

**The integrative
Laboratory
Information
and
Management
System**

jwLIMS

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Perspective

The jwLIMS is a laboratory information management system that was specially designed for the process industry (chemical industry, pharmaceutical industry and food industry) in the SAP R/3™ environment. The most important aspect of its development was to meet all demands a company from one of the above-mentioned industries makes on such a system.

As a basic principle the jwLIMS is implemented without modification of the SAP R/3 standard code and it has proven to survive release upgrades, thereby guaranteeing our customers a secure investment. The jwLIMS was implemented as an add-on using only the SAP R/3 workbench and no other interface. The jwLIMS is distinguished by remarkably high flexibility.

This makes it possible to fast and cost-effectively adjust the LIMS to the special requirements of the particular customer. Thus, the company has the opportunity to standardize heterogeneous system environments and to integrate the entire area of quality assurance (QA) and quality management (QM) including the bidirectional traceability into the existing SAP R/3 or the one which still needs to be established.

Effect

Such a method brings clear advantages in different categories:

Costs:

- no additional software licenses for SAP R/3 external LIMS
- no additional hardware platforms and therefore
- lower maintenance costs
- lower effort for necessary data backup
- higher reliability
- no interfaces between vitally important programs in the logistic chain of the company
- reduction of necessary employee training

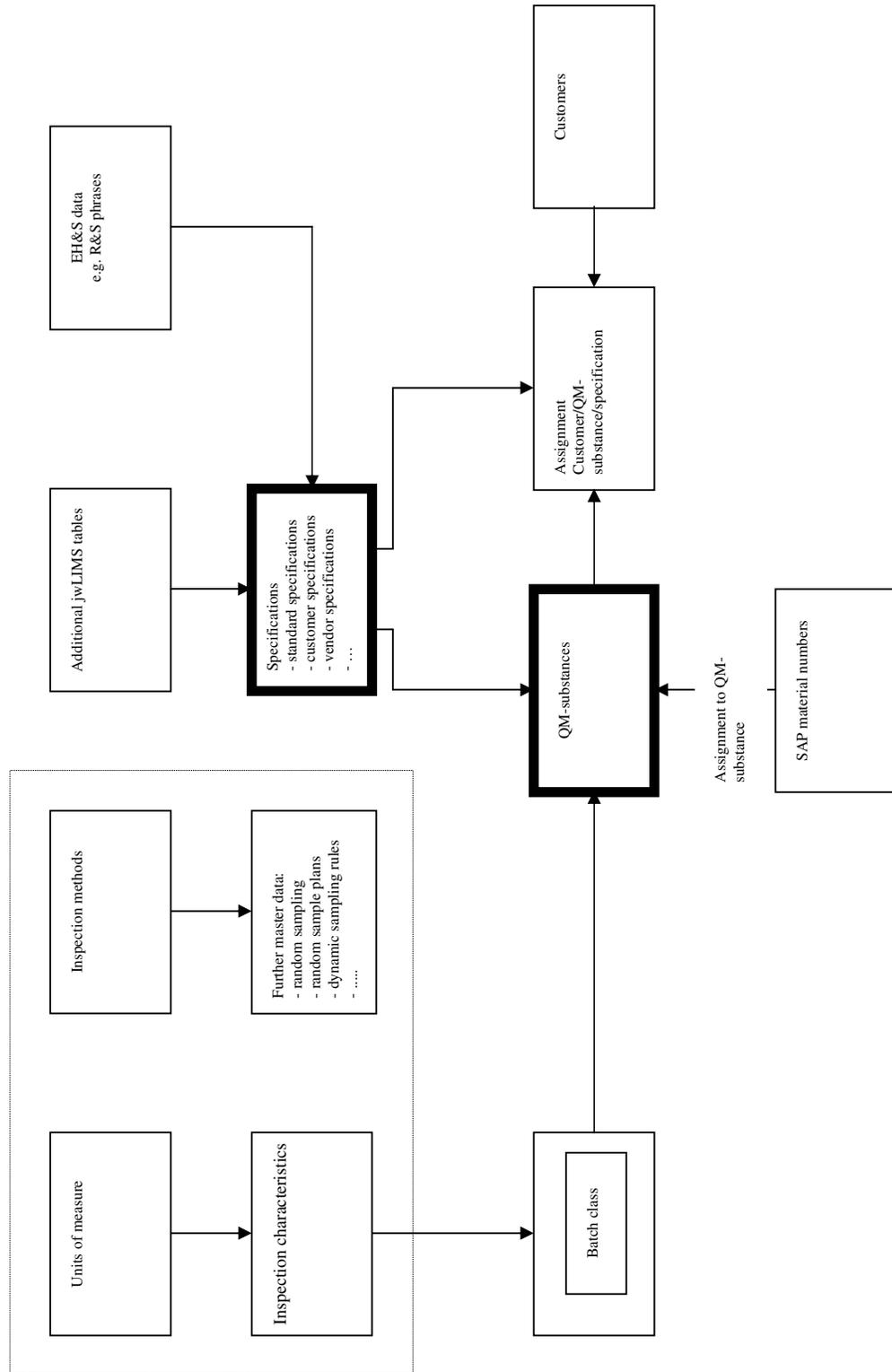
Handling:

- all employees in a laboratory or all laboratories work with a single system.
- the results of all inspections are acquired in one system.
- clear reduction of training costs

Data:

- all inspection data, starting with research & development up to final inspection of the product, is in one data bank, together with all logistic data of the company.
- thus, the smooth and complete data exchange and exchange of information between the different departments as well as a complete data analysis and statistic are as easy and fast as they are cost-effective

jwLIMS master data concept



The jwLIMS is adapted to the requirements of all departments concerning QA and QM. Here are some of its functions:

Logistics department:

- incoming goods inspections
- in-process inspections
- retests
- final inspections of products
- logistics special samples (unplanned)

Further inspections

- research & development inspections
- environmental analysis
- management of test instruments / calibration
- competitor's samples inspections

Integration

Specification management

The jwLIMS makes it possible to uniformly define central master data worldwide, e.g. inspection methods or specifications, and to manage this data centrally or decentrally. The user can deposit a deliberate number of specifications for a product. For example, standard specifications (internal specifications) and customer specifications (external specifications) for finished products. This makes it possible to arrange external specifications with vendors and customers, but to flexibly adjust the particular inspection effort.

These specifications are managed in the system, they can be printed out or send to customers or vendors in a PDF-file if required. Customers or customer groups can be assigned to the individual specifications. Thus, a customer's special quality requirements for a particular product are deposited in the system.

The usage decision always includes the inspection of the batch qualification against all valid specifications. The entire information is transferred to logistics. When the order is registered a specification-related availability check can be carried out and a suitable batch can be determined automatically in the delivery.

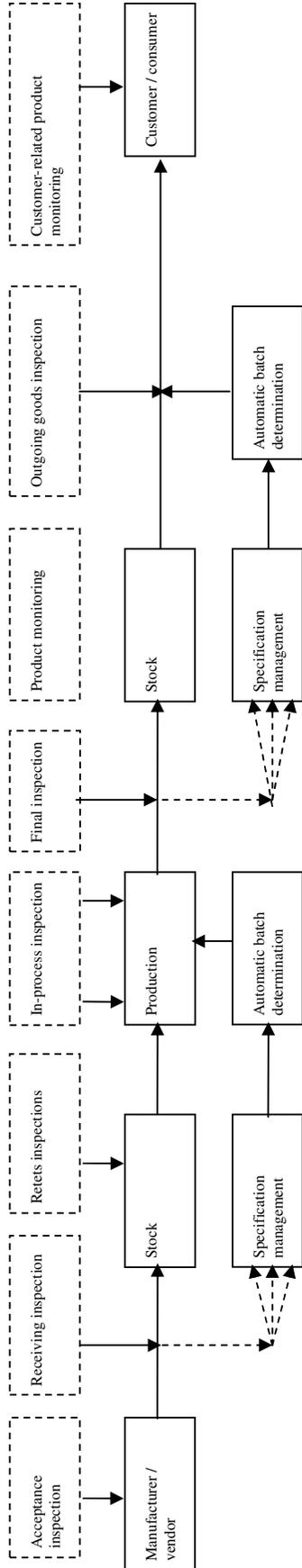
Multidimensional usage decision

The jwLIMS enables a usage decision on three levels

1. **Stock type**, i.e. the batch goes from the quality inspection stock e.g. into the free or blocked stock
2. **Specification**, i.e. even if the batch was registered in the free stock, it is only salable for the released specifications.
3. **Customers**: On this level batches can be released or blocked for particular customers. Thus, batches that are intended for a particular customer according to an arrangement can be reserved.

