



System Appreciation Guide 2.1

LabSys LIMS

LabSys Ltd.

Purpose of this Guide

Regulated Industry sectors, such as pharmaceutical, chemical and food/beverage, are becoming more and more regulated as time goes by. There are increasing pressures from competitors, markets and shareholders to improve performance and results. Information systems, automation and ERP help companies comply with governmental regulation and ensure the safety/quality of their products. They also cut costs and allow a processor to integrate information in keeping with the increasingly vertical way that the processor does business.

The purpose of this guide paper is to outline new technology solutions for Quality Information Management for the Regulated Industries from LabSys.

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1 Company and Product Highlights

- Founded in 1990 by AGB Scientific & Intermec Irl. Ltd.
- ISO 9001, BS5750 and TickIT registered.
- Headquarters - Dublin Ireland
- Multi-language support - five languages
- Installed in 13 countries.

1.1 Platforms Available

Servers	Operating System	Data Bases
AS/400	OS/400	DB2/400
Intel	Windows NT4.0	Progress
		SQL Server
		Oracle

LabSys LIMS runs on an impressive range of hardware platforms, operating environments, user interfaces, and transparently supports various network protocols to give you the flexibility to work within the environment most suited to your needs. LabSys policy is to support all leading databases to provide application portability.

1.2 User Sites

LIMS systems from LabSys have been installed in some of the world's largest Pharmaceutical, Chemical, and, Food and Beverage companies.

Some User sites include:

Pharmaceutical

Pfizer Corporation
Novartis
Schering Plough
CCL Custom Manufacturing

Food/Beverage

Irish Distillers
Con Agra Malt
Meggie
LU (Danone)

Chemical

Ciba Specialty Chemicals
Clariant
Rockwood Electronic Materials
Johnson Matthey

Others

Pasminco Budel Zinc

2 Overview

At a time when the regulated industries are going through a period of major change, there are also significant regulatory and compliance issues from the FDA and various government bodies that have to be addressed, not just at a local level but globally. Such pressures create an atmosphere of insecurity and paralysis that can inhibit decision-making and the implementation of solutions to these problems.

Over the recent decades there has been an astonishing growth in the amount of raw data collected in the laboratory. With the increase of computer controlled and sophisticated laboratory instruments this trend is likely to continue, although at a faster rate.

A quality Laboratory Information Management System (LIMS), such as LabSys LIMS, provides a wide range of benefits in the laboratory and to a company as a whole. Such a system is used to collect, store, tabulate and report large amounts of data within the organization. Data once entered into the Quality System can easily be electronically transferred to other computing applications like Enterprise Requirements Planning (ERP) systems. This integrated approach can greatly enhance the speed of routine ERP transactions while cutting down on the potential for error.

LabSys LIMS is a system designed to manage quality related information within an organisation. It has been installed in some of the world's largest Pharmaceutical, Chemical, and Food corporations and has helped these companies achieve ISO 9000 and supported FDA compliance. It is currently available in a number of different languages including French, Italian, German, Dutch and English.

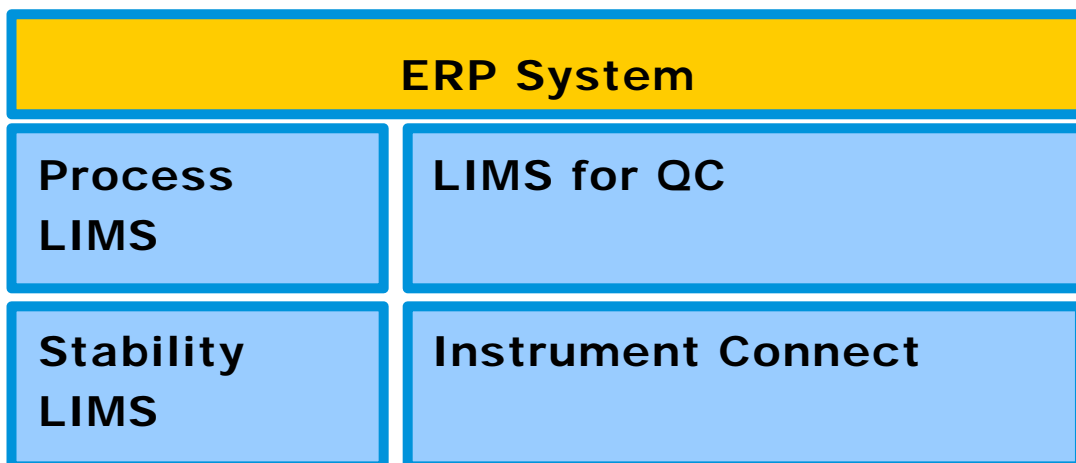


Fig 1 LabSys LIMS Modules

3 Summary Functions

LIMS for QC

Setup & Configuration:	Allows the system to be configured to site-specific requirements.
Sample Management:	Sample life cycle including all the standard functionality normally associated with a stand-alone LIMS system. It supports many additional QA functions.
Vendor Monitoring:	Controls different sampling plans and skips lot-testing parameters per vendor/product relationship. It tracks vendor performance and provides vendor performance reports
ERP Integration:	Allows data to be interchanged between LabSys LIMS and ERP systems.
Document Management Link:	Allows links to documents and external Document Management systems for tests, sample, products etc.

Process LIMS

In-Process Sampling:	Controls sample testing during the manufacturing stages of a batch process.
Batch Tree Traceability:	Full batch traceability with ERP Interface

Stability LIMS

Stability Trial Template:	Allows definitions of Time-Points, Conditions and the testing to be performed at each stage.
Trial Management:	Used to manage all Stability Trials and provide reporting on each.
Stability Scheduler:	Automatically schedules samples for testing when the time-point arrives.

Instrument Connect

Simple Instruments:	Collects and passes data from simple instruments such as balances and meters and can process this before reporting to LIMS.
Complex Instruments:	Collects and passes data from complex PC controlled instruments such as HPLC's and GC's. Can be configured to deliver a worklist from LIMS to the instrument and subsequently upload the results from the instrument to LIMS.

3.1 Good Manufacturing Practice

LabSys LIMS manages GMP (Good Manufacturing Practice) related quality aspects of a business, and ensures compliance to these strict standards. It interfaces as standard to ERP applications such as PRISM and Protean, JD Edwards and BPCS. The open architecture means that it may also integrate with other packaged or in house developed applications.

LabSys employees, its products and services have helped numerous organisations achieve ISO 9000 certification and maintain FDA compliance. LabSys has expertise and experience in LIMS, GMP, GAMP, GLP, ERP, Validation and Systems Integration.

