Software Support for Metrology
Best Practice Guide No. 9

Selection and Use of LIMS

S M Lower

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Editor : S M Lower
Sira Test & Certification Ltd
South Hill, Chislehurst, Kent, United Kingdom. BR7 5EH

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Abstract

This guide gives best practice on the procurement, implementation and use of Laboratory Information Systems. This independent guide sets out the issues that should be considered at all stages, backed up with case studies and a list of potential LIMS suppliers.

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Authorised by Dr Dave Rayner
Programme Manager, Software Support for Metrology Programme

National Physical Laboratory
Teddington, Middlesex, United Kingdom. TW11 OLW

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Executive Summary

A laboratory produces a vast amount of information. Because of the regulatory climate in which many laboratories work and because of the drive for demonstrable quality assurance, it is important to retain information for a long time and to be able to find and process it throughout that period. The information can be disparate – it might include test data, staff training and workload records. Such an information management problem lends itself to computerisation, particularly through the use of Laboratory Information Management Systems (LIMS). LIMS can bring major benefits in terms of productivity, resource management and reduction of paperwork and customer enquiries.

The performance of the LIMS is vital to the laboratory. Selecting and implementing a LIMS is not a small or simple task. A LIMS can be bespoke or an off the shelf package. The trend is towards packages that can be configured to meet the laboratory needs. Preparation of the right system specification is vital and it is recommended that a laboratory audit is undertaken to define what will be required. This will include a review of the workflow, the instruments, the reports, security and the systems with which the LIMS will have to interface.

The specification will also consider the retention of records in electronic or paper format, the control of the software itself and the medium on which it is stored. Thought will need to be given and assurances received about an upgrade and development path. In order to obtain a return on the substantial investment required, a LIMS should be seen as a long-term tool lasting at least eight years.

One of the keys to getting the desired performance is to build a good partnership relationship with the supplier. Planning, an agreed scope, flexibility and change management are all important in getting the best from the system. It can take at least six months and often much more to install, configure, validate and adopt a LIMS system in a laboratory. A vital part of this is the quality of training offered by the vendor, as well as the quality of the supporting documentation.

The requirements will evolve, not least because users will become more aware of the capabilities of the system, and thus there needs to be a system of change control. The system needs to be validated but this can be tricky. In most cases it is not possible fully to understand the intricacies of the software and the ‘black box’ testing approach needs to be implemented. This treats the system as an entity and provides inputs (test data) and validates outputs. Consideration needs to be given to ‘what if ‘ tests as well as thorough preparation of usual scenarios. Calculations, including roundings need to be closely checked.

Once the installation of the LIMS is successfully completed, there are enormous potential benefits to be attained. These will best be obtained by choosing a LIMS based on you’re the anticipated future technology needs, selected after thorough research to find a match with a supplier that can be expected to work well with your own company.

The product alone does not make for a successful LIMS implementation, that requires the right approach and methodology plus appropriate people skills. When this is achieved, the result can be a substantial the return on investment.

This Best Practice Guide aims to give practical advice on the selection and use of LIMS, particularly in physical measurement and calibration laboratories. It has been produced by Sira Test & Certification as one of ten best practice guides from the DTI’s National Measurement System programme on Software Support for Metrology (1998-2001). All ten can be obtained from the programme’s web site: www.npl.co.uk/ssfm

1 INTRODUCTION

This best practice guide was produced as one of a set of 10 best practice guides for the National Measurement System (NMS) *Software Support for Metrology* (SS*f*M) programme. It has been produced as the output of the SS*f*M *Automation of Measurement and Calibration Processes* project as part of the programme's theme on supporting measurement and calibration processes.

For details of the programme and the other SS*f*M best practice guides, see the SS*f*M web site: http://www.npl.co.uk/ssfm/

It is recognised that there is a large gap in understanding and experience of Laboratory Information Management Systems (LIMS) between those fields in which they have been used for many years (particularly chemical analysis laboratories and the pharmaceutical and medical industries) and most other fields impacted by the NMS (specifically physical and engineering measurement laboratories). Most of the material available on LIMS is specifically aimed at chemists, and therefore is almost unknown to physicists and engineers. The purpose of this guide is, therefore, to introduce those involved in physical and engineering measurements to the concept of LIMS, to show the relevance to them and to give them guidance on the selection and use of LIMS within their calibration and testing laboratories.

Any laboratory produces a vast amount of information. A special problem with laboratories is that it is difficult to decide which apparently trivial piece of information might prove vital decades later. Because of this, and the regulatory climate in which they operate, laboratories need to keep a great deal of information and keep it for a long time.

A laboratory information system is any procedure or combination of procedures, which helps manage this mass of information. In the past, it was just possible to do this with paper, laboratory notebooks, recorded research and results. Work sheets monitored processes, customers details were kept on files or file cards, calibration records on a sheet of paper in a dirty plastic folder next to the instrument and so forth.

The ability of computers to store and compare has led to their adoption in every form of data handling. It was a natural progression that they should be turned to the inchoate paperwork generated by a laboratory. The use of a computer to manage information in a laboratory is signified as a Laboratory Information Management System, or LIMS.

Deciding to implement a LIMS is not a small project. Taking a LIMS decision from initial concept through to conclusion involves: defining business needs, defining user requirements, relating user requirements to LIMS products, writing functional specifications, writing design specifications, configuration and customisation, producing test scripts, preparing validation collateral, module testing, system testing, integration testing, system validation, user training, roll out, and system maintenance.

This document is intended to provide a concise guide to LIMS, to de-mystify the subject, to tell you if you need one and if so, how to select a supplier. Technical terms have been kept to a minimum and all are explained in the glossary.

2 What is a LIMS?

Laboratory Information Management Systems originated around the time of the minicomputer. The advent of reduced cost; relatively high-powered computers alongside reasonably robust hardware made electronic storage of data a viable alternative to paper records.

At that time, traditional laboratory records consisted of, and in some cases still do, laboratory notebooks, chart paper and printed spectra and measurements, along with any number of supporting documents. The immediate improvement seen with the introduction of LIMS was that you no longer required an excellent filing system, or an excellent memory for that matter, to be able to extract information from the volumes of data that had been collected. The LIMS should provide good filing capability. Database technology allowed the LIMS user to search for key features within the data and collate the results of that search.

Staff changes and loss of long term personnel can result in loss of access to information, even simple records about where reports are stored. Knowledge management is becoming important to physicists and engineers working across many laboratories, and a LIMS, by providing electronic and central storage of information, helps to eliminate the damage inflicted by staff loss.

A LIMS manages data, but needs to be more than a spreadsheet. The aim of a LIMS is simply to help run a laboratory more efficiently. LIMS provides a convenient way to store laboratory data and assist in the management of the laboratory functions.

LIMS are computer systems designed to allow the user to benefit from a range of data that is collected within the laboratory environment. As you would expect, LIMS can be used to process results from instruments, trend data over a series of time points, automatically apply testing profiles to items*, result reporting, along with numerous other item based activities. In addition, the LIMS should help manage the laboratory environment. After all, the 'M' in LIMS stands for Management, so features such as instrument management, personnel training records, qualifications, workload management are also a normal part of LIMS functionality. (*items refers to calibration or test items and other samples tested within the laboratory).

A 'standard' LIMS offers a range of functions for management of item records, including logging, tracking, reporting, archiving, querying, worklist generation, etc. A LIMS will store information about items that have come into the laboratory, the tests that have been performed on them, the results as well as the service record of the instruments that are used and the names, authorisation and role of the personnel that carry out the tests.

It will store information about what goes on in the laboratory and what — in the way of hazards, for instance — it contains.

A LIMS should make the laboratory more efficient by automating routine functions and providing up-to-the-minute information about what is happening in the laboratory. LIMS can be used to generate metrics for laboratory work, e.g. item turn around times. Instrument workloads are easily obtainable at any time. Laboratory data handling has become extremely important in providing quality information to the internal and external customers of the laboratory and, in this respect, LIMS has become as much of a tool in the commercial laboratory as analytical instruments.

It should provide automatic methods for searching for items, giving warning when supplies of consumables are running low or there is a bottleneck in production and producing audit reports. Because a LIMS is a computerised system there is no distinction between data; all of it is present, at some level, in binary form. This leads to the greatest power of a LIMS: its ability to integrate all the information in the laboratory and to interface with outside systems — such as those used for accounts, management reports and stock ordering or sales. A typical LIMS bridges gaps between analysis and financial management information systems and should *meet the needs of both the laboratory and the company.*

3 What can a LIMS do?

It is obvious that the great advantage of a LIMS is that it organises all the information produced by a laboratory. It brings this information together in a form that is easy to search and recall. This means that it is able to produce reports of any subsets of data in a form that can be understood by a metrologist or engineer, a manager, an accountant or even, a lawyer.

Specific areas are:

Items

- Origin (who sent it in? When?)
- Tests (which are needed? when are results wanted?)
- Tracking (where is it now? what is its status?)
- Calibration history
- Uncertainties (how are they recorded?)

Measurements

- Who performed the tests? On which instruments? Who entered the data?
- Are the results within appropriate limits?
- How was the uncertainty budget estimated?
- What are the significant contributions?
- How are the error distributions estimated?
- How is all this information input into the LIMS and processed within it?

Instruments

- Where are they in the laboratory?
- When were they last calibrated? By whom? When are they next due for calibration or servicing?
- How are the results and their associated uncertainties transferred to the LIMS?

Personnel

- Who has access to the LIMS?
- What is their role?
- Qualification/training status?

General

- What is produced by the laboratory? How much does it cost? How much is in stock?
- What hazards are in the laboratory? Where are they? How are they stored? How long have they been there?

