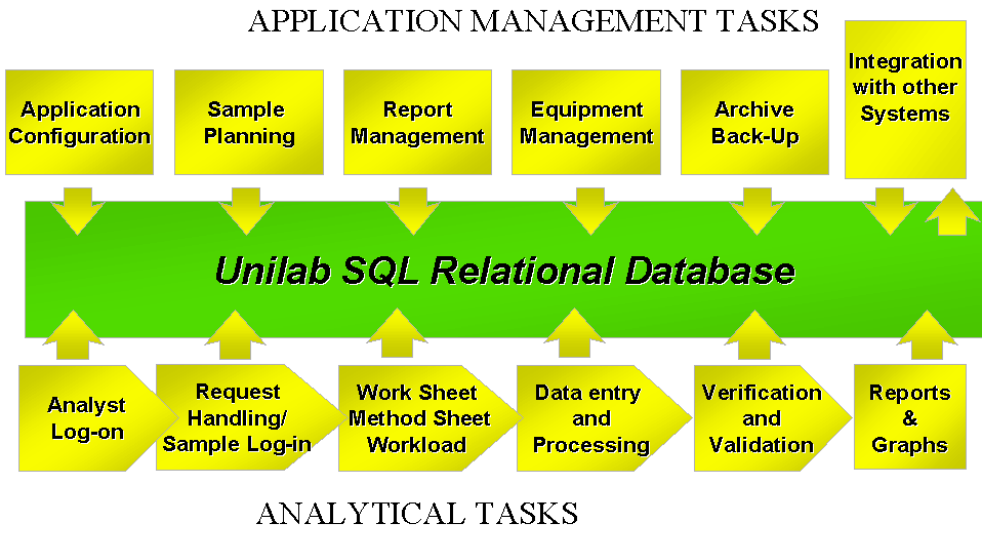
For more information on interfaces, please refer to Concepts and Use > Interfaces manuals in the Product Library.

2.2 Functional Overview

Many people with different skills and interests use Unilab. However, two main categories of tasks can be distinguished:

- Analytical tasks: the daily work performed by analysts in the laboratory
- Application management tasks: the configuration and maintenance of the knowledge present in the laboratory (test plans, sample types, etc.) in Unilab.

The figure below shows an overview of the Unilab functionality.



2.2.1 Analytical Tasks

Log on by analyst

Whenever a user launches a Unilab application, they must identify themselves by means of a user identifier (ID) and a password. This information is used by the system to determine the user's access rights to the system's resources at two levels:

- The functional level: which applications the user can use and which functions are accessible to that user within these applications
- The data level: which data the user is allowed to consult or modify.

The identification of the analyst by means of a user ID and password is a security-related issue. It minimizes inadvertent changes to data and helps to prevent data sabotage. Moreover, it helps to validate lab data, since the user ID will be recorded in the audit trail to identify the person who entered or modified the data.

Handling of analysis requests / sample login

The main task of a laboratory is to handle analysis requests. If an analysis request concerns just one sample, it can be handled by standard sample management functions. However, there are quite a number of situations where one analysis request consists of several samples. In such situations, Unilab maintains an easily- and quickly-accessible link between these samples. Handling the reception of sample packages is a typical example of analysis requests.

The sample or request login can be done in two ways:

- Automatically, according to a fixed sampling plan
- Manually, by the analyst.

The system generates a unique code for each request and sample. Together with this code, the info card can store additional information such as the name of the supplier, the date and place of sampling and the sample storage conditions.

Because a sample is linked to a product or location, it is possible to draw up a test plan. This means that the appropriate analyses are scheduled when the sample is logged in. Ad-hoc analyses can be added during sample login, or even later when the analyses have already started.

Worklist management / Workload

When new samples are logged in, Unilab uses its configuration information to assign the appropriate tests to the appropriate worklists. A worklist displays the workload for the individual analysts, for a shift, for a specific method, for an instrument, etc.

From the analyst's standpoint, worklists are available on-line as data entry screens. For the lab manager, worklists are the perfect tools to extract workload details and re-assign lab resources, if required.

Data entry and processing

Different kinds of information are entered into Unilab.