4 LIMS for QC

4.1 Setup & Configuration

- User defined, user specific menus
- Access other network applications
- Multi-Language
- Multiple databases
- Barcode label design & printing
- Parameter configuration by division
- Comprehensive browse and query facilities
- Automatic Reports
- Calendar set-up & control
- Large text comments for tests, samples, results, approvals
- On/off system parameter settings
- Security set-up
- Multi-Company/Division
- Comprehensive user defined security

LabSys LIMS has configurable parameters that allow each customer to configure the system uniquely. Screen and report text are held separate from the data.

4.2 Sample Management

The LIMS for QC module provides a comprehensive sample management structure. This structure is referred to as the **sample life-cycle**. This **life-cycle** is used for all sample types including raw materials, intermediates, finished goods, in-process samples, stability samples, customer complaint samples or calibration samples. It sets up the mechanism for all sample handling, allowing the tailoring of the sample cycle to accommodate the sample type being processed. Samples may have tests automatically allocated and when results are entered for these tests, they are checked on-line against 3 levels of specification limits. LabSys LIMS accommodates the execution of automatic calculations. Inter and intra test calculations are automatically run once the raw data results are entered. Calculated results are automatically checked against limits.

4.2.1 Main Functions

- Specification Manager
- Sample Manager
- Bar-code label printing and support
- Graphical analysis of data
- Automatic calculations
- Products, Customer and Vendor specific specifications
- Multi level limit checking, Specification, Warning, Outer and User Defined limits.
- Supports alphanumeric and/or numeric result formats with limit checking.
- Conditional Event Triggers
- Instrument Maintenance/Calibration scheduling & recording
- Multiple result approval/validation levels
- Automatic Approval functions
- Qualified Person approval functions
- On-line SOP's
- On-line Safety, Disposal, Handling and Sampling Instruction documents
- Electronic mail
- Automatic Reports
- Reduced/Full analysis cycles
- Quality Costing
- Certificates of Analysis
- Automatic sample registration/login
- Reagent standardization's

4.2.2 Specification Management

At the core of any Laboratory Information Management System is the management of specifications. This function allows for the creation, maintenance and approval of version controlled test methods, calculations, product specifications, and customer specifications.

4.2.3 Test Methods

Test methods define what tests can be carried out in the lab and are independent of the product being tested. For example: a simple pH test may be required during the testing process. This test may be applicable to many products but only needs to be defined in the system once. The basic definition of the test also allows valid entries to be entered. In the case of pH these valid entries would be a numeric value between 0 - 14. These valid entries allow for a variety of options e.g. numeric as in the case of pH or a purely descriptive term such as 'Clear' or 'Cloudy'. A more complex example is Moisture Content. This requires several pieces of raw data such as weight of dish, weight of wet sample and weight of dry sample. These entries enable the production of a final calculated result. The calculations are user definable and are validatable within the system. Using a calculator, Excel or any other external operation to do these calculations introduces the possibility of errors and raises validation concerns. Having the calculation embedded in the test method during a one-time, validatable set-up procedure removes all of these concerns.

Each of these results may have different limits, units of measure, etc. The ability to set up re-usable test methods such as these ensures consistency, reduces time and effort required in creating specifications and builds in quality assurance.

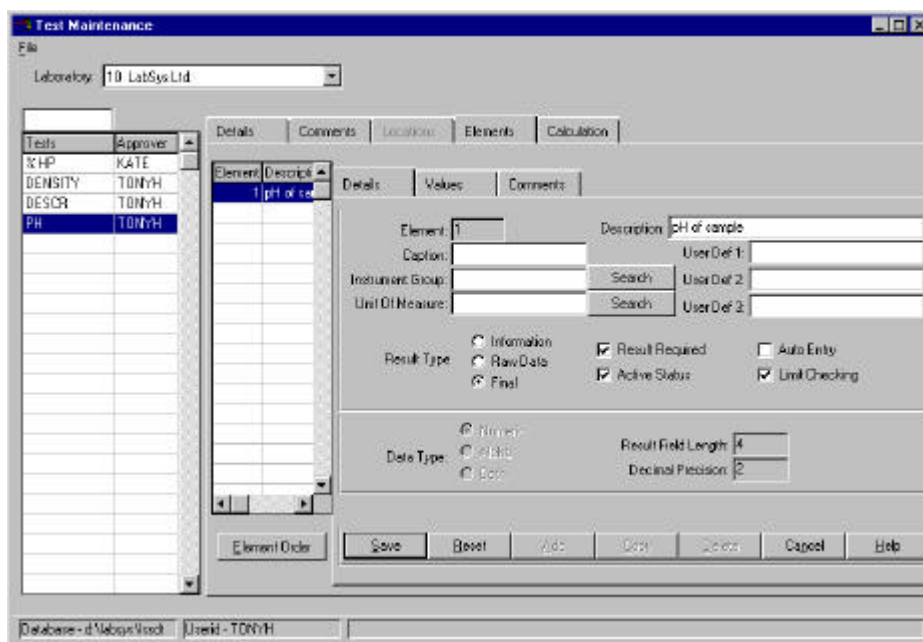


Fig 2. Test Maintenance

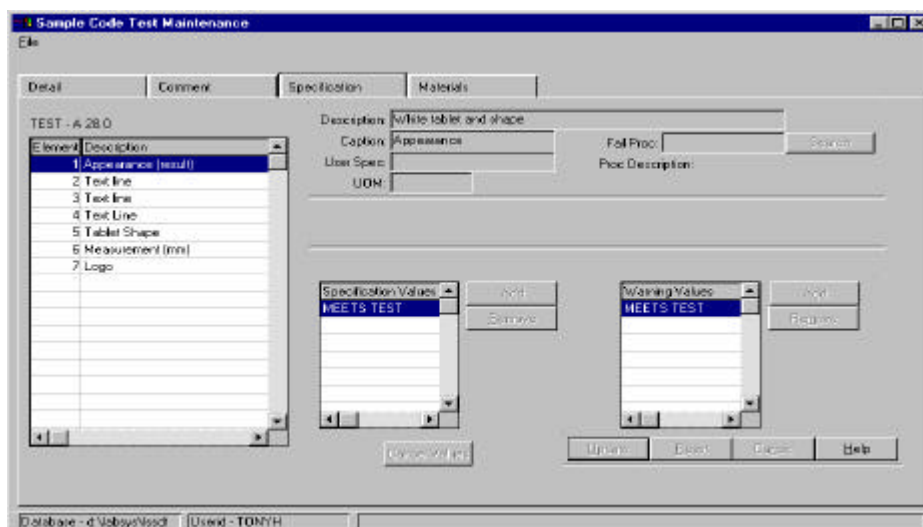


Fig 3. Specification Maintenance

4.2.4 Specifications

A product specification determines which suite of tests will be carried out on a product. A product can have many specifications during the production process. For example: internally PARACETAMOL tablets may be finished from the intermediate product in several stages - Granulation, Tableting, Coating and Packaging. Each of these stages may require different specifications and testing while being identified as the same product/lot within the system. This same final product may also have many different specifications that must also be checked.