Because of its database format, a LIMS provides tools to search for information relating to items etc in typical and traditional text field-based queries. Instrument-specific and vendor-specific data formats are not common within a LIMS, whose database is therefore not usually able to handle the data translation and storage requirements for all instruments (such as oscilloscopes, SEM, UV-Vis etc.)

Using an automated system can drastically reduce the duplication of staff workload. The immediate cost advantage is the huge reduction in time resulting from the accessibility of the information and the automation of many repetitive data entry tasks. A LIMS allows the movement of as much information as necessary from local "desktop databases" and file cabinets to a centralised repository that can be accessible company-wide. The LIMS will reduce the errors inherent in manual data entry and will help to achieve (but not obtain) accreditation to relevant regulatory requirements. The last point should be stressed.

No software, however sophisticated, can of itself ensure that an organisation meets UKAS accreditation or other regulatory requirements. It is the procedures of the laboratory and the operation of those procedures, how the laboratory is organised and run, that ensures compliance. Appropriate software can help to ensure that procedures are properly followed.

The most a LIMS vendor can claim is that the software has been developed in accordance with specified guidelines. Any vendor who claims that its product is compliant to FDA (US) and other general regulatory requirements should be regarded with suspicion.

Organisations that submit analytical data to regulatory bodies for acceptance globally are required to conform to common Good Laboratory Practice (GLP) requirements to assure QA/QC practices within the laboratory. Other organisations may have similar requirements or may choose to conform to GLP as part of their commitment to quality. One of the most important GLP standards is the 'OECD Principles of Good Laboratory Practice' produced by the Organization for Economic Co-operation and Development (OECD) and accepted internationally.

User firms are ultimately responsible for ensuring the adequacy of the LIMS. The purchaser should look for a LIMS vendor with a proven track record of implementing systems in compliant environments. The validation of the software system should be a partnership between the vendor and user.

A LIMS will save time in tracking items, alert managers to production bottlenecks and warn when stocks of consumables are running low. As well as organising the work and products of the laboratory, it will greatly ease the financial control of the laboratory, helping with purchasing decisions and their timing, and producing fuller information for pricing the product.

3.1 Reasons for LIMS Selection

The most frequently cited reasons for installing LIMS, in order of importance, are:

1. Money (saving money lost on inefficient production and use of materials)
2. Quality control
3. Time saving
4. Flexibility
5. Regulatory compliance

Cheshire-based Montell (previously Shell) made predictions before its LIMS implementation against a predetermined list of expectations for what the LIMS would deliver. This was then reviewed post-implementation. Montell identified the tangible benefits of its new LIMS as:

- Assigned monetary figures
- Less paperwork
- Reduction in time generating reports
- Less time on customer inquiries
- Better management of laboratory costs
- Better QA/QC

There were also several more intangible benefits identified:

- Improved image
- Better customer service
- More effective use of analysts' time
- Benefits

The predicted total savings of the LIMS installation at Montell were anticipated as £120K. Following the review of the project, the findings were recognised as:

Area of benefit	**Predicted**	**Actual**
Lab productivity	£50K	£55K
Data handling	£25K	£25K
Resource Mgmt	£20K	£25K
Automated reports	£15K	£22K
Test assig / Spec	£10K	£13K
TOTAL	**£120K**	**£140K**

The Montell LIMS review team found that in financial terms, the overall benefit in laboratory costs has been £140K. In addition, however, one unanticipated benefit with far-reaching financial implications was also identified:

Before the LIMS was installed, some grades of the polymer product manufactured by Montell was previously 'given away' from stock because it was not deemed of 'selling' quality. After the LIMS was installed, however, additional information became available, through the link between the LIMS and the Mainframe, to Montell's sales and marketing personnel. This information was based on data about the grades of specification of the finished product. 'Off specification' product could now be sold as a lower grade, rather than scrapped. This has enabled $4.6 million per year to be generated in new and unanticipated sales

The most frequently cited reasons for buying a replacement LIMS, in order of importance, are:

1. The laboratory has outgrown its current LIMS
2. Current LIMS is obsolete
3. Compliance
4. Dissatisfaction with current LIMS

Most LIMS will be either bespoke systems or purchased off-the-shelf packages:-

There is not much to choose between the major LIMS products on the market place, and hence selection should be made on the basis of the understanding of the user requirements, the lifetime costs and the support available.

There are significant costs and timescales associated with specification, selection, purchase, configuration and roll-out of LIMS. (This is dealt with in section 5 – How to choose a LIMS.)

A balance needs to be maintained between the company (corporate) interests and the laboratory (technical) interests if the LIMS implementation is to be effective.

3.2 Security

Database, desktop and Internet security must all be considered when any software, including a LIMS, is deployed. At all levels, the organisation, the manager of the system and the laboratory user need to be sure that LIMS data is reliable and secure.

Essentially, the owner of a system resource has the right to decide who can access it and that the operating system can detect when data is accessed and by whom. This provision has to be built into a LIMS so that the administrator can programme the installation to determine access privileges for given users or groups of users.

In most instances, every user is associated with a security ID, and before any operation, the programme security is checked to determine if the user has the permission or rights required to perform the operation.

This, of course, depends on being able to identify and authenticate the user, which is accomplished by the log-on sequence. This requires the user to provide a username and password. It is possible for security to be further enhanced by using a card reader or bar-code reader to identify a particular user, which would allow mobility within the laboratory with minimum inconvenience to the operators.

Finally, if security is breached accidentally, maliciously or deliberately then it is important that the system administrator finds out. This requires an auditing policy. For example, it is possible for the system to keep track of unsuccessful logons or unsuccessful attempts to access files or directories without permission which may indicate malicious activities such as hacking. The LIMS administrator must be able to view the logs so that it is possible for any unauthorised event to be flagged for the attention of the administrator automatically.

Previously, when paper was the main storage medium, data was authenticated or authorised by a hand-written signature. This functionality is now required for electronic data so that it is possible to see who, when, where and how data has been entered in the system. The FDA (US) published a rule governing electronic records (21 CFR Part 11) to limit confusion about what is permissible in a regulated environment. The FDA (US) guidelines, introduced in 1998 in the USA, have, in the absence of introduction of similar European-guidelines, been adopted as the only current standards to follow anywhere in the world for electronic signatures. The environmental industry is introducing similar guidelines called C.R.O.M.E.R.R. (Cross-Media Electronic Reporting and Reward—keeping Rule) but until each industry has applied its own guidelines for electronic media, the original CFR rules are in 2000, the only ones agreed and finalised worldwide.

This ruling requires that the LIMS must have system security controls limiting system access only to authorised persons, and that the LIMS must have functional security controls limiting users' access to functions and data. Since LIMS products now tend to conform to this standard, they will include these security features automatically. These features will be adequate to meet most other regulatory requirements. Unless the laboratory operates in a specially restrictive security environment, a typical LIMS will meet most needs.

To control identification codes and passwords, system procedures and LIMS functionality shall ensure the security and integrity of electronic signatures in the following way:

- Combined user IDs and passwords should be unique
- User IDs should be unique across time

A number of LIMS now offer an Internet browser front end to view, and process and report laboratory data. This allows data to be presented to non-laboratory users, without the requirements for end user training. Web browsers can be used either within a company-wide area network (ie Intranet) to access the data, or via a modem or the Internet, given suitable security provisions, which may be strictly enforced. Additional security provision may be necessary, e.g. firewall software to prevent unauthorised or malicious access.

4 Can a LIMS be beneficial in any Measurement laboratory?

Very few organisations across most industries would ***not*** benefit from equipping their laboratories with a LIMS.

Traditionally, LIMS is viewed as a tool for Quality Control laboratories, and used in continuous processes such as chemical industries. These laboratories provide a service to production that needs to know as soon as possible what it is they are making. This is needed to apply remedial work or to pump the intermediary product to the next phase in production or to pass the material as meeting a customer's specification and thus fit for release.

These criteria can be generalised to cover the requirements of any measurement laboratory to monitor its workflow, to control the quality of its operations, to ensure that a sufficiently thorough audit trail is maintained, and to provide the necessary information to management on the efficiency of the operation to show that both customer and cost control requirements are being met. The urgency to address such requirements will vary from industry to industry, and laboratory to laboratory.

Pharmaceutical companies get special benefit in that LIMS makes it easier to provide information for regulatory bodies like the FDA (US) to audit the processes taking place. A similar benefit could be found in other highly regulated areas, such as ionising radiation measurement.

For UKAS accredited laboratories in less regulated industries, the motivation to consider introducing LIMS will be more concerned with the other benefits of LIMS than the possibility that UKAS audits may be a little easier. The focus will be on some combination of workflow, quality control, cost control and customer satisfaction. When seen in this light, there is no reason why the benefits of LIMS could not be felt in most measurement laboratories. LIMS are not only applicable to chemical, pharmaceutical and food and drink industries, but also to industries like defence, aerospace, electrical and electronic equipment, utilities, transport infrastructure, vehicle manufacture, scientific and medical instruments, telecommunications, and construction.

Even small R&D laboratories can reap productivity, data integrity and information availability benefits.

It can be said that the only product that could be sold to any laboratory is LIMS. This is because LIMS provides unique and universal functionality. A LIMS must be generic enough to map onto any laboratory processes, but also must be configurable (and also customisable) enough to satisfy the specific requirements of any industry.

Historically, vendors have had a choice: -

- To develop a one-size-fits-all LIMS, with industry-specific features tailored to individual industries, or
- To develop a LIMS for each industry.

By adopting the first approach, customers from different industries benefit from features that are common to all industries, whilst the vendor can concentrate more on development effort and improving the overall product.