- Data not related to the analyses

  When a request or sample is logged in, descriptive information about the sample can be captured and entered into the info card. This information is often alphanumeric or date-related. Examples of descriptive data include information on sampling conditions (sampling date, location, supplier, etc), sample storage conditions (location, container, etc), or analysis-related issues (responsible analyst, intended customer, etc). Information can also be entered after the analysis has been completed and may include conclusions or comments about the analyses.

- Analyses-related data

  A second category of data is all data originating from the actual analyses. Typically, this data is entered as raw data; then it is processed to obtain the final analysis results. Raw data can be entered either manually via the keyboard or directly by using data-acquisition software interfaced with lab instruments. Unilab can automatically perform calculations to obtain the final analysis results. To achieve this, formulas are stored for each test method. Automatic calculations reduce mathematical mistakes and data-transcription errors.

Verification and validation

Verification of results means that the results are checked against physical constraints. For instance, the pH result must have a value between 0 and 14; a percentage cannot be higher than 100. The analyst is notified whenever the value entered does not fall within the applicable limits. Verification helps to prevent typing errors.

Validation of results means that the results are checked against different types of specifications and/or limits. The specifications may have been set internally (by the company, the laboratory, etc.) or externally (by customers, by law, etc.).

Depending on the result of the checks performed, analysis results are validated or not. The exact procedure of validating results and the release of individual analysis results, samples, products, analysis requests, etc. largely depends on the specific organization of the lab (and the related departments).

Reports and graphs

Unilab includes an integrated report/graph generation capability.

Daily reports, certificates of analysis, control graphs, statistical process control (SPC) graphs and sample analysis results are easily accessible to the relevant departments via the network.

To build ad-hoc reports, the user can access the Unilab database in a user-friendly manner. A semantic layer, called the universe, provides a laboratory presentation of the data contained in the database. The user retrieves the desired data by sample drag-and-drop without requiring knowledge about the database structure or data-retrieval languages, such as SQL.

Unilab provides statistical quality control (SQC) graphs for assessing the quality of the laboratory or the production line. More advanced statistics can be handled by interfacing the system with specialized packages such as Statistica, SPSS or SAS.

2.2.2 Application Management Tasks

Configuration

Unilab must be customized in order to meet the specific needs of the laboratory. All sample types, specifications, parameters, methods, info cards, and equipment must be defined in the system. The laboratory workflow and the different lab procedures must also be set up. Customization implies that the system can be adjusted without having to modify the standard software itself. This guarantees that customers benefit from functional enhancements in future releases.

As a configurable LIMS, Unilab provides all the functions required tailoring the system to the laboratory's specific environment. If trained properly, the customer is able to perform 80 % of the customization on his/her own, independent of any vendor services. Moreover, the customer can perform updates on a regular basis to keep up with changing situations in the laboratory.

Configurable and flexible as they may be, marketed LIMS systems such as Unilab may not cover all the needs of a specific laboratory. Some of these needs may have to be implemented by means of custom functions: PL/SQL (on the server side) or Visual C++ (on the client side) functions developed by the vendor or by IT staff at the customer's side to include special requirements in the LIMS. Examples of such special requirements are: complex calculations, laboratory-specific data validation, alarm handling, special conditions or actions associated with the different object life cycles, etc.

In some cases, the required functionality calls for the implementation of an entirely new application (= add-on application).

Sample Planning

Samples of a specific type may arrive in the laboratory on a regular basis. For example, in a manufacturing environment, a sample may be taken on the production line every hour. A supplier may deliver a batch of raw material once a week. A waste water sample may be collected twice a day. Such samples, and all the analyses that should be performed on them, can easily be scheduled by means of a sample-planning module.

Report Management

For routine reporting, the lab manager defines a number of standard reports that are used by analysts in the laboratory. Routine reports are stored in a central repository. The lab manager can define access rights for each report, defining who is authorized to use it and who is not.

Routine reports can also be generated automatically. The certificates of analysis (COA), for instance, ought to prove to the customer that the produced goods meet the specifications. They are generated automatically after all the analyses on a sample have been performed and approved. Other reports, such as periodic overviews, are scheduled with a specific frequency. They are generated automatically once the scheduled period has elapsed. Report distribution rules can be defined, indicating to whom a copy of the report must be sent in case of automatic generation and distribution.