Each of the tests on these specifications may have different acceptance and warning limits. Only if the result determined is within the acceptance limits can the test be approved. Warning limits also allow for an early detection system for deviations.

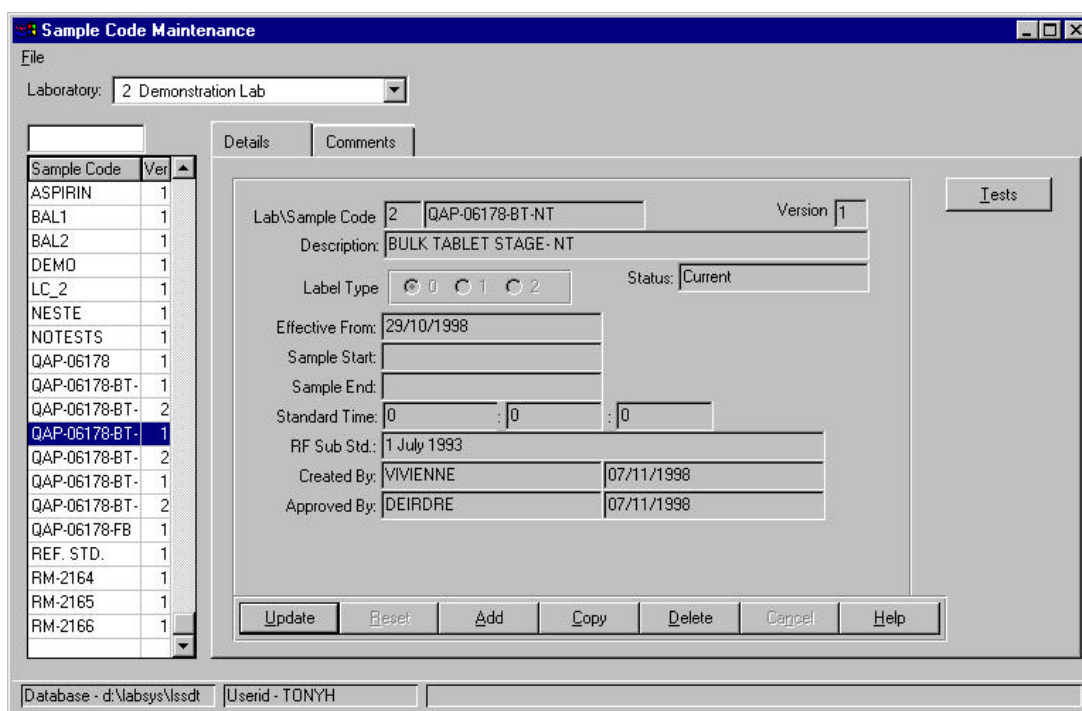


Fig 4. Specification Limits

4.2.5 Sample Management

Sample management provides a comprehensive structure for the handling of different sample types including raw materials, intermediates, finished goods, in-process samples, calibration, reagent and environmental samples, whether routine or non-routine. It ensures that scheduled tests are completed and as results are entered, defined calculations are automatically executed. Entered or calculated results are compared to multiple levels of limits. Instrument calibration schedules are held on-line and reports listing instruments requiring calibration can be automatically printed. It provides for the tracking and status control of each test and each sample within the system. Certificate of Analysis reports can be defined and generated per customer.

Product samples move through the Laboratory Information Management System in a series of steps.

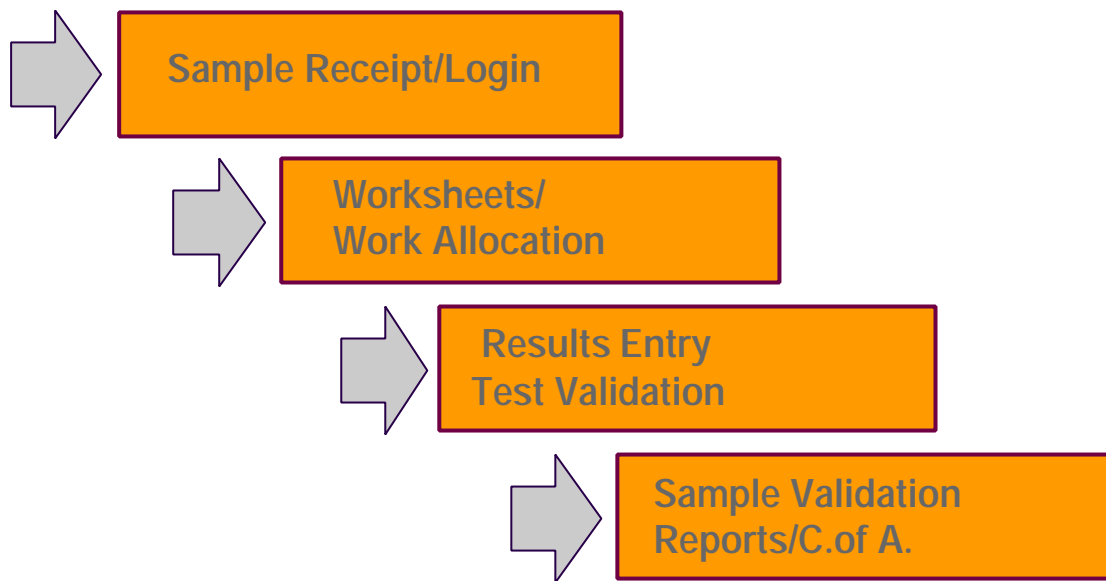


Fig 5. Sample Flow

4.2.6 Sample Registration/Login

The sample life can start manually, automatically or be triggered remotely. At this stage the sample is given a unique identifier and barcode labels can be produced for the sample container. The latest current version of the associated manufacturing specification is assigned to the sample and this determines the suite of tests that will be carried out and the limits against which the results will be checked.

4.2.7 Work Scheduling/Worksheets

Sample based worksheets can automatically be printed as part of sample login. The laboratory supervisor outlining the tests to be completed by that user can generate user specific numbered worksheets. These worksheets are also available in a file format for downloading to another computer system for use in the generation of an instrument sample queue.

4.2.8 Results Entry

Results entry is probably the most commonly used program in any Laboratory Information Management System. Results may be input by sample, test, location, product, date, project, worksheet number etc. A comprehensive query function is available for selecting the tests required for results input. Large text comments may be entered for each sample and each result. All entered comments are accessible thereafter. All entered or calculated results are checked against three levels of limits. Instrument calibration flagging is automatic based on times used or days passed since last calibration.