The laboratory often decides to implement a LIMS according to its primary laboratory function rather than the industry in which it operates. Quality Control and Assurance, Measurement and Calibration, Research & Development and Analytical laboratories all require management of their information, whether they are involved in materials testing and analysis, calibration of testing equipment, pressure testing etc.

The regulatory environment in which the laboratory operates often governs the necessity of a LIMS implementation and this in turn can also drive up the cost of the installation, as the need for regular audits drives up the cost of the software. This is because additional staff are required to add the necessary software programs into the product as well as write the accompanying documentation and validation material such as testscripts. Testscripts are documents which can run automatically after the system is set up to prove it is performing as originally designed.

LIMS also provides integration to instrumentation and measuring equipment to generate increased efficiency in turnaround times and by reducing transcription errors. Steel manufacture is a continuous process and without instrument integration, getting the results back to production quickly and accurately is paramount. There are huge savings in energy alone if seconds are saved.

Further to this is that LIMS plays a pivotal role in integrating into Enterprise Resource Planning (ERP) systems, providing functionality missing from these products and working in a way that is friendly to laboratory users. ERPs are used across many larger industries that include process, agriculture and food, as well as Contract Laboratories, etc. ERP provides an organisation with a global system for managing their processes from material delivery, through production, packaging and distribution. Quality modules within ERP systems manage and maintain the organisation's quality plans on a macro level. LIMS interfaces into the Quality modules of ERPs which are necessary so that information produced within the laboratory is immediately made available to the enterprise via the ERP. The benefits include automatic login of items and specification checking. The specification checking can be used to determine the quality of a product and to show that the laboratory and its methods are functioning correctly. LIMS is especially useful for environmental testing due to its quality control capabilities.

Other areas increasingly of importance are charging and workflow. Contract Laboratories, amongst others, need to know from a scheduling and budgeting point of view, whether they can do the work in the required time and their customers need to know the cost. The advantage of having this within LIMS is that it covers instrument and operator availability, costs per analysis, suite of tests, etc. That is, it provides an overall picture of the workings of the laboratory.

LIMS provides a service to the laboratory management, production and accounting departments and if correctly configured can meet the demands of the project-based R&D areas of a company. R&D testing is ad hoc in the main. Despite this many experiments conducted in an R&D laboratory can be built up by selecting measurement-modules which can be just as subject to analytical Quality Control, whereas the Quality Control environment requires more regular testing programmes. LIMS can be flexible enough to meet many R&D laboratory practices without becoming cumbersome.

The view is that LIMS is applicable to almost all laboratories in all industries where the business requirements justify its purchase.

5 How to choose a LIMS

For summary information please refer to Appendix 7 – A checklist for LIMS Purchasers.

Firstly, you need to decide whether you need a LIMS – usually a product that helps you be flexible, move to new techniques, adopt new measurement types etc, will be a benefit to your staff.

Once you identify the need for a LIMS, there are three options available to the laboratory:

- Stay as you are
- Do It Yourself
- Evaluate a product covering most needs and fill the gaps

Traditionally, LIMS were customised to meet the needs of individual laboratories, but increasingly customers are moving away from this bespoke approach (too costly and limiting in terms of management and upgrades) and moving onto off-the-shelf products that have flexibility designed into them and can be configured to match the laboratory needs.

You will rely on your LIMS vendor far more than on many other suppliers. Luckily, a successful LIMS implementation is almost as important for the vendor as for you. A dissatisfied customer is something no LIMS vendor can afford.

At the beginning of a contract the customer will have a hazy, perhaps even mistaken, view of the product, and the vendor may only have the vaguest idea of the customer's operation.

A vendor with experience of similar projects is obviously a good choice. In any case, it is in the interests of both parties to begin with a long period of discussion so that there can be no confusion later. Any reputable LIMS vendor will help the customer navigate the early stages of the project while the customer gains system expertise.

It is essential to research the history of a prospective vendor. Ask for the names of previous customers and talk to them. Most vendors will offer reference sites from their customer base at the shortlist stage. Talk to colleagues, Trade Associations, even your opposite number in other firms.

Stages to undertake in choosing a LIMS:

1 Desk research

2 Shortlist

3 Consultant

4 Writing a specification and issuing an RFP

3 Vendor selection

5.1 Consultants

Many LIMS vendors now advocate that potential purchasers appoint LIMS consultants to assist with the selection, justification and implementation processes. The aim is to ensure that your consultant brings *added value* to the project. Like your vendor, they should have experience of implementing successful LIMS and bring a defined and structured approach to the project from the outset.

There are a number of independent consultants who will offer to do the work for you. Most of these consultants will have more knowledge of one system over the others, or may be more familiar with a small number of systems in the whole range available.

There are however, still a number of advantages. The most obvious is that they are not trying to sell you a LIMS. A consultant should have the experience to draft a tight specification and suggest which companies to approach.

The consultant, for a fee, will be able to work with the purchasing laboratory to make a selection of vendor and system, to specify the product and to project manage its successful implementation. Typically, consultants will provide an unbiased view to draw up:

- Analysis of the needs
- Analysis of the laboratory workflow
- Analysis of requirements
- Preparation of RFP (Request for Proposal) or Invitation to Tender documents
- Evaluating the LIMS vendor responses
- Audit of LIMS vendor(s)

The consultant might be able to suggest features and concerns that had not occurred to you. And whereas a LIMS vendor will put you in contact with satisfied customers, a consultant should also know why dissatisfied customers are dissatisfied.

Of course, there are consultants and consultants. As in every other area there are consultants who know absolutely nothing about your business or their own. In choosing a consultant, check that they actually use and are able to test LIMS. Ask them where they test the packages and what they use to do so. Ask to watch them do it.

Make sure that they are independent and check on their reputation.

Whether using a consultant, or handling the LIMS project in-house, it is important to define who should be involved in the project (see more detail under Implementation).

5.2 The specification

System specification is half the battle in purchasing a LIMS.

Define the scope for your system and agree the boundaries

It is essential at the outset that prospective purchasers have clear aims and objectives regarding the LIMS. You should know why you want a LIMS and what benefits you can expect. Are you trying to increase productivity and integrity, to provide timely item information or perhaps to reduce the laboratory head count? A good start would be to talk to existing LIMS users and discuss what benefits they have gained rather than what benefits you anticipate. *If someone else has already been through the "justification–purchase–implementation" cycle then take advantage of their experiences.*

The most common form of specification takes the format of Request for Proposal (RFP) or Invitation to Tender (ITT) responses. The purchaser and/or his consultant produce a document consisting of the LIMS requirements they have identified. These are sent to a number of suppliers and a choice of system is made based on the replies to these documents and on a demonstration of the system.

For instance, it is a UKAS requirement (ISO/IEC 17105:1999(E): 4.12.1.1) that procedures are established for the identification, collection, indexing, access, filing, storage, maintenance and disposal of records. A period of retention for records will need to be established and this will have to be adequate for the work of the laboratory. Furthermore the certificate or report itself may be issued as hard copy or in electronic form so long as the normal reporting requirements are met (ISO/IEC 17105:1999(E): 5.10).

Is the software produced under a quality system, such as TickIT? What about validation? Is the vendor certified to ISO 9000 Part 1? What documentation is supplied? Is the design specification available? What is the code? Who will write software patches for the system? Can it interface with your instruments straightaway, or will you need a driver? The connection of instruments falls broadly into two parts – collection of a signal and then data manipulation. The professional approach to instrument interfacing is to supply an interface which not only electronically hooks up the devices but also manipulates the data in the desired way in order to reach the required final results in the LIMS. All of this should be audited of course. Some LIMS suppliers just supply software ("drivers") and then leave the customer to make the connections. This can be hugely time consuming for the customer.

Look at what type of data will be stored and on what medium. Both the durability of the records and their long-term accessibility need to be considered. The system used for storage needs to be both capable of holding the data securely and keeping it available for its required lifetime.

Possible degradation of magnetic or optical media can be provided for by regular backing up or transfer, if there is any doubt about the integrity of the media over long periods of time. As an example, records relating to employees occupational health are required to be maintained for a period of 40 years. If in the early 80's a decision had been made to use the 'best' video storage system available at that time, all that data would now have been on a Betamax tape.

The important consideration is to ensure that the data remains accessible and to ensure that contingency plans exist to transfer the data into a new medium if the original format ceases to be viable or supported. This also applies to acquisition programmes and their versions. For more information please refer to SSfM report: Format Standards for Measurements Data (www.npl.co.uk/ssfm/download/index.html).

Typically a LIMS database will be installed on a system which does not have the LIMS software loaded and thus the operating system at the database server will depend on the choice of database. This is most likely to be either UNIX or Windows NT/2000. The underlying database, if all sizes of systems are to be considered, is not most likely to be Oracle, although it is a very popular choice for big systems or for certain industries such as the pharmaceutical industry. Other well-used databases will include SQL Server, DB2, SQL Anywhere and Access. The client machines most commonly will run a version of Windows ranging from even 3.1 to 95, 98 NT to 2000.

Consider whether you need small, isolated systems or a single central system, a PC network or a minicomputer/mainframe implementation. Will it perform adequately for your workload? What about Internet connectivity? Will your clients want to access to the system? Which parts?

It is helpful to draw up a long list of questions, rather like the enquiries before contract when buying a house, or the due diligence in a merger or acquisition. A checklist at the back of this booklet will help you. Don't forget the financial aspect. A LIMS will interface to all the firm's systems. What about accountancy standards and regulations?

Ask for a demonstration of the system, and take along those who will use it. Most LIMS vendors run workshops or training days. Go to one. Sometimes the major differences will only become apparent during the implementation, but during a workshop these can be assessed by actually seeing how the system is set-up with real on-site examples. This enables you to assess how good is the functionality match, how easy it is to configure and assess what skills they will require to enable them to do it. If possible, ask about visiting other customer sites to see the proposed LIMS working in a similar environment.