Define Equipment

Analytical instruments play an essential part in modern laboratories. For the equipment used within and outside the laboratory, certain information must be maintained to comply with (international) quality standards. Equipment calibration and maintenance rules must be managed as well.

Unilab provides tools to manage the various interventions that must be performed on equipment. All intervention rules are monitored automatically; their triggering can be either time-based or usage count-based.

The user can also schedule reference samples or tests to verify the equipment is still operating correctly, regardless of the intervention frequency. Such an action may result in an immediate intervention (for instance a (re)-calibration).

The traceability of instrument interventions is very important with respect to data validation. Trends of intervention results provide valuable information to evaluate the functioning of the equipment. The same goes for equipment constants. This is why all intervention results are kept for easy trending and SPC/SQC.

Archiving and Backup

On-line laboratory data is stored on disk and can be retrieved almost immediately. As the capacity of the disk(s) is limited, some data (usually the oldest data) is archived on tape (or any other backup medium) and removed from the disk to free space for new laboratory data. Data that is copied and removed from the disk is called archived data.

Data that that is not frequently accessed for analyses or reporting should be archived. Archived data can be stored in a separate database or in a file, and can be restored at any time (provided that there is sufficient free disk space available; otherwise it may be necessary to archive another data set first).

The purpose of a backup is to have a safety copy of the data, which can be restored in case the hardware (disk) fails. Backup procedures must be run on a routine and frequent schedule.

Note that the Unilab archiving and backup procedures need to be integrated into global company archiving and backup policies.

Integration with other systems

In modern laboratories, LIMS is ever-more integrated with external systems. These external systems include both analytical instruments used in the laboratory, as well as other software packages that need to interface with Unilab. Unilab provides a standard solution for integrating with other systems.

Logical versus physical connection

Many instruments are connected to Unilab and send their analysis results directly to the LIMS. The primary requirement for establishing a successful communication between Unilab and an analytical device is the setup of a physical connection for the exchange of data.

However, an analytical instrument does not need to be physically connected to Unilab in order to trace where the analysis results came from. Unilab can also maintain a logical link between the analysis result and the equipment used to obtain that result. The analyst should specify this logical link to the equipment when entering the analysis results manually. This information can then be used for auditing purposes.

Connecting other systems through Unilink and Uniconnect

Depending on the external system, there are two ways to capture the raw data. Some external systems provide data files (ASCII files) that can be picked up by Unilab. Other systems however are connected through serial port(s) on the local client. In the case of connections through serial ports, a data logger generates a raw data file. All obtained raw data files are then picked up and saved in a standardized format. The UNICONNECT module performs the capture and standardization of data coming from the external system. After the captured data has been saved in a standardized format, UNILINK processes the data and inserts it into the appropriate tables of the Unilab database.

2.2.3 User Management and Security

In a laboratory, many different types of users work with Unilab. Each user is allowed to use only a part of the Unilab functionality. Likewise, each user is allowed to access or modify only a subset of the data stored in the Unilab database. On top of that, Unilab must behave in such a manner that each user can execute the tasks he/she has to perform in an efficient way.

In Unilab, functional access rights and system behaviour are implemented through user profiles. Data access is mainly implemented by means of data domains.

Data domains

The data access rights for the individual entries in Unilab are controlled through maximum 128 independent working areas called data domains. Within each data domain, it is specified for each individual object whether the users have write, read or no access.

User profiles

A user profile groups a number of users with the same functional and data access rights. Unilab allows defining an unlimited number of user profiles. Each Unilab user can belong to one or more user profiles. The user profile to which a user determines:

- The applications a user can use and the functionality at his/her disposal within that application (functional access rights)
- The data a user is allowed to access or modify (by linking the user profile to a data domain)
- The tools a user has at his/her disposal to select the set of data necessary during the execution of a specific task
- The preferences and settings that control Unilab behaviour.

3 SIMATIC IT Unilab Architecture

This chapter introduces the main SIMATIC IT Unilab applications. It also provides a summary of the client/server architecture and explains how data security is implemented.

3.1 SIMATIC IT Unilab Applications

SIMATIC IT Unilab includes two types of applications:

- The operational applications are used by the analysts in the laboratory in support of their analytical tasks.
- The configuration applications are used by the application manager in support of the application management tasks.