4.2.9 Results Confirmation

Results confirmation can be carried out at test and/or sample level. All results entered are checked against all limits and flagged appropriately. Second person review at test level is optional because some products being tested will not merit it. If all results pass specification the system recommends a sample completion status of COMPLIES. Certain product classes can be automatically approved - provided that the results entered are within specifications. This helps streamline the laboratory function by reducing the approvals required to those samples that have failed specifications. During the validation process the user assigns a completion status to the sample e.g. COMPLIES, REJECTED, RESAMPLE or CONDITIONAL APPROVAL.

4.2.10

Graphical Analysis

A graphical analysis function allows for the display result trends. For selected criteria it gives averages, standard deviation, running averages, xy plots, scatter plots, etc.

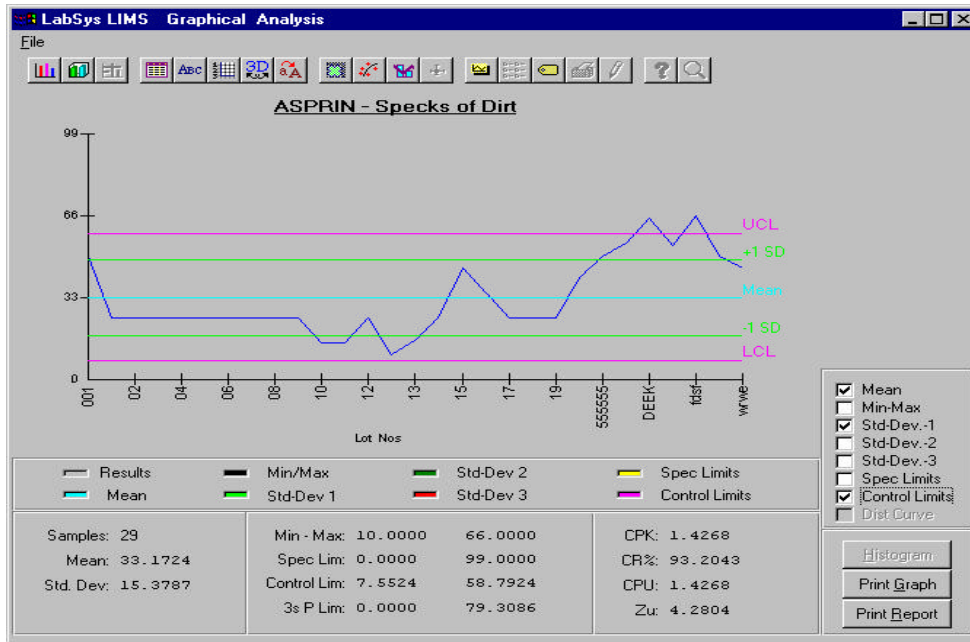


Fig 6. Graphical Analysis

4.2.11

Decision Support

In addition to satisfying the requirements for GMP, GLP, GALP and integration standards, the LIMS can offer additional functions, reduce the workload of the laboratory and allow users to manage by exception. Support in the decision making process can bring significant and real benefits in today's high priced labour market. With this type of capability the system can handle the majority of the routine decision-making and therefore free up senior staff for other duties.

4.2.12

Comprehensive and Flexible

The unique LabSys LIMS Sample Life provides a comprehensive structure for the handling of different sample types whether routine or non-routine. It ensures that scheduled tests are completed and, as results are entered, defined calculations are automatically executed. Entered or calculated results are compared to multiple levels of limits. Instrument calibration schedules are held on-line and reports listing instruments requiring calibration can be automatically printed. Certificate of Analysis reports can be defined and generated per customer. Flexible report generation tools enable users to generate custom reports or create data files for import into other software packages for reporting or further processing.

LabSys LIMS can be used on the plant floor to collect quality related information for in-process batch testing. The Process LIMS module has been designed specifically for the multi-batch multi-process manufacturing industry. LIMS data can be stored, reviewed and processed whenever needed, under the protection of comprehensive security and authorization procedures.

■ **Event Triggers**

An event trigger will cause pre-determined actions to execute automatically when a specific event occurs. For example: when a sample is created in the LIMS an event is triggered, this event could send email, print a report, etc.

■ Customisation without modification

The creation and implementation of event triggers allows the system to be customised without modification to the source code. This customisation without modification complies with GLP and GAMP guidelines by not having, and not needing, source code while at the same time allowing the system to be tailored to user specific needs. Support for result, test, specification, status, product specific event triggers plus event triggers at a system level means that the system can be adapted to suit your work practice.

Cascading events can also be created; there is no reasonable limit to the depth to which you can cascade events. For example: if a test fails then it may indicate that further testing is required. With an event trigger (on the failure of the test) these tests can be scheduled automatically. If these tests also fail then more tests can be scheduled.

Likewise in a fractionation test the completion of the first test should, based on the results, automatically schedule more/repeat tests.

■ Laboratory Management Functions

The Laboratory Manager can easily see which samples are passing or failing specifications. Reports can be obtained of all results for a production batch indicating compliance to specifications. Instrument calibration reports, sample listings, sample approval rates, sample distribution report, sample backlog report, special sample and non-routine sample listings can be obtained.

To assist with the ease of sample management the LabSys LIMS product also provides the following functionality: -

■ Barcode label printing and support

Samples are given a unique bar-coded identifier when created and this is used throughout the life of the sample. This is linked to the product/lot and can never be reallocated to another product/lot.

■ Graphical analysis of data

Trends can be spotted in result data using a graphical analysis.

■ Automatic calculations

Calculations are performed automatically when all the prerequisite data has been entered or previously calculated.

■ Products, customer and Vendor specific specifications

As results are entered they are checked against manufacturing specifications. When all results have been entered the complete set is checked against all other relevant specifications.

■ Product grading

Based on the specifications present the product is graded.

■ Limit Checking

These include multi level limit checking, specification limits, warning limits, outer limits, user defined, supporting alphanumeric and numeric result formats with limit checking.

■ Conditional Event Triggers

Allows workflow customisation of the sample test. Based on the results of a test you may wish to perform additional tests. In this way the minimum set of tests can be automatically allocated to the sample and only if one or more of these fail are the remainder performed.

■ Instrument Maintenance/Calibration scheduling & recording

Records details of all instrument maintenance and calibration records and marks all results from un-calibrated instruments as outside specification. This helps build quality assurance into the product and is a component of GLP.

■ Reagent standardisations

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Like instrument calibration this function records details of all reagent standardisations. Reagent values can be calculated and made available to other samples using the calculation functionality. This again helps build quality assurance into the product and is a component of GLP.

- **Multiple result approval/validation levels and automatic approval functions**

This ensures only authorised personnel can perform approval functions. Electronic signatures are also possible, enabling compliance with FDA 21CFR 11 ruling on electronic signatures.

- **Reduced/Full analysis cycles**

All products may not need to be fully tested each time they are sampled. It may be sufficient to perform a subset of tests from the specification and periodically perform the full set, provided that it can be statistically shown that this does not affect the quality of the product.