Once you have the specification clear, you need to agree a timetable of installation, testing and training (how much is included in the price?). Most LIMS are bespoke systems. There will usually be some fine tuning. How will this interfere with the running of the laboratory? What can the vendor do about it?

There are 'off-the-shelf' LIMS packages. The questions to ask are the same as far as suitability is concerned, but the ease of configuration becomes especially important.

Remember that businesses change. Ask about upgrades and ask whether there is a planned future for the product. The product alone is the easy part. Subsequently, support and maintenance are essential if your system is to be a success.

One of the key points to remember when specifying a LIMS is to concentrate on business needs over the long-term and to ensure these requirements are managed to ensure the best fit of technology with your individual business.

5.3 Upgrading

This is one of the most overlooked areas in LIMS selection (although it is the reason for more than 15% of LIMS purchases) and often one of the most painful and frustrating experiences customers can go through. Many find they are locked into a legacy product or forced to upgrade to a brand new product for which there is no real upgrade path. The more regulated the environment, the less likely the customer will be to upgrade immediately, as re-validation and extensive testing will be required prior to upgrading.

Upgrades can, and are often carried out quickly and painlessly depending on the LIMS product selected, but will always need careful planning. Generally speaking, the further away from the core product you move, and the more extensive the customisation or specials that are provided, the more complex will be the upgrade process. At a certain point, the overall cost to the business outweighs the advantages for upgrading and upgrades will cease.

Thus it is important that the selection process focuses on how much effort is involved, and then how much time and cost were required. A product that is very new to the market will often be changing dramatically from version to version and therefore upgrades will potentially be more difficult. Similarly a system initially developed with customisation in mind will also bear potential obstacles and it is important to keep this in mind before you start.

Assessing vendor release history can be helpful, looking at the areas where different LIMS products have or are offered and what upgrade paths exist. How has the vendor supported advances in technology? How many different versions (major and minor) have been released? Find out how many of their customer base are using the current version, and look at the time, effort and overall cost involved in upgrading their systems. Check the end user experiences during reference calls or site visits.

5.4 Compatibility

Hitherto, universal standards for data sharing have not been considered when software is designed. Increasingly, developers of software, such as LIMS, are trying to ensure that all systems will be able to communicate using a common framework or protocol. An example of a common data format is XML (Extensible Markup Language), whereby data can be transferred between target systems using a common structure. (See SSfM report :Format Standards for Measurements Data on http://www.npl.co.uk/ssfm/download/index.html).

This new approach to universal standards for data sharing means, in theory at least, that the purchaser of a LIMS can begin to think in terms of a software that can fit into their growing business and accommodate future changes.

An open systems architecture for the LIMS is the best approach for compatible software interfaces and will allow seamless integration of third party applications.

This requires the LIMS to be written around independent architectures and common tools, so you are assured of compatibility and ease of operation. Standard common platforms also facilitate the upgrade path for the software, whereas legacy languages can result in unsupported and unusable LIMS. Independent architecture means that the operating system can run on different computers (examples include Unix, Windows NT, VAX/VMS etc.).

A LIMS selected on one of the more common IT platforms will interface with more software packages that are also available in that platform. For example, WINDOWS NT and WINDOWS 95/98 are the world's most common platforms. Similarly the industry-standard relational databases are Oracle and Microsoft Access. The common access mechanism is the internationally standardised language SQL. The interface between a LIMS and databases should be SQL to give maximum flexibility.

Current industry-standard tools should be used for the LIMS underlying database access code, application code, and user interface code. By selecting a LIMS designed in a component format (COM is a binary standard for cross process machine and platform communication with OLE, DDE, or ODBC capabilities) such as ActiveX, COM, DCOM, ADO, the purchaser is guaranteed of being able to link to major applications in MS Excel, MS Word, Lotus Notes and VB.

The purchaser should consider existing packages in use in the laboratory before specifying the LIMS, to ensure that their future needs are taken into account. E-mail and accounting packages are good examples of other systems to remember to include in a specification.

If an industry has its own IT infrastructure, it is extremely useful that a member of that infrastructure is involved at all stages in the LIMS selection process. If a particular industry does not have access to such an infrastructure, it must consider the implications of this at each stage of the process and future maintenance.

5.5 Paying for a LIMS

A LIMS is as expensive as any piece of custom software. At Year 2000 prices for a single user LIMS can be as inexpensive as £8,000, upgradeable in an almost infinite number of steps. At the top end of the the market more than 5% of purchasers of LIMS have a budget of more than £500,000! For such a large expense, it helps to get definite costings as soon as you can. You can lease and even rent a LIMS, and there are a few specialised bureaux where you can rent time on a LIMS. In the case of the latter, consider the constraints on when you can use the LIMS and look carefully at the security (in the sense of integrity and confidentiality) of your data. What will you do if the bureau goes out of business? What if it burns down?

Key points for choosing an affordable, cost-effective LIMS involve cutting the requirements down to what is really needed and a consultant can help this process by guiding you to avoid extraneous expenditure. Equally, keeping some options for later, if they are proven to be necessary through experience of usage, allows spend to be spread.

However, it should also be recognised that if functionality is dropped from the LIMS requirement specification (e.g. certificate production) then there will be additional costs of interfacing the LIMS to any legacy software. For more information please refer to the SSfM document:
Legacy Systems in Metrology (www. http://www.npl.co.uk/ssfm/download/index.html).

5.6 Choice of Supplier

Be aware that many, if not all the major vendors, are capable of providing you with a LIMS that will meet your current needs. You need to be aware your aim should not only be *"**a successful LIMS implementation"*** but also the need to *"**install a successful LIMS".***

Ideally, your system should have a lifetime of at least 8 years and for this to be viable it will need to grow with your laboratory. You will need to perform many upgrades over the coming years as new features become available. By building a successful vendor/customer relationship you will give yourself every chance of success. Therefore, when evaluating the systems offered, take time to consider the vendor and enquire about their strategies for customer services, company stability and future development of their product.

In addition, the choice of supplier should focus on the support the supplier can provide – do they really understand your type of laboratory, do they offer the right level of support, are they sufficiently on-hand (at minimum with a UK base) to meet your needs?

6 Implementation

Implementation is often underestimated and never completed because more usage is found for the system as time marches on. For a large system the average time to implement a complete LIMS system is 11 months (multiple man-months of effort) (only 15% of LIMS are completely installed in under 6 months and many take more than 18 months to install). The best LIMS software in the world can be compromised by poor implementation.

It is advisable to divide the installation into realistic goals for completion at regular intervals. At each stage ensure that you can demonstrate a working system.

It is better to fully implement a LIMS from sample registration to reporting for one product type than to implement sample registration for all possible product and sample types.

The implementation process does not start once the software product has been purchased. It is something that should be planned immediately a decision is made to consider a LIMS for the laboratory.

The term 'implementation' is wide-ranging in the case of LIMS. Depending upon the size of the laboratory, the number of users, the complexity of the LIMS software, the integration requirements, and the timeframe permissible, the implementation can be a short (hours and days) project or a long contract lasting many months.

Typically, several of the following tasks will be required as part of the implementation:

- Review of business processes
- Design specification
- Software development
- Configuration and customisation
- Project management
- Installation
- Software testing and validation
- Training
- Integration
- Roll out

The end objective of the implementation is to receive a LIMS on time, on budget, and that functionally meets the absolute necessities of the laboratory as defined.

To work successfully, an implementation project requires a good plan. The realisation of the plan will depend upon quality and mix of the team responsible for the implementation.

6.1 Content of your Request document

(For more information please see Appendix 3 - Putting together a Justification for a LIMS)

Appreciate that for any dynamic laboratory, the business needs will evolve during the LIMS implementation and quite possibly during the selection process. You are trying to cater for the ever-changing laboratory process, so avoid detail on how you will achieve your requirements and concentrate instead on your needs; the "Why you need something" and "What you are trying to do".

It is vital to remember that the LIMS must meet the current and future expectations of the users. Furthermore, it must ***meet the needs of both the laboratory and the company***. Regardless if one side drives the justification and project, unless you give both the laboratory and company equal weighting, then ultimately the LIMS will not be considered a success.

6.2 Communication

Working in partnership with the LIMS supplier is the key to the implementation meeting your needs and being delivered on time.

Outsourcing and third party implementation services carried out by teams not supplied by the vendor do not work unless these service providers are very closely aligned to the aims and ambitions of the supplier whose system they are implementing.

Any part of the team participating in the implementation must either:

- Represent your, the purchaser's, needs (and different viewpoints, ie management as well as users, IT, as well as laboratory etc.), or
- Represent the vendor

They must know the product, and/or know the customer environment. Third parties do not usually have close enough ties with the supplier and are not prepared to invest in the necessary training.

A balanced team to project manage the implementation will include representatives from the user community in the laboratory, and individual departments if these need to be included. It is important to involve the people who actually do the work directly with the implementation team from the LIMS supplier.

The logical steps to a successful implementation include:

- Plan in advance
- Define the scope of the LIMS using managers, users and suppliers
- Agree the necessary inclusions, the preferred functions and those areas that, time permitting, will be included or dropped
- Be flexible and prepared to change the implementation if needs change
- Keep to timeframes
- Plan suitable change management techniques.

Work on the assumption that different personnel will have different requirements of the LIMS. Added to this is the fact that much standard functionality in a software package such as a LIMS, may rarely be used in your environment. It is therefore vital that you, the purchaser, have agreed with the LIMS supplier the areas of LIMS that best match your business, and focus on ensuring that you get the best from this functionality during the implementation.