3.1.1 Operational Applications

Analyzer

Unilab includes one major operational application: the **Analyzer** application. The analyzer application manages sample lists, request lists, worklists, worksheet lists and stability studies.

An outlookbar lists all available tasks for a user. All tasks of the same task type are grouped in the same outlookbar page. By default, outlookbar pages are available for:

- Sample list
- Sample creation
- Request list
- Request creation
- Method list (worklist)
- Worksheet list

The outlookbar pages and tasks available for each user are controlled through functional access rights. Depending on the selected task, the appropriate objects list is opened.

Sample management is handled through sample list and sample creation tasks. The login of individual samples is performed using sample creation tasks. Sample list tasks provide the user with a list of samples in accordance with his/her group key selection. For the selected samples, the user can process results and info cards per sample. In addition, it allows all the other actions that may have to be performed on the samples: assigning additional analyses, validating results manually, cancelling analyses or samples, and requesting re-analyses.

Request management is handled through request creation and request list tasks. The login of requests is performed by selecting a request creation task. When a request is logged in, a matrix can be provided for selection of the tests to be performed on the individual samples within the request. Administrative details with respect to the requests can be filled out on the corresponding info cards. A data-entry screen is available for bulk entry of analysis results.

Worklist management is handled through method tasks. On the basis of the analyses assigned to the samples and requests that have been logged in, worklists are generated per analyst, equipment, method, etc. The worklists can be consulted and used on-line as data entry screens by selecting a worklist task (method list). For individual samples, the same functionality is available as in a sample list task.

Worksheet tasks provide functionality to deal with info fields and methods of samples in a more direct way. A worksheet presents info fields and methods of samples in a cross tab way. Unlike the other Unilab tasks, worksheet tasks combine the configuration and the operational part: worksheet types and operational worksheets can be created and used within the same application. The system is setup is such a way because the configuration of a worksheet type is considered to be dynamic.

Define Equipment

The **Define Equipment** application allows laboratory personnel to manage the analytical instruments used in the laboratory. **Define Equipment** includes the definition of new equipment, the management of the information required for regulatory compliance and the definition of equipment constants. In addition, the application keeps track of calibration and maintenance rules and their logging. However, most of the actual functionality is implemented on the operational side of Unilab (in the **Analyzer** application), where the defined rules actually apply.

In the operational module, the user can:

- Select the equipment used to execute a method
- Consult the status of equipment
- Enter intervention results
- View intervention details
- Validate or invalidate an intervention manually
- Start a scheduled intervention immediately.

3.1.2 Configuration Applications

Two building blocks represent the applications used for system configuration (the application management tasks):

- The first one includes the main configuration applications, used to define the main objects of Unilab. The applications of this type are used on a regular basis to maintain system configuration
- The second one includes the applications used to define additional objects, keys, life cycles, layouts and addresses. The applications of this type are intensively used during the initial setup of Unilab, but less afterwards.

Main Configuration Application

The main configuration application include **Request Type Definition, Sample Type Definition** and **Stability Protocol Definition.**

In the **Request Type Definition** application, request types are defined and the appropriate sample types, info profiles and parameter profiles are assigned to them.

The **Sample Type Definition** application is used to manage individual sample types and allows a number of additional functions to be performed simultaneously on groups of sample types (previously selected by the user).

In addition, the main configuration application is used to define the other main objects of Unilab (parameter profiles, parameters, methods, info profiles, info fields and attributes) and to assign info profiles and/or parameter profiles to sample types / request types.

User Profile Definition and Task Definition

The **User Profile Definition** application is used to manage the different users and user profiles. Functional access rights, system preferences and a task list are defined per user profile. The tasks themselves are defined in the **Task Definition** application.

Additional Configuration Applications

The additional configuration applications are **Life Cycle Definition, Group Key Definition, Layout Definition** and **Address Definition**.

The **Life Cycle Definition** application is used to define life cycles. From the **Life Cycle Definition** application.

The group keys defined in the **Group Key Definition** application can be used for task definition.

For each table window inside Unilab, it can be defined what columns must be displayed and in what order the data in the tables is sorted. All of this is defined by means of a layout definition in the **Layout Definition** application.

The creation of a new user in the **User Profile Definition** application corresponds to the creation of a new address. When a new user is created, the **Address Definition** application is called. The **Address Definition** application is used to manage the different addresses, including the Unilab users themselves.