- **Quality Costing**

Standard costs can be recorded for samples for allocation of overheads to departments or for job costing.

- **Certificates of Analysis**

A COA creation for a lot is one of the primary roles of the laboratory testing. There is a wide variation in content and style for Certificates of Analysis based on the customer, market, language, product, grade, etc. The ability to create and modify certificates using a flexible reporting tool is essential.

4.3 Vendor Monitoring & Skip Lot Processing

Vendor monitoring allows for the set-up and use of specifications based on the source of the material. For example: a material from an internal or an approved supplier may not need to have the full suite of tests performed, so a reduced testing profile is used. Materials may be sourced from many locations for the production process. It could be that other companies within the same group provide certain raw materials or intermediates and sometimes they are purchased from external suppliers. So, depending on the supplier, customers may wish to test the incoming material differently or perform different sets of tests.

Even with approved suppliers GLP requires that periodic audits be performed to ensure the supplier continues to adhere to the agreed specification. Using vendor monitoring this process can be streamlined.

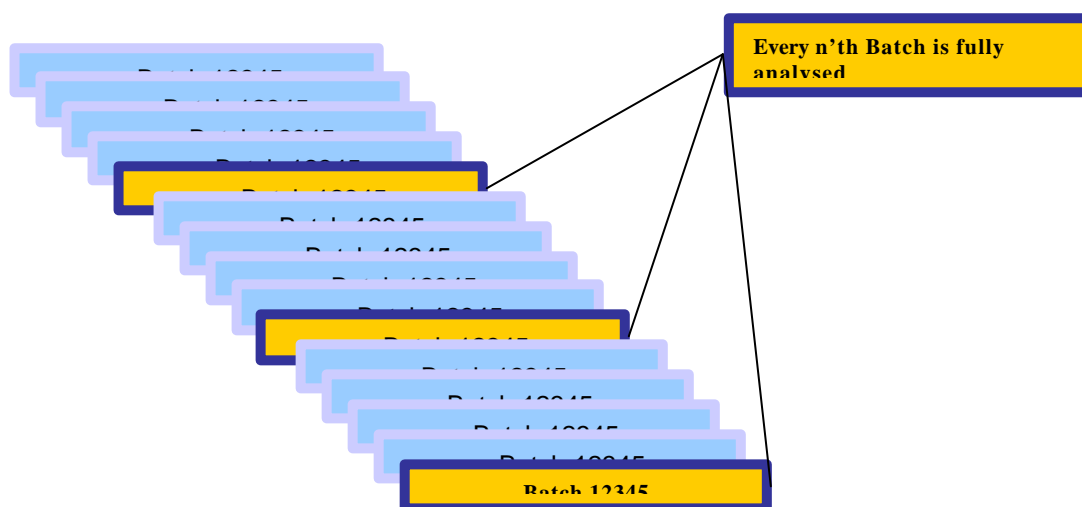


Fig 7. Vendor Monitoring

Depending upon the quality of the material supplied historically, the system can schedule reduced or full testing based on a preset frequency pattern. This pattern is dependent upon date and/or number of samples/deliveries, with a set number of consecutive passes required for a product/vendor combination before reduced testing is allowed. The system can automatically trigger a full testing program every set number of deliveries or every period, whichever happens first. If a failure occurs during reduced testing, the system will not allow reduced testing again until the vendor has supplied a specified number of defect free lots of product.

4.3.1 Graphical Analysis

It is possible to select a quality parameter for a given Product from a given Vendor and view the trend. This trend can be visually compared against the same parameter and product but from a different vendor. The ability to easily compare a quality parameter from different vendors is a major advantage in today's competitive market.

4.3.2 Vendor Rating Report

A vendor/product history report outlining the quality history for the vendor over a period is also available. This gives a rating to each vendor, calculated on the number of deliveries passed against the number tested.

4.4 ERP Integration

In order to achieve the full benefits of a complete LIMS and address the issues of the regulated industries, integration of the LIMS with the ERP system is imperative.

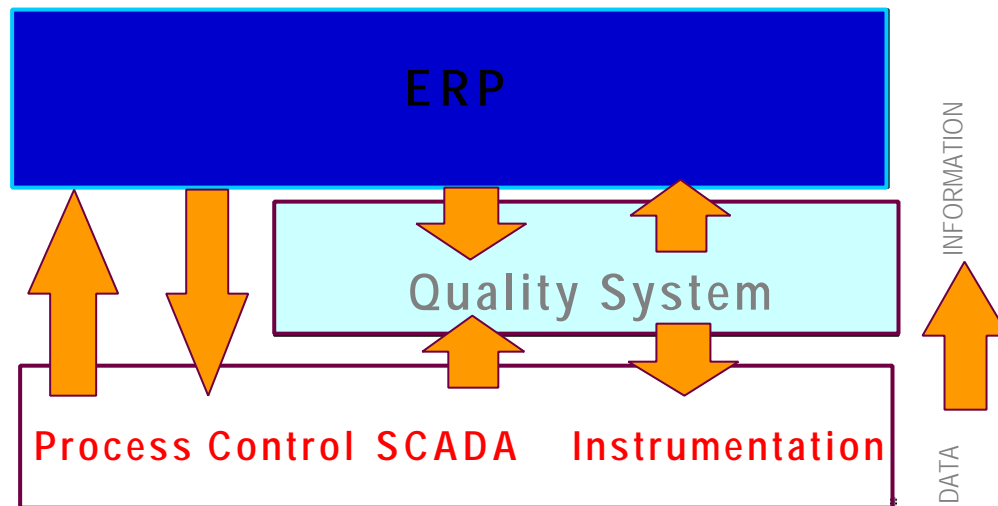


Fig 8 ERP Integration

4.4.1 Overview

ERP systems control a range of business functions within an organisation consisting of a range of integrated modules covering functions like Finance, Purchasing, Materials Control, Batch Recipes, Resource Planning and Production Scheduling/Planning. The information provided by a LIMS plays an integral role in any company's information systems and as such should integrate into these systems/modules.

A LIMS fits into the information hierarchy as shown above. As raw data is collected from various instruments, supervisory control and data acquisition (SCADA) and process control systems it is distilled through the LIMS system which then refines the data. The data distillation process may or may not pass through the quality system and may or may not be transformed in the process. There could be situations where the ERP system integrates directly or indirectly with process control systems. This usually only happens where the production process is very well defined and is highly automated.

4.4.2 Data Collection

Data collected will ultimately end up in the ERP system and will influence the product release decision. Along the route to the ERP system, the distillation process converts the raw data into information that can be used in the decision-making process. Questions such as "Who is this product suitable for?" can be answered more easily. It is the function of the LIMS system to facilitate this process and ensure that value is added to the data as it is processed.