To do this, it is highly recommended that your requirements are defined and agreed by both parties *before* the implementation commences.

6.3 Who should be involved at your end?

The customer Project Team should have Operating System and Database administration expertise, and detailed knowledge of your IT landscape. The actual number of IT staff people needed for this expertise is typically one per laboratory, but of course this depends upon the size of the laboratory and the scale of the project. It is imperative for the success of your LIMS project that proper involvement of your personnel is maintained. Companies who outsource their IT should think seriously about involving a consultant who can oversee the LIMS specification.

Take time to bring together a productive project team consisting of members who will be stakeholders for the new system. It is never too early to start the communication and gather information.

6.4 Getting the best from your vendor

Almost certainly the vendors will have more experience with LIMS implementations than you, so give them the scope to use their greater experience and suggest/propose how to find a solution, let them solve the ***"How's".***

Do not forget to consider your preferred way of working and interacting, and build this into your RFP document. What is the extent of interaction allowed/required between you and the vendor's personnel during the development and implementation phases? How will this be done (electronically, site visits, phone etc.)? Ensure that the proposals suit your staff and your working environment, as well as allowing for the best way in which the LIMS vendor is geared to service you.

Depending on what sort of LIMS you have chosen will determine what is required for getting the best from your vendor. Bear in mind that certainly, initially, the objectives for both you and the vendor are the same, with a successful LIMS installation and operation, top of the priority lists. The project now moves from the saying to the doing, and great care has to be taken that everybody is focused and committed to delivering on the project objectives.

A partnership approach will provide major benefits for a successful relationship with your selected vendor. Behind every LIMS is the contract, but this should not be used as the basis for a relationship, it should only be used as a last resort when all else has failed.

During the implementation stages, the interaction will be with the vendors' implementation personnel, but these early stages of the project are where vendor and customers are at their most vulnerable. The customer does not know the product in-depth, and the vendor has little knowledge of the customers' actual operation. Using the vendor's experience of previous projects will help you navigate successfully through the early stages of the project while you gain system expertise.

The customer will have agreed to their roles and responsibilities and the vendor will have agreed their roles and responsibilities, the functionality is agreed, the timetable is set and the project can start. As the project proceeds different pressures will be brought to bear, the team's objectives will be to overcome any issues brought up and therefore should be given the ability to deal with those issues by making decisions. Support and back-up are essential for the combined project team during these periods from both the customer and the vendor when tough decisions have to be taken. Expectation setting from both sides is very important and a sense of realism will also be needed if the implementation is going to be successful.

There will most likely be areas where compromise is required, due to the fact that previously stated requirements have changed or are different to what was initially envisaged. This is why a good partnership approach is necessary for smooth running, as issues that arise can be dealt with effectively and with clarity.

An open and understanding approach between vendor and customer will usually provide a better outcome than through confrontation, as there is rarely a situation where one side is absolutely in the wrong. By working with the vendor to allow promotion of the site, such as providing references and testimonials, will ensure that the relationship is a win-win partnership.

6.5 Take the opportunity to redevelop your business rules

Whether you are replacing a manual system or an earlier generation LIMS, you should take the opportunity to avoid replacing "like for like" without examining the business needs of the laboratory. Too often, we perform tasks for historical reasons only resulting in inefficient working practices.

7 Initial laboratory audit

A laboratory audit before purchase helps to identify what you require the LIMS to do once installed.

Do's for prospective LIMS purchasers:

- Review the existing IT/Computer infrastructure.
- The LIMS must be able to fit in with your existing investments and be flexible.
- Review the current number of IT users and anticipate future growth of your laboratory for 10 years before deciding on licence requirements for the LIMS. Allow for all anticipated expansion of both people and workload.
- Undertake a total review of your laboratory workflow – projects, experiments, analyses, items and quantities etc. Consider who currently undertakes what, why this is their responsibility, how you want the LIMS to improve on current practice. Bear in mind all the elements of item logging, tracking, reporting, archiving, querying, worklist generation etc. undertaken in the laboratory.
- Undertake a total review of your instruments and how frequently they are used. If possible, map the item path related to the instruments used so that you can assess which data is required/associated with each item.
- Consider the reports that the LIMS will need to generate. Who will need to receive what information? In what format? What is the current procedure for reporting? How can this be improved?
- Review security. Who is authorised to do what and why? Will this change?
- Review your regulatory environment. How often is the laboratory audited and for what purposes? Build these requirements into your specification.
- Review the variability of testing or calibration performed – parameter ranges, uncertainties, different specifications or standards used, different equipment used, different materials/chemicals/gases used, etc.
- Identify what are the data handling requirements and parameterisation requirements coming from this variability?
- Identify what is needed on a test report or certificate? Can it or should it be streamlined from what is offered now? Is all that is offered now really needed by customers? Is any more needed that is not currently provided?

8 How to run a system

LIMS are usually supplied with a full warranty period. Off-the-shelf solutions usually have a pre-defined contract allowance for support, training etc within the scope of the terms. Ensure before you place the order that you are comfortable that these suit your needs. The warranty period for the LIMS cannot commence before you have received a satisfactory implementation.

As a customer, for your peace of mind, ensure that your total LIMS project timetable allows for a suitable time frame for the user training, and that this coincides satisfactorily with your implementation and warranty timings. The users of the system are more likely to be using the system, and requiring the services of the vendor's support services following the system training. You therefore do not want the training to come after the warranty has expired!

8.1 System Management

The LIMS can be managed internally by a nominated and trained member of staff, or managed by the vendor. If the internal nominated system manager requires a more in-depth LIMS training programme, plan this into the total LIMS project to take place before the users are trained in the system. Consider the demands on your staff resources to manage the LIMS in-house. Is this at least part-time for one person? The amount of time depends on the size and complexity of the finished system. For a system of relatively simple design, it should be less than one person full-time.

8.2 Training

User acceptance of the new LIMS is often reliant upon how familiar and comfortable they are with the system and that it meets their 'perceived' needs. To meet any accepted quality system requirements, such as required by UKAS accreditation or ISO 9001 registration, it will be necessary to be able to demonstrate that all staff are adequately trained, and thus that those using the LIMS system are adequately trained in its use.

Adequate training and training records is a requirement of ISO 9001 and ISO/IEC 17025 (the replacement for ISO/IEC Guide 25). In some regulatory environments this extends to a requirement for certification of personnel.

LIMS training is offered in many different ways by different vendors. Remember that your own users will have different levels of expertise and these must be taken into account before the training begins to offer you the best value.

Find out from your chosen vendor in advance what they recommend to meet your training needs, not simply what they offer you. Define to the vendor what you want, where you want it to take place, and how long it can last. Once you are satisfied, ensure that this is a part of their contract.

Training may be offered on-site or at a vendor's premises by an instructor. Training may be offered face-to-face, or utilising remote tools such as via the web, or multi-media tools including 'Help' options built into the software. Some vendors advocate a 'train the trainer' or 'cascade' approach, which means that one member of staff is trained by the vendor and tasked to provide an internal support for their colleagues.

Find out how many members of your team will need to be trained, and whether they will benefit from being trained independent of each other, and whether exposure to other users from other industries on training courses will increase their grasp of the software. If you need training to be offered in multiple languages, such as English, French, Spanish and German, check that your chosen supplier is capable of offering this.

At the very least, ensure that you are provided with up-to-date and usable printed training materials and documentation related to the version of the LIMS purchased, as a part of your LIMS delivery.

8.3 How to use a LIMS

The project lifecycle, from commissioning to up-and-running will be from six months to a year. Right at the beginning, ask the vendor how long the LIMS will take to install and how long it will take to train staff.

Don't underestimate the time spent on entering data into the new system. When Boots Contract Manufacturing introduced a LIMS in 1997, each of four sites spent at least 16 weeks in dedicated data entry.

8.4 Connections

There was a time when the instruments, workstations and servers were simply connected with cabling. This has changed with the growth of Intranets (a fancy name for a Local Area Network) and Extranet (ditto for a Wide Area Network). There are programs — such as that from Hypervision which will connect everything by radio, using 2.4 or 5.7GHz. A wireless LAN is useful in buildings difficult to cable (because they are listed, for instance) and in explosive environments.

But most LIMS will be cabled, and that will mean disruption.

8.5 Interfacing

One of the main reasons for implementing a LIMS is to integrate laboratory instruments. The instruments that will report to the LIMS (and perhaps even controlled by it) will have formed part of the specification. The vendor should have allowed for all of these. Historically, the evolution of technology has hindered the completion of all instrument integration into most LIMS because of the time required to undertake this and the lack of open integration standards common for all software. Some instruments produce their data in specific formats. To incorporate this data automatically, the LIMS has to be able to integrate raw data in different formats. It is highly likely that you will add instruments during the lifetime of the LIMS. Will these be easy to integrate? The vendor will help — perhaps at a price. There are various third party programs, such as LIMS Link, which claim to link any instrument to any LIMS. Other vendors provide the tools within or as a bolt-on to their LIMS.

It is important at specification stage to take into account your need to transfer data automatically within your laboratory into the LIMS, and to consider the cost implications if this will be an additional expense. Do not find yourself in the position of having selected a LIMS that will not easily meet these needs.

8.6 Data Storage

The maintenance of the data is a key function of a LIMS. All information produced by the laboratory is stored in a database, usually located on a central server. To access data, the database selects the relevant stored data from a database table on the server.

Most LIMS use relational databases developed by specialist companies, such as Oracle and SQL etc., rather than on a custom-developed database.

A relational database means the tables in which the data are stored can be linked to each other, making the data easier to access. Data is stored in fields, and records of the laboratory are therefore stored as data fields for future access in the LIMS database.