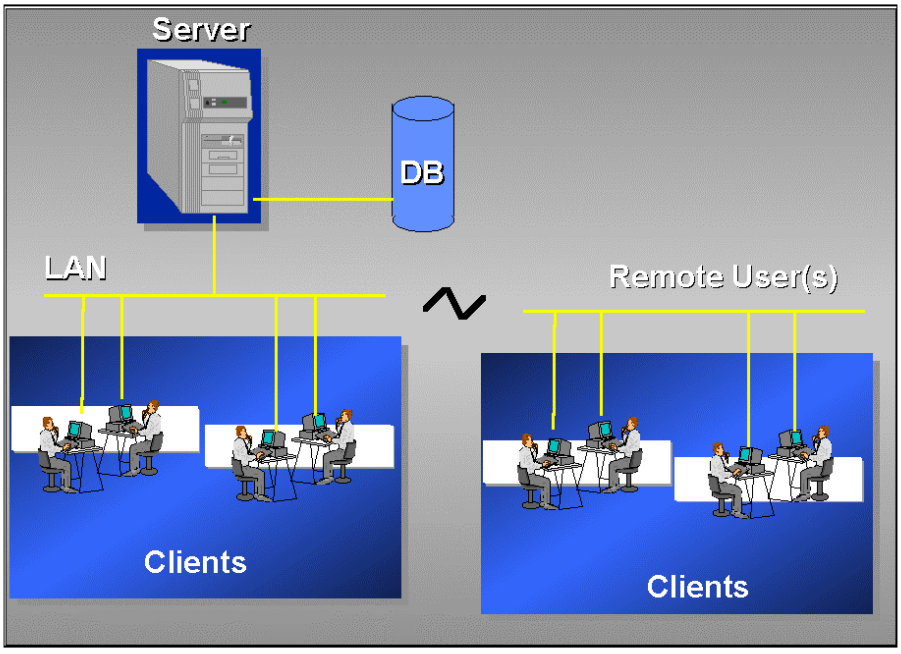
3.1.3 Applications Running in Background

The **Event Manager** is an application that runs in the background and handles all the events in the Unilab database. It consists of a server part (which does most of the work) and a client part (which handles functions that cannot be executed within the database context).

3.2 Client-Server Model

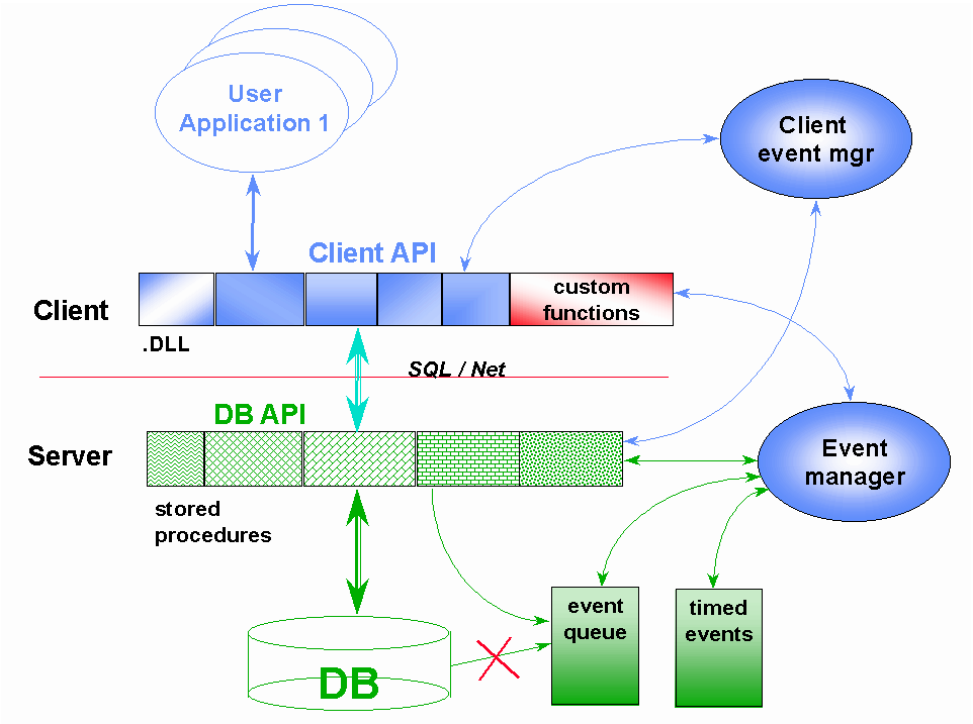
Unilab is a true client-server solution, allowing users on different sites to share the data available in the (server) database.