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ERP system developers have traditionally concentrated on the business aspects of an organisation. The movement of data from low level to a higher level must involve the transformation of that data into information. Productivity increases are realised by having the LIMS and the ERP system integrated.

4.4.3 Integration

A LIMS that can integrate directly with Purchasing, Inventory Management, Production, Receipts and Client Order Management cuts down on the time required to update various ERP records and systems. It guarantees, through automation that all required product testing from raw materials, through in process, to finished product was carried out to the required specifications. A true LIMS system needs to integrate with the ERP application at the following points: -

Purchasing / Receipts

As the basis of any production process the raw materials are the first components that must be monitored. The industry requires that materials used in the product and certain printed packaging materials are strictly controlled from the time of receipt to the shipment of finished product to the Client. On arrival, the materials need to be quarantined, sampled and tested. Only authorised staff can release the material from quarantine and should only do so once the material has been tested and approved.

Inventory Management

Most materials used in production have a shelf life beyond which they must be retested to make sure that they are usable. Regulatory compliance requires expired materials be quarantined and retested and re-approved before use.

Production

Once the material has been approved and subsequently issued to a production schedule then in-process testing must be recorded at various stages. Depending on the production model used there may be numerous points at which the product being manufactured needs to be sampled, tested and the results reported. These results may confirm that the production process is functioning correctly or may indicate that corrective measures need to be taken. Values determined during the testing process, such as assays for potency, moisture content, etc. may need immediate reporting to production as they can directly affect the process.

Production Receipts

When a batch of product (intermediate or finished product) has completed all stages of the production process it is usually necessary to test the product before final release.

Customer Order Management

Whether a Client manufactures to customer specifications or internal manufacturing specifications, it will need to ensure that product lots being allocated for fulfilment of a customer order meet all the customer requirements. These requirements can include potency levels, colour, special labelling or packaging, grades, etc. Matching customer requirements to available lots can be a nightmare, and has cost/margin implications, where various grades of product are sold to different markets and customers. The LabSys LIMS system addresses all of the above requirements.

4.5 Document Management Link

Document Management Link is a function within LIMS for QC for managing many different types of Controlled Documents such as SOP's (Standard Operating Procedures), Safety Documentation, Product Specifications, etc.

It is possible to link documents from such applications as Microsoft Office, Lotus WordPro and Adobe Acrobat and also documents that are created and controlled by some of the most common Document Management Systems to Test Codes/Methods, Specifications, Products, Instruments and Standards in LIMS for QC.

Once the appropriate link to a document has been created, it is then possible to view a document in such functions as Sample Submission, Results Entry and the Validation/Approval, Maintenance and Inquiry functions in LIMS for QC.

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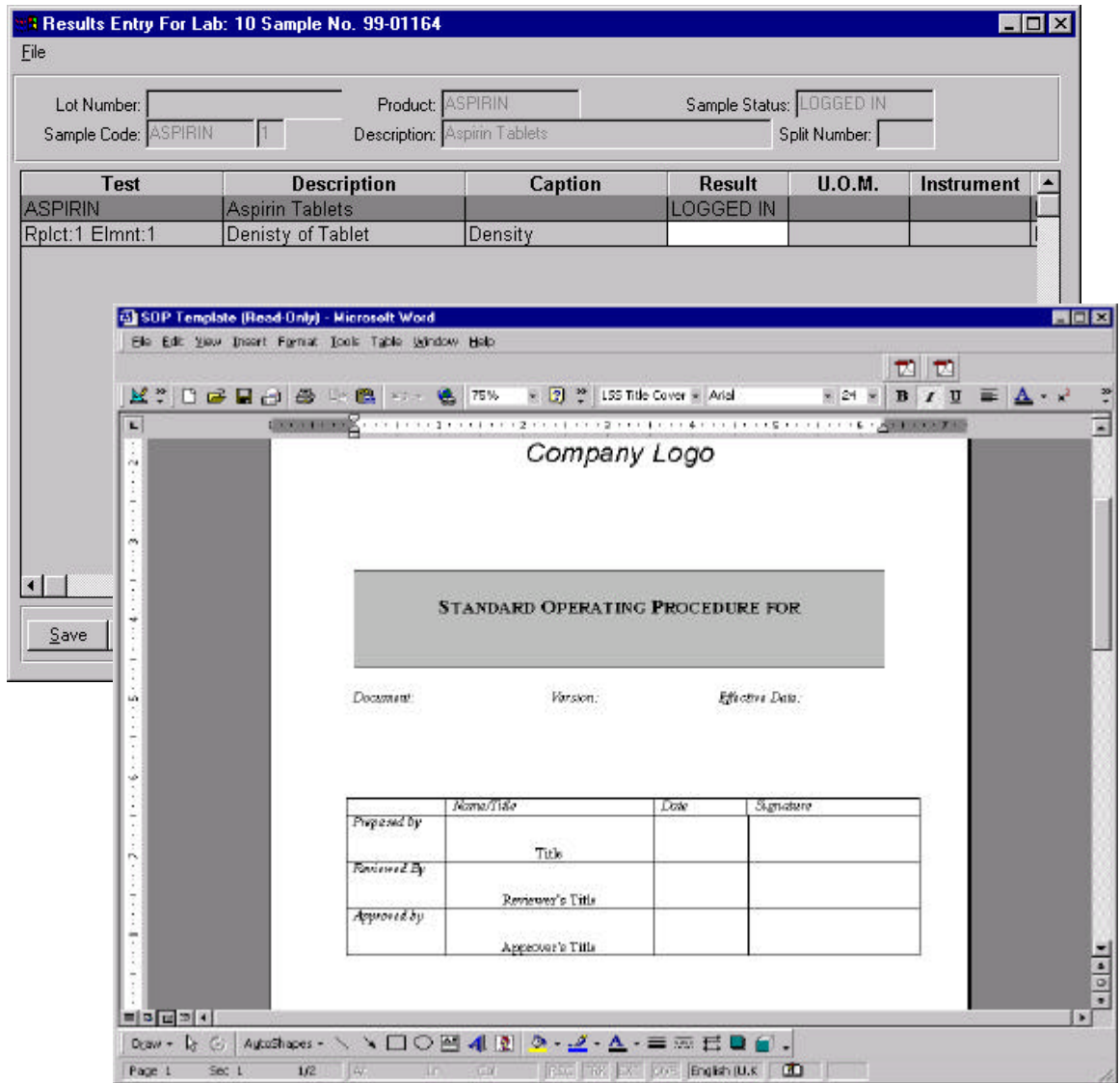


Fig. 9 Viewing Controlled Documents

5 Process LIMS

Designed specifically for the multi-product multi-batch processing industry, this module, called Process LIMS, manages the specifications, sample management and reporting of all samples and results data related to production batches.