As with any software, the LIMS server must be kept secure and a competent backup programme must be in place to ensure that data is not lost in the event of server downtime.

8.7 System Support

Most vendors offer support hotlines and e-mail facilities for customers to access 24 hour support desks. Consider your times of need. Decide whether you need LIMS support during business hours on business days or around the clock in all time zones.

8.8 Change Control

Typically, the original requirements **will** change even between drawing up your specification and getting to implementation stage. Sometimes, just involving users closely will allow them to identify where original details of the 'overview specification' were incorrect or how their own needs have changed since being originally defined, and new requirements will be identified as they become familiar with the possible opportunities offered to them by the LIMS.

By producing a plan of your required functions, your preferred functions etc. with the vendor, the plan can be used to create the functional specifications, design specifications, module specifications and test specifications for the system that form an important part of the validation material that is required.

Indeed, it may be acceptable to replace the original requirements specification totally! The individual requirements in a new or revised plan should refer back to the many requirements defined in the original RFP or ITT, providing complete traceability. Because of this traceability, change control (due to changing business needs, and other reasons) will become simpler to manage during implementation.

Normal change control mechanisms can be put in place. The best way to prepare for changing needs is to plan for them. Assume at the outset that the original specification will change and assume that your final delivered LIMS may be a totally different (and better) system than the one you originally anticipated receiving.

9 Validation

For more information please refer to SSfM best practice guide no. 1: Measurement System Validation: Validation of measurement software, by Brian Wichmann, April 2000 (www. http://www.npl.co.uk/ssfm/index.html), as well as: A Methodology for Testing Spreadsheets and Other Packages Used in Metrology, by H R Cook, M G Cox, M P Dainton, and P M Harris, NPL Report CIDE 25/99, September 1999; and SSfM best practice guide no. 2: The Development of Virtual Instruments, by Luke Emmet and Peter Froome, Adelard.

The initial testing of a system is something which needs to be considered in the initial stages of its specification. Having decided on the requirements for a system it is important to consider how the supplier is to demonstrate that the requirements have been delivered.

9.1 Validation Planning and Execution.

Can you have too much validation? Probably, but who wants to be responsible for drawing the line if a corporate standard for software validation isn't present, or doesn't really address LIMS?

Furthermore, one needs to distinguish between testing that a user can do (e.g. for acceptance testing of a LIMS) and validation that only a supplier can perform. LIMS purchasers should initially seek evidence from the supplier of what validation has been carried out, giving guidance on what is acceptable. The LIMS should be fully tested by the purchaser in each configuration in which it is to be used, using a combination of test data and dummy running of the laboratory service that it is being used to control.

More information and guidance is provided in SSfM Best Practice Guide Number 1. There are several main approaches to testing a LIMS system, as outlined below:

I. Complete validation of the source code for the software

This will usually only be practical for the very smallest of applications, and it may be difficult to consider all the possible conditions which will affect the operation of the program.

II. Testing with known items

For an analytical system items with a known value (reference standards) can be analysed using the system and the measured result compared with the known. Alternatively it may be possible to analyse items in duplicate, one by means of the LIMS and the other by the 'standard' methodology.

III. Testing with test data

This type of testing can take many forms, at its simplest level one might test a spreadsheet used for calculating results by entering data and comparing the spreadsheet result with one calculated by alternative means (calculator, abacus or fingers and toes). A more complex system might involve the use of a signal generator to simulate the output of an instrument, the expected result of which is known, and checking the reported result from the system.

The three most common procedures for LIMS validation are:

- IQ (Initial Qualification)
- OQ (Operational Qualification)
- PV (Performance Validation)

These terms are standard across the laboratory market among users of LIMS. There is a ying-yang relationship between too much (higher cost/less risk) and too little (less cost/increased risk).

Do you know your company's line of demarcation? While IQ and OQ scripts and guides may be available (usually at a cost) for some products, PV is up to you, and your specific implementation.

It is expected that most or all LIMS will have to be subjected to all three stages. The validation is often undertaken by the user, or can be carried out by the vendor or a third party.

9.2 Black Boxes

Computer software is inherently complex and often, to the user, unintelligible. As a consequence it is common to treat computerised systems as black boxes and consider them solely as things into which data is put and from which the answers issue. This approach operates from the stance that the inputted data can be worked on by other methods which are known to be sound and if the data so obtained is consistent with that produced by the black box, then it can be assumed to be functioning properly.

The danger with this approach is that it is not possible to apply test data which will demonstrate that the black box will operate properly in all circumstances. This can only be achieved by a detailed knowledge of the workings inside. Unfortunately, it is probably not possible to have an adequate knowledge of the software inside the box either; MS Windows 95 contains around 5 million lines of code.

The best that can be achieved for the validation of a black box is that an adequate set of test data is used which will replicate all the likely scenarios that can be envisaged. Even then, it is likely to be possible to propose 'what if?' problems which will not have been addressed by the validation. As an example, consider a hypothetical instrument that is used to analyse blood items for prohibited drugs. It would be very hard to devise a validation protocol that would ensure that the software engineer had not inserted commands to the effect. "If my name is entered as the test subject then provide a null result". This sort of hidden bug would also be difficult, although not impossible, to detect from an examination of the source code.

The practical solution to the problem may be to ensure that the software is developed under a system which eliminates programming features which will affect functionality and to test this with a validation which ensures that the system operates as expected within normal operating parameters.

Not all hidden problems are malicious. Some are caused by misplaced calculations or algorithms, rounding routines are one example of this. There are many ways of rounding the 'surplus' digits in numbers, all of which have an effect on the final result of a calculation. The obvious way of rounding in a particular application is not always what is contained on the software, particularly proprietary software. Three examples of ways of rounding are:

- Rounding before calculating instead of calculating using all significant figures and rounding the final result. (In fact the latter is impossible in floating point as rounding is built-in to all floating point calculations)
- Rounding dependent upon the integer of the number – odd rounds up, even rounds down 1.7 => 2 ; 2.7 => 2
- Rounding dependent upon range. <2 round to 2 decimal places, <10 round to 1 decimal place, < 50 round to integers.

Clearly, each will give different results in differing circumstances, some of which will be consistent with one another, others not and identifying the cause of problems identified during validation can be very difficult without detailed knowledge of what is going on inside the black box.

9.2 Calibration

When calibrating instruments it is important to consider the effect, or potential effect, of their connection with a LIMS system. It is often easier to calibrate a specific instrument in isolation from the LIMS system, particularly if the results normally appear somewhere remote from the instrument itself. However, there is a need to ensure that the data which is displayed/recorded locally to the instrument is the same as that which is presented after being processed through the LIMS.

9.3 Running a LIMS

Of course, you must have your own contingency plans for disasters. You also need to consider regular (internal quality) audits to demonstrate that there is eveidence the system continues to perform as required, that it remains fit for purpose. To this end the vendor must provide the user with testing scripts to facilitate the validation of the standard system.

Regular reviews should look at the availability and necessity of upgrades. Staff need a training programme.

10 CONCLUSION

Selecting a LIMS that is right for your company will yield enormous benefits in terms of productivity, staff morale, reduction of transcription errors and improved item tracking and reporting. By planning the procedure very carefully and allocating sufficient resource and time to the project, it will be probable that you will be rewarded with a system that repays your financial investment and which will play a fundamental role in your laboratory for the following five to ten years.

The LIMS you choose is largely irrelevant to the project. Most vendors will not tell you, but there is little to choose between one off-the-shelf LIMS product and another. They should all offer you the simple LIMS functions of item login, item management etc. Bearing in mind the many changes that you will go through from your first decision and your final delivered product, it is rash to judge the LIMS choice on software alone.

The differences will become apparent in the way that the vendors work with you. It is important to select and work with a vendor who is truly a LIMS specialist with a good track record. To be avoided are the larger number of people and organisations who may claim to be able to meet your requirement for a LIMS, but are more "jacks of all trades", with no real experience or track record of delivering and installing LIMS systems.

Choose the LIMS based on:

- Your future technology needs, not your historic or current status quo
- The three LIMS products which, following desk research, emerge with the best reputation *in your own field*
- The vendors who have a best 'interpersonal' match with your company
- The budget and timescales
- The functional match of your needs and the standard product, not the *customised* proposals.

The LIMS user forum is truly international and no UK-based organisation serves it. To help you choose a LIMS and to find information from other users, there is an independent international LIMS server at www.taratec.com which is subscribed to by existing LIMS users worldwide. Solicit their opinion at every step of your decision, as they will all have been through the same stages that you are about to embark on. The subscribers can offer a wealth of experience covering most areas relating to LIMS, and many UK-based users are highly participatory and will do their utmost to reply to your questions.

The Product alone will not mean a successful LIMS implementation. The implementation approach and methodology, as well as the skill sets of the people, are all essential in ensuring your project runs to plan. Subsequently, support and maintenance are essential if your system is to be deemed a success.

10.1 Company Focus

Are you just another order for the company, and therefore will they then pay you scant attention, or are you important to their business and will they therefore be attentive to your requirements. The overall focus of the company will be of importance. How important is LIMS to the company concerned, how diffused are their activities? Remember just because you employ 10,000 staff and advertise the fact that you are the 'biggest' and therefore 'best' does not mean that you actually provide the best products and service!

Also of importance is to look for any potential future conflict, such as if the company has more than one product in the same market, which product will eventually win? If you have chosen the wrong one, will you be left with a matured product?

10.2 Functionality & Flexibility

Does the system provide the functionality required? If you are taking an approach where you want to take the benefits of a configured solution, can the system then be configured to do what you want, and who has to do it? Finding the boundaries to the product is essential ie what you can and cannot do easily.