The figure below illustrates the client-server architecture of Unilab.



The system logic of Unilab is split into a client part and a server part. The applications themselves run on the client side. On the server, Unilab data is stored in an **Oracle** relational database. All database logic runs on the server side.

The figure below shows the client-server model for Unilab.



Client APIs

On the client side, Unilab functionality is accessed through client API (Application Programming Interfaces); these contain all the common functions, which may require user interaction. Client APIs are implemented by means of dynamic link libraries (DLLs).

DB APIs

The data in the database is accessed through DB APIs (Database Application Programming Interfaces). The DB APIs are a set of stored procedures that define all possible transactions on the data model, implementing the main functionality of Unilab.

Traffic on the network is kept as low as possible by using data arrays in the APIs. In this manner, data is grouped or pre-processed before it is actually transmitted over the network.

Besides performing the necessary updates in the database, the APIs also generate events. These events are primarily used to trigger life cycle evaluation and the evaluation of certain assignment rules (such as the group key assignment rules). On the server side, these events are entered into an event queue (table) and processed by the event manager (s). An event manager is a server-independent database job, which reads and processes events in the event queue. Multiple event managers may run on the same server, allowing faster (= parallel) processing of events.

It is not possible to call any client program logic from the database event manager. This is required, for instance, to trigger label printing functions, or execute Microsoft Windows commands. To deal with such operations, the client event manager has been introduced. In case client program logic needs to be executed, the database event manager sends an alert to the client event manager.

3.3 Security

Unilab has the ability to support various laboratories. Using a single database on one system, it can support a number of production labs, as well as a central lab. In a multilab environment, strict control of the data access rights is imperative.

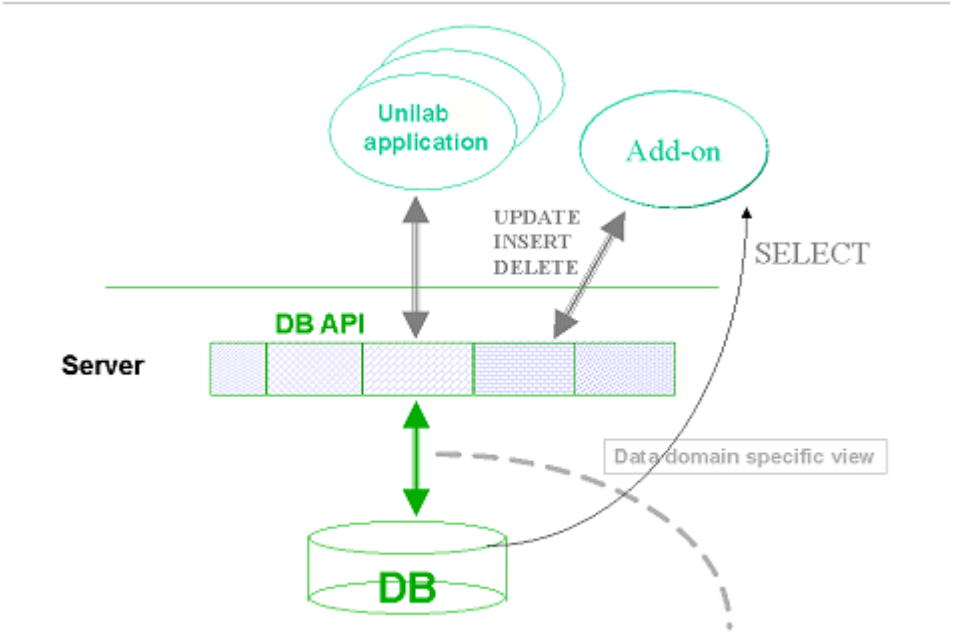
3.3.1 Data access rights

Accessing the database using Unilab

Data access rights to the individual objects are implemented by means of data domains (maximum 128 data domains). Each user profile is explicitly linked to one data domain. In this manner, the individual users get the data access rights from the data domain linked to their current user profile.