5.1 In-Process Sampling

When setting out to manufacture a batch of product a strict set of manufacturing instructions, described in the monograph, must be followed. These instructions include manufacturing quantities, instructions, testing instructions, packaging instructions, etc. The manufacturing quantities and instructions are set up and implemented in ERP, while the testing instructions are set up and implemented in Process LIMS.

For each stage in the production model, a sample (or collection of samples) may be needed, it may even be necessary to complete the testing of a stage in Process LIMS before moving on to the next stage in ERP. For example a moisture content check or dryer check may need to be done, the results must be a certain value before the process is allowed to continue.

Within Process LIMS a collection of samples for a stage is called a Control Point. These Process LIMS Control Points are equivalent to HACCP Control Points and using this structure helps enable compliance with the HACCP Guidelines. The Process LIMS Specification can be used to mirror the production model and record all quality-related information about the batch production.

These Process Specifications are version controlled and require second level approval before use. This ensures that all changes and improvements to the production process are reviewed and approved before use.

Cake Production Schedule	Testing plan
1. Heat oven	1. Check oven temperature
2. Measure ingredients	
3. Add ingredients to bowl and mix	3. Check ingredients mixed thoroughly
4. Add water and mix	4. Check enough water added
5. Prepare baking tray	
6. Put mix on baking tray	
7. Place in oven and Bake	7. Check when baked
8. Clean	8. Check utensils cleaned
9. Remove from oven	9. Check cake cooked
	10. Eat some

Fig 10. Process Control Points

5.2 Batch Tree Traceability

The system ensures that when a Production/Manufacturing Order is released in ERP, an appropriate Process Batch is created in Process LIMS. This Process Batch records all samples taken during the processing of that batch. A Process Specification can be seen as a collection of Batch sample schedules, which may include quality checks, normally carried out on the plant floor. This data is entered into Process LIMS and forms part of the electronic batch record. All samples taken follow the LabSys LIMS sample cycle and therefore inherit the sample cycle functionality.

Using Process ILIMS, Production is immediately made aware of the status of each Control point sample, thereby improving the turnaround times for samples and batches.

Batch status reports are available showing all laboratory results for both completed and in-process batches. Complete QA Batch Tree functions are available when integrated with your ERP showing the following:

- Listing raw materials & results
- In-process testing
- Documentation checks
- Instrumentation calibration checks
- Final product test results
- Final validation checks

5.3 Batch Production Management

Plant Process Control computers can interface to this module to automatically schedule samples. Upon sample completion, either the actual test results or the status of a sample can be sent from LabSys LIMS to the Process Control computer.

In addition, the sample results can be broadcast automatically via 'Live Screen Update' to selected screens in the plant. This function enables plant floor personnel to obtain results from LabSys LIMS without the need to sign on to the system, and ensures the transfer of sample results data as soon as they are available.

5.4 Batch Disposition

When all of the control points have been completed on the Batch, a disposition is given. This disposition, when integrated with ERP, is used to pass a similar disposition on the batch in ERP. Batch dispositions are user definable including Accept, Reject, Close, Waive and Blend. Blending a batch allows you to merge it with one or more batches and to keep full traceability of these batches in Process LIMS.

Fig.11. Batch Disposition

CtPt	Description	Sample No	Status	Sample Code	Version	Complete
1	Mother liquor feed	99S000001	FIN-UNVER	ASP-01	001	
2	Mother liquor feed	99S000002	FIN-UNVER	ASP-01	001	
3	Aspirin Tablets	99S000003	FIN-UNVER	ASPIRIN	001	

etc. that uniquely identify the cell of the trial. Automatic scheduling of samples due for testing within a specified time window is provided.

6.3 Stability Scheduler

All samples in the profile are taken according to the schedule and the stability profile is analysed on completion of the schedule, which is then closed off.

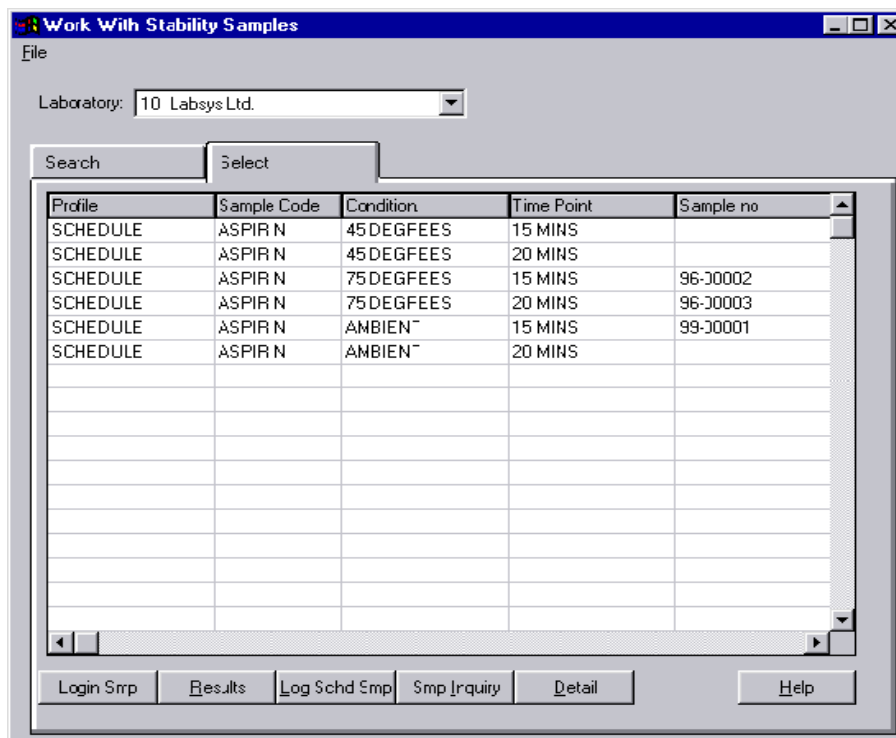


Fig 13. Stability Samples

Graphical trend analysis is available to see how the stability trial is performing over various conditions and the results available can be used in shelf life calculation.