How does the system cope with changing business requirements? A rule of thumb is that a business will change by 10% per year and that is without mergers! As your business changes the requirements for the laboratory will probably change as well, and at that point you have to be sure that the system can cater for these new requirements, and that you can undertake them as required.

10.3 Configuration versus Customisation

Can the product be configured easily by you, or does it rely too heavily on vendor people to do things for you? Turning this on its head is also important. Can the system be expanded easily into new areas as your business changes or is it too rigid and any additions require bolt-on code provided by the vendor?

Ask for a Workshop during the selection process – 'all LIMS are the same' is a common statement from companies based on a couple of hours overview demonstration. Sometimes the major differences will only become apparent during the implementation, but during a workshop these can be assessed by actually seeing how the system is set-up with real on-site examples. This enables the customer to assess how good is the functionality match, how easy it is to configure, and what skills the staff will require to enable them to do this.

Proven successful track record – when selecting a LIMS, one of the key issues is to be able to decide whether the LIMS company is right for you. Have they a track record of successful implementations to back up the claims? The user base will often give you an indication, but it is important to look at recent examples.

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12 Update Information

If you would like to be kept informed of future developments in LIMS, training courses, presentations, etc, please email or fax your contact details to:

Mr S M Lower

Sira Test & Certification Ltd

Tel: 020 8467 2636

Fax: 020 8295 3005

Email: smlower@siratc.co.uk

APPENDIX 1

Glossary of Terms

CSV	Computer Systems Validation
CFR	Code of Federal Regulations
EPA	Environmental Protection Agency (United States)
CROMERR	Cross-Media Electronic Reporting and Record-keeping Rule.
ERP	Enterprise Resource Planning
FDA	Food and Drug Administration (United States)
GALP	Good Automated Laboratory Practice. Guideline produced by EPA (US) for guidance on the validation and operation of a LIMS in an EPA (US) regulated laboratory
GAMP	Good Automated Manufacturing Practice. Guideline produced by the GAMP forum in association with the International Society for Pharmaceutical Engineering and the International Association for Pharmaceutical Technology
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
ITT	Invitation to Tender
LAN	Local Area Network
LIMS	Laboratory Information Management System
NMS	National Measurement System
ODBC	Open DataBase Connectivity
OECD	Organisation of Economic Co-operation & Development
PDA	Parental Drug Association
PhRMA	Pharmaceutical Research and Manufactures of America
QA	Quality Assurance
QC	Quality Control

QMS	Quality Management System
RFP	Request for Proposal
SAP	(vendor – see www.sap.com)
SEM	Scanning Electron Microscope
SOP	Standard Operating Procedures
SQL	Structured Query Language
SSfM	Software Support for Metrology
UKAS	United Kingdom Accreditation Service
Validation	Qualification of software and related processes to assure, and continue to assure, correct operation through appropriate and documented planning, specification, testing and reporting activities
WAN	Wide Area Network
WLAN	Wireless Local Area Network
XML	Extensible Markup Language

APPENDIX 2

Checklist of questions to ask a manufacturer

There are many reasons to purchase a LIMS. They tend to range from financial justification, intangible quality gains, and regulatory pressures or to provide a competitive advantage. When looking for a LIMS there are fundamental questions to ask the manufacturer, some of which are listed below:

Company and product history

What is the manufacturer's history in the business?

Are they based in UK, or do they have local staff to support you?

Does the manufacturer have a proven track record?

Does the manufacturer have a proven track record of rolling out the product over multiple sites?

Is there a comprehensive list of customers using the product to give confidence?

Can you visit a reference site for an independent customer opinion of the proposed supplier?

Is there a record of accomplishment of being in my industry?

Have a large number of LIMS been implemented in your sector?

Is the entire user base using the current version of the system?

Commercial

How much does the company depend on the LIMS business for survival?

Are you being offered the correct product?

Can you be supported locally and globally?

Development budget as a percentage of revenue

Do you want to take ownership of the LIMS system?

How long is the warranty?

Is the company financially sound and likely to be in business during the lifetime of your LIMS

Is the vendor supplying more than one product?

Is there a planned future for the product?

Is there a requirement to integrate instruments?

Is there the corporate ERP or other systems to be integrated?

Last full year financials?

What is your price range?

What is the cost of that support?

What level of ownership is there in relation to what the customer can bring to the project?

Technical considerations

If there are any specific industry related modules required, like shelf life testing, water management, etc? can the company supply them?

Are there restrictions on the database structure – is there a limit on the number of tables, etc?

Are there specific IT restrictions on how things can be set-up?

Does the manufacturer need to be involved every time you need to change something?

Does the manufacturer only produce customised systems?

Does the manufacturer offer the technical solution you want?

Does the product have a record of successful upgrading?

Is the product an open system that is portable?

How does the system address changing requirements? – who can do these changes?

Is it to be configured only?

Is the level of support required sufficient?

Is the product intuitive and readily configurable by the customer?

The company may impose hardware and software restrictions and these must be identified early on in any project. What are they? What if they change?

What level of support does the vendor offer and at what cost?

Staff

What is the number of direct employees?

What is the number of implementation employees?

What is the number of support and service staff?

Does the Company employ project managers who can handle my project?

Accreditation

Is the company registered to ISO 9001, including TickIT?

Which certification body has been used?

Is it accredited by UKAS or by another accreditation body recognised by UKAS?

What is the date of original registration and scope of current registration?

Does the LIMS conform to international patent and intellectual property regulations for proven non-breaches of security?

Is conformance to FDA (US) rules required? If so, does the product conform to the FDA (US) rules governing electronic records (21 CFR Part 11)?

General

Is there current litigation against the company?

Is the product multi-lingual?

What training would be recommended for my project?

Will the manufacturer vendor provide suitable training and at what cost?

Are they the type of organisation that you feel you can work with?

Does the company inspire me with confidence they can deliver?

APPENDIX 3

Putting Together a Justification for a LIMS:

Justifying a LIMS internally and upwards to managers is usually the responsibility of the laboratory manager. Specification of any system is justified by a combination of user requirements, shifts in technology, and the need to update existing systems and budget availability. If the demand and justification is great enough, a company can usually justify the budget allocation.

The justification is usually the first stage of the project and therefore requires some consideration to whom you are having to justify. Often, the justification will need to go to the IT department, the Purchasing department, the Financial Director and the Managing Director.

The justification should account for or include:

- Itemise your current status quo, and reasons for requiring a LIMS
- Explanation of what a LIMS is and what it will deliver
- Requirements (internal and external) that it must meet
- Expected benefits
- Financial cost benefit analysis

It will help your cause if you can itemise the time and effort afforded by personnel on tasks that will be automated with a LIMS, for example:

- Item turnaround time
- Job tracking time and obstacles
- Current ease/difficulty of management reporting
- Job scheduling and resource allocation
- Time spent on data transcription including re-entering results etc.

If possible, quantify the savings you anticipate in financial or hourly terms. For example, once you have successfully audited some of the key areas that the LIMS will impact on, itemise the possible changes in terms of the amount of time the liberated personnel can allocate to other tasks. Occasionally, staff worry that a LIMS will replace their jobs, but it is frequently found that the LIMS offers true job satisfaction rewards to its users by eliminating menial and repetitive tasks, and allowing them to concentrate on more skilled and productive work.

You may discover, once you have the LIMS, that it offers you unanticipated benefits over and above your initial expectations. Normal areas which will be affected, and which you should therefore include in your justification, are:

- Data handling time
- Resource management
- Automated reporting
- Laboratory productivity

Many existing LIMS users carry out regular (3 yearly for example) reviews and assessments of the LIMS usage and its benefits. It should be possible to approach these users to ascertain their own measurements of the LIMS they are using and how its cost benefit ratio has been justified.

The section below includes typical examples of overview justifications for LIMS:

A LIMS is a software package for storage of result data, organisation and scheduling of laboratory work and also acts as a management tool for improving efficiency in the laboratory. It can also be used to handle the "ad hoc" requirements of the consultancy business.

It will enable our laboratory to increase productivity, allowing additional testing without increasing staff numbers and provide a superior service to its customers.

Implementation of LIMS will :-

- Improve the quality system by having visible traceability of all laboratory actions. This will significantly help UKAS accreditation.
- Provide management with tools for optimisation of both laboratory and business resources and identify profitable business streams within the operation.
- Reduce paperwork and speed up dissemination of laboratory results.
- Improve the level and quality of reporting.
- Improve the quality of analysis by reduction of transcription errors. Data is automatically captured from key laboratory instruments.
- Even out analyst's workloads and make the best use of resources.
- Create quotations and invoices.

The requirements that our company has of a LIMS include:

- Validation – compliance to GLP, GMP and quality system requirements to meet ISO 9001 or ISO/IEC 17025 as applicable
- Ease-of-use – MS Office™ explores 'look and feel' will reduce the learning curve
- Robustness
- Credibility – a vendor with reliable pedigree
- Cost – must present a positive cost benefit case
- Flexible – allowing for in-house configuration
- Open access – using non-proprietary hardware, software and databases

APPENDIX 4

Satisfying Good Laboratory Practice (GLP) guidelines

The LIMS package must satisfy Good Laboratory Practice (GLP) guidelines.