All releases and blockings are inspected thoroughly by the system during the sales processing. This makes it impossible to sell batches to customers that are not in accordance with the desired specifications. - We call this "protection of the specification-related delivery" by the LIMS.

jwLIMS Integration into logistics

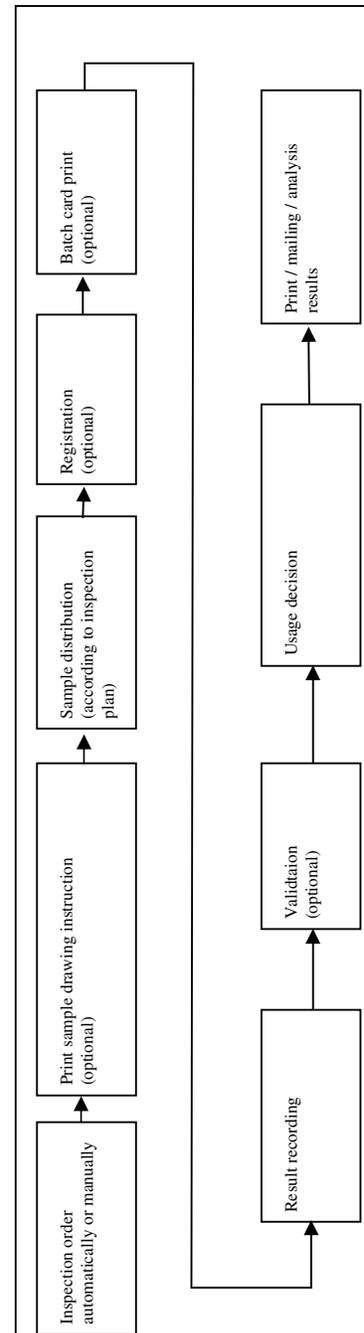


Upstream	Batch tracing Internal	Downstream
Vendor complaints (vendor assessment)	Complaints management Internal problem reports	Customer complaints
iwLIMS modules	Reporting / statistics	
	3-dimensional usage decision	
	Result recording	
	Central working stock for all inspections	
	Order sample management	
	Inspection planning incl. automatic periodic planning	
	Specification management for n-specifications for each single material	
	QM master data	

Process flow

Batch traceability

- **Internal, for processing and internal distribution**
 - Specification management
 - Internal specifications
 - Customer specifications
 - Incoming goods inspections
 - Internal batch traceability for production
 - Internal complaints management
- **Upstream, toward manufacturers, vendors incl. forwarders**
 - Specification management to vendor and/or manufacturer
 - Acquisition of data from dispatch inspection of the vendor / manufacturer
 - Complaints management
 - Vendor assessment
 - Handling of vendor audits
 - Management of certification data
 - Incoming goods inspection
 - Carrying of the vendor batch numbers
 - Carrying of further specification characteristics of batches
- **Downstream, toward downstream manufacturer, consumers incl. forwarders**
 - Customer-related product monitoring
 - (automatical) determination of relevant deliveries and rearrangements in subsequent batch blockings
 - Customer complaints
 - **Complete determination of stock and processing data**
 - **Targeted application limitation/batch blockings**
 - **Targeted returns pick-up from customer**
 - **Sanctions against vendors / forwarders**
 - **Fast access to data**
 - **Evaluation and statistics functionalities**



Peripheral

Further functions

- Implementation of several organisation levels in the laboratory
- Inspections distributed among several laboratories and plants incl. flexible handover of inspection orders
- Management of third-party passed inspections

- Optional sample registration for each laboratory with:
 - Skip-Option for particular characteristics
 - Extension of the inspection scope by additional characteristics or specifications
- Optional, variable validation of results and samples for each laboratory / employee
- Parallel acquisition of own measure data and/or data from vendor certifications
- Automatic certification print out
- Adjustment of current stock of a material in case of specification changes
- Dynamic modification of the inspection scope
- Automatic, periodic inspection creation for IPC, testing instruments and environmental inspections
- Automatic detailed settlement of inspection costs
 - Time based for internal customers
 - Order based for external customers
- Own special sample module
 - Easy and flexible creation of inspection orders
 - Multidimensional result acquisition (values, reports, specs, ...)
 - Easy management of all non-SAP materials, such as auxiliary substances and reagents
 - In case of unplanned samples all inspection parameters are modifiable until result registration
 - Free combination of the inspection scope in case of unplanned samples from all inspection plans and / or specifications

In addition, the jwLIMS enables a so-called product monitoring. Product batches, which are subject to, this monitoring, are automatically and periodically registered for monitoring inspections over a defined period. Period, interval and inspection scope are flexible.

This functionality is also available with customer relation. The monitoring inspection depends on each delivery of a batch to a given customer.

This provides the opportunity, e.g. to observe new or critical products after the production or the delivery on the basis of retained samples and to take appropriate action if necessary.

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