The DB APIs involved in data selection directly access the tables in the database. They implement the access rights by accessing the data through data domain specific views. Views exclude all rows for which the access rights of a specific data domain are set to `None`. This mechanism, combined with the fact that updates on the database must always be performed by means of DB APIs, guarantees consistency in both read and write access to the data.

The figure below shows how to access the data stored in the database through data domain views.



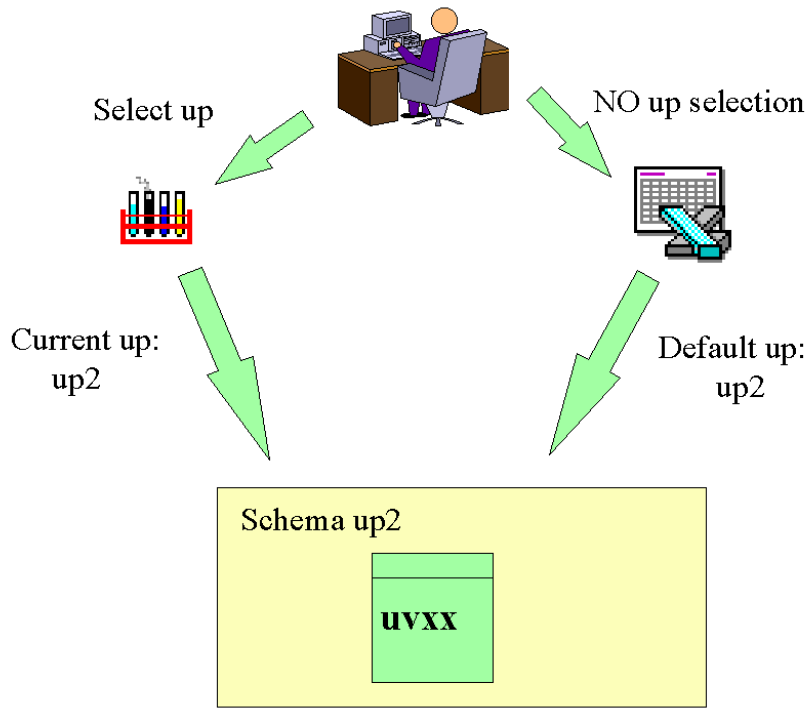
The DB APIs themselves always access the database with DBA privileges. The DBA is always granted access to any object in the database.

Accessing the database using an external application

When a user accesses the Unilab database through a Unilab application, a user profile is selected. As a consequence, the user then gets the data access rights of the data domain linked to the selected user profile.

However, when a user logs on to the Unilab database using an external application, such as TOAD or BusinessObjects, no user profile is selected. The user will then always get the data access rights of the data domain linked to its default user profile.

The figure below shows how to access data through external applications.



When a user accesses the database using an external application, he/she cannot switch to another user profile. As a consequence, a user will only be able to access the data through the views for the data domain linked to its default user profile.

3.3.2 Multiple users working on the same data

The DB APIs also guarantee consistency in case multiple users are working on the same data. When data is extracted from the database, a local copy is made on the client PC. No locks on the database are used to secure the data, which means that multiple users can work on the same data set simultaneously.

When a user saves data to the database, the necessary tables in the database are updated and the events associated with this action will be processed. All updates on the database are considered as transactions. Once the transaction has been started, no one can interfere with it. If a second user tries to update the same set of data while a transaction is being processed, he/she will get the message that the data is in transition. That user will only be able to save the data once the ongoing transaction is finished (and provided that the data set is still modifiable after processing of the previous transaction).

If another user tries to modify the same data set, he/she receives a message that informs him about the new situation. If the data can no longer be modified, he/she can only refresh the data set on their client PC.

3.3.3 Custom Functions and Add-on Applications

It must be prevented that custom functions and customer-specific add-on applications corrupt the referential integrity of the Unilab database.

Since the DB APIs play a very important role in keeping the database consistent, implementing data access rights and triggering life cycle evaluations, all database interactions must be carried out by means of DB APIs. This implies that custom functions and custom applications (add-on applications) are only allowed to interact with the Unilab database by calling the appropriate APIs.