- Audit trial capabilities (who does what, where and when?)
- Item identification numbers must be unique
- It must be possible to regulate access rights to the LIMS
- It must be possible to restore the database following system crashes
- Recording of date and time
- It must not be possible to amend data from records simultaneously
- Security mechanisms must be installed (passwords, logout mechanisms, etc.)
- Automatic data collection
- Data verification and authorisation capabilities must be available
- The development of the software must be validated according to established procedures
- The following documents must be loaded and/or retrievable
    - Functional specifications
    - System description
    - Source listings
    - Error-recovery procedures
    - Back-up procedures
    - System-security procedures
    - Hardware and software manuals
    - Declarations of competence
    - Installation validation
- It must be possible to log routine items easily in the LIMS. The type/category of item must be known so that a fixed number of data relating to a item category can be automatically logged in the LIMS.
- Logging of ad-hoc items must be as simple as possible.
- Logging of items must be possible at any given time when the LIMS is operational.
- A logged item must be available for inputting within 5 seconds.
- The LIMS must have the capability to input item information for each item.
- The LIMS must have the capability to input information for each assay.

- It must subsequently be possible to add or amend results and/or item information from items that have already been processed.
- It must subsequently be possible to add or cancel assays on items that have already been processed.
- It must be possible to input every type of analytical results (numeric, alphanumeric, etc.)
- At least three levels of authorisation with regard to items (result, assay, item).
- Authorisation step for the confirmation of product specifications.
- It must be possible to use simple calculation formulae.
- The possibility to round off analytical results.
- The possibility to add comments at different levels.

Reporting capabilities in the form of:

- Results from an item with its item information and specifications.
- Results from a series of items and relating to a given common specification with simple statistical data.
- Results from a selected number of items and relating to a given common specification with simple statistical data.
- The assay that was used, together with its expiry and/or issue date.
- Clearly arranged lists of inputted data for use by the LIMS application manager.
- Unfinished tests on items.
- Unfinished items.
- Standard forms in case the LIMS is not operational.
- Report response times of less than 1 minute in top-priority cases.
- It must be possible, from the LIMS, to establish a correlation with a specific assay using a device (for the purpose of calibration status, detection limits).
- The capability to change item-identification (user) numbers if necessary, while still maintaining their unique character.
- The capability to change the status of a item or assay manually.
- The flexibility to send reports to specific printer destinations.
- Analytical results can test for different categories of specifications (product, detection or logical specifications).

- Analytical results can test for product specifications other than those established during the logging procedure.
- The capability to "prompt" from various menus or positions (a retrievable list) in order to be able to select an input.
- The capability to search easily and flexibly for items, information, etc. (eg using wild cards).
- The availability of different approaches for inputting analytical results.
- Various on-line help capabilities within the LIMS.
- It must be possible to automate repeated tasks as far as possible (macros).
- The capability to create standard reports easily and rapidly (from the application-management level).
- For the purposes of trouble-shooting or debugging, the capability to request the status of operations (log book).
- The capability to register/change/remove users easily within the LIMS.

In order to increase user-friendliness:

- Graphic user interface (eg Windows95, NT).
- User interface in English.
- A LIMS structure that is simple and logical from the point of view of users and managers.
- Manuals in English.
- The capability to show reports as "example on screen".
- Warning capabilities with various sorts of alarms, such as those available in Windows.
- Extensive debugging capabilities for use by the application manager.
- The LIMS must be able to handle duplicates, repeat items, repeat analyses, etc.

APPENDIX 5

Satisfying United Kingdom Accreditation Service (UKAS) and ISO 9000 guidelines

The basis of laboratory accreditation is now ISO/IEC 17025:1999 'General requirements for the competence of testing and calibration laboratories'.

The International Standard has been produced as the result of extensive experience in the implementation of ISO/IEC Guide 25 and EN 45001, both of which it now replaces. It contains all of the requirements that testing and calibration laboratories have to meet if they wish to demonstrate that they operate a quality system, are technically competent and are able to generate technically valid results.

The growth in the use of quality systems generally has increased the need to ensure that laboratories which form part of larger organisations or offer other services can operate to a quality system that is seen as compliant with ISO 9001 or ISO 9002 as well as this International Standard. Care has been taken, therefore, to incorporate all those requirements of ISO 9001 and ISO 9002 that are relevant to the scope of testing and calibration services that are covered by the laboratory's quality system.

Testing and calibration laboratories that comply with this International Standard will therefore also operate in accordance with ISO 9001 and ISO 9002.

Certification against ISO 9001 and ISO 9002 does not of itself demonstrate competence of the laboratory to produce technically valid data and results.

The specific reference in the standard relevant to the installation of a LIMS is as follows:

5.4.7 Control of data

5.4.7.1 Calculations and data transfers shall be subject to appropriate checks in a systematic manner.

5.4.7.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:

a) Computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use.

b) Procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing.

c) Computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.

NOTE:

Commercial off-the-shelf software (e.g. word processing, database and statistical programmes) in general use within their designed application range may be considered to be sufficiently validated. However the laboratory software configuration/modifications should be validated as in 5.4.7.2a).

APPENDIX 6

A check list for auditors

A number of LIMS suppliers will have an ISO 9001/9002/9003 quality management system from an UKAS accredited certification body. If the company cannot demonstrate this certification you may like to carry out your own company audit. Set out below are the activities which you should undertake:

To undertake a successful audit, it is useful to use the following checklist. containing broad headings such as:

- Company Overview
- Organization and Quality Management System
- Software Development Life-Cycle
- Planning and Product/Project Management
- Operation and Maintenance and Supporting Activities

The **Company Audit** covers examination of the organisation and any Quality Management System, whereas the **Product Audit** focuses on specific products or services only.

Typically, there are four stages in the vendor auditing process:

- Initial evaluation
- Detailed audit
- Follow-up audit
- Surveillance audit

The objective of the initial evaluation is to obtain enough information to take a broad view on the suitability of prospective vendors. A questionnaire is often used, and the initial evaluation does not usually involve visiting the vendors, although an initial evaluation may certainly precede a detailed audit. It is a useful method for producing a short-list of potential vendors.

The detailed audit precedes any contractual commitment, and is both in-depth and full-quality. It examines in detail all the business and development activities of the vendor. This type of audit should be conducted prior to placing the contract and be an intrinsic part of the procurement process.

The follow-up audit is the monitoring opportunity. It is used to check on issues generally raised during a detailed audit. It can also be used to provide evidence on any agreed corrective and preventive actions.

The surveillance audit is periodic (every twelve months is best) to verify that the vendor is maintaining the required standards, as per contract or as seen on previous audits.

Detailed audits should be conducted by at least two people, one of which must be the lead auditor. Follow-up or surveillance audits can be performed by a single lead auditor. The lead auditor should have overall responsibility for the entire audit process, and should be the main interface in coming to terms with the vendor.

APPENDIX 7

A check list for LIMS purchasers:

This section identifies some of the warnings about what can go wrong, why LIMS projects fail, why they can be a drain on resources and money. It is intended to guide you to avoid pitfalls.

- Get a very thorough understanding of the requirements to be met by the LIMS
- Get a proper balance between the needs of the company management (e.g. financial control) and those of the laboratory (e.g. technical)
- In multi-lab organisations, ensure that the LIMS can be tailored to meet the individual needs of each laboratory
- Don't impose a single solution from above in a simplistic way – there may be vital detail missing for the operation in a particular lab
- Don't be too ambitious, take simple achievable steps, but always maintain the feasibility of extension to meet future needs
- Look at the choices available to you: - can you remain with the status quo? Is a solution available off-the-shelf? Are your practices unique?
- Identify why you need a LIMS
- What are you looking for from your LIMS?
- Look at the laboratory – what processes or systems can the LIMS replace or help with?
- Select the product and vendor carefully
- What guidelines does your laboratory operate under, whether regulatory or not? What benefits will you gain from using a LIMS?
- Remember to plan and manage the changeover, both for users and managers of the LIMS

Remember: It is difficult to find a product that meets 100 % research needs so the closest fit is often the best that you can do.

APPENDIX 8

The Suppliers

Company	Address	Contact details	LIMS in UK	Turnover in UK	Systems installed in UK	ISO 9000	TickIT
Automated Technology Europe	The Annexe, Chantry House	Mr Colin Carberry	yes	£ 1m	2 or 3	yes	no
	High Street						
	COLESHILL						
	Warwickshire						
	B46 3PP	☎ 01675 466 945					
		🖷 01675 466 915					
		🖧 crc@ataindy.com					
Autoscribe Ltd	Unit 9, Moor Place Farm	Mr John Boother	yes	not available	57	ISO 9001	no
	Plough Lane						
	BRAMSHILL	www.autoscribe.co.uk					
	Hampshire						
	RG27 0RF	☎ 0118 932 6196					
		🖷 0118 932 6197					
		🖧 sales@autoscribe.co.uk					
BCS Limited	Savoy House	Mr Keith Manning	yes	not available	8 or 9	no	no
	Savoy Centre, Sauchiehall Street						
	GLASGOW	www.berkeleycs.co.uk					
	Scotland	☎ 0141 332 0891					
	G2 3DH	🖷 0141 333 9300					
		🖧 nick.willow@berkeleycs.co.uk					

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Company	Address	Contact details	LIMS in UK	Turnover in UK	Systems installed in UK	ISO 9000	TickIT
Beckman Coulter Inc.	Oakley Court, Kingsmead Business Park	Mr Stephen Turnock	yes	variable	variable	yes	no
	London Road						
	HIGH WYCOMBE	www.beckmancoulter.com					
	Buckinghamshire						
	HP11 1JU	☎ 01494 441 181					
		🖷 01494 461 935					
Blaze Systems Ltd	29 Harvard Road	Mr Val Boyle	yes	not available	not available	no	no
	ISLEWORTH	www.blazesystems.com					
	Middlesex						
	TW7 4PA	☎ 020 8580 1992					
		🖷 020 8560 5865					
Digital Analysis Ltd	Carlton Business and Whitehouse Technology Centre		yes	not available	not available	no	no
	Units 15-16 Station Road, Carlton						
	NOTTINGHAM	