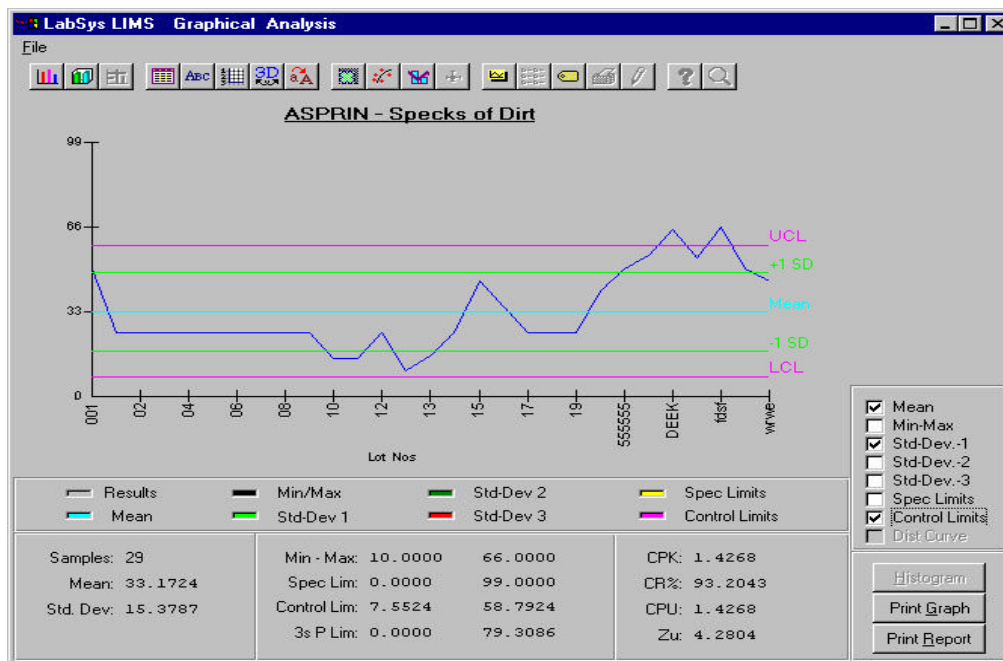


Fig 14 Graphical Analysis

7 Instrument Connect

Intelligent data collection from laboratory instruments can provide significant productivity gains, by eliminating redundant manual entry of data, and the need to transcribe or keep paper records from instruments. Transcription errors are greatly reduced by direct transfer of data to the LIMS.

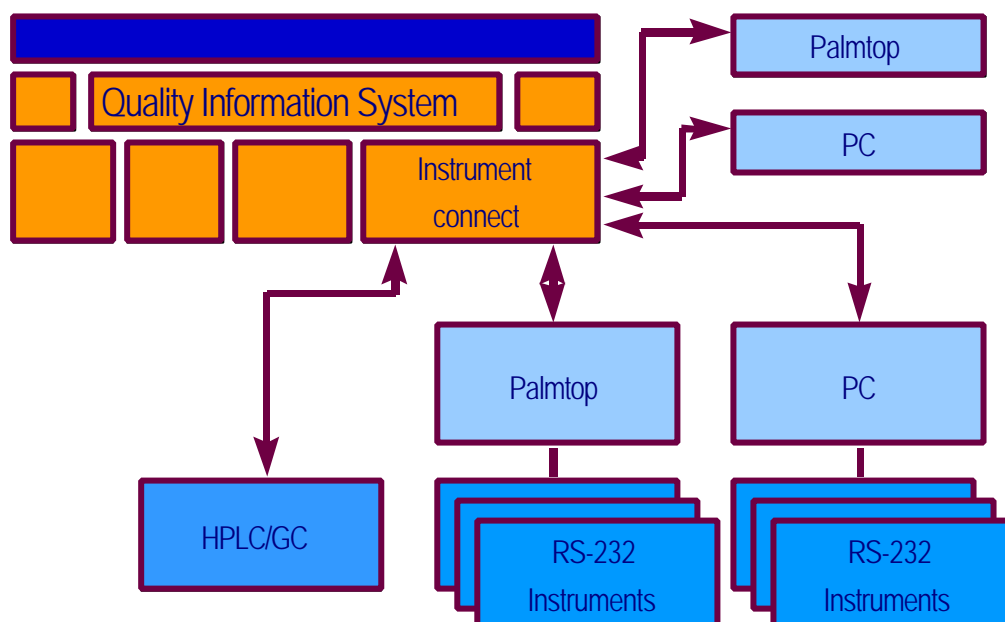


Fig 15. Instrument Connect

One of the key elements in any system is the integrity of the data being collected. Two-way communication with instruments, where possible, allows greater data integrity, in that the instruments being used can be loaded with samples/tests from the LIMS and results for those tests are collated from the instrument. It allows the user to specify instructions for each test being performed. The data collected is checked at the instrument location, against specifications and limits, before being accepted by the LIMS.

With the huge variation in laboratory instruments available, lack of interface standards at instrument level and multiple networking options available data collection in the laboratory can be a significant task. A flexible user configurable method of connecting instruments to the LIMS is required. Authorised users need to be able to set-up new instruments and/or methods without requiring any programming ability.

While interfacing these instruments and collecting data, Lab technicians need to be able to have some control over what data goes to the LIMS, giving them the power to control their work and rectify errors at an early stage.

8 Customer Support Services

Professionals designed LabSys LIMS, with extensive experience in the area of LIMS, GMP, GLP, GAMP, Validation and Systems Integration. LabSys IT professionals are available to help you integrate LabSys LIMS into your Business Systems, providing you with a truly integrated solution.

■ Support in Implementation

LabSys provides a comprehensive range of implementation services including: Requirements Analysis, Implementation Planning, On-site Assistance, Configuration Support and Project Management.

■ Support in Training

A comprehensive range of standard training courses are available to back up all aspects of the implementation and operation of your LabSys LIMS system. In addition specifically tailored courses can be provided to suit your individual needs.

■ Support in Validation

LabSys LIMS has been implemented and validated in some of the largest pharmaceutical companies in the world. We have assisted in all aspects when requested. Our experienced Application Engineers can help you plan and implement a Master Validation plan for your system that conforms to your corporate standards. In addition, LabSys run occasional seminars on Validation which appeals to a cross section of industry.

■ Support in New Versions/Releases

LabSys are acutely aware of the need for strict change control procedures in your organisations. To assist you in maintaining your LabSys LIMS, keeping it up-to-date and validated, we supply all new releases and versions with comprehensive release notes indicating what programs have changed, and specify how those changes effect each customer. Automatic installation procedures handle all aspects related to upgrades or new releases.

9 Product Development

The LabSys LIMS product undergoes continuous enhancement following routine Customer contacts, user meetings and ideas registered with our Customer Support System (CSS). Many of the enhancements are generic in nature and apply to all users. This means that all LIMS users have the same core product and can benefit from enhancements which have been implemented for other industries. All new releases of LabSys LIMS are provided free to customers with a maintenance contract.

10 Committed to Quality

LabSys is an ISO-9000, BS5750 and TickIT registered company. We have a Quality Improvement Plan (QIP) in place which is designed to monitor and improve our products and services. We are committed to enhancing our products and services in line with our customers' requirements, market trends, developments in technology, developments in GMP/GLP and developments in the area of Computer Systems Validation.

We strive to supply our Customers with the very best products and services to enable them to manage their Quality Information in an integrated fashion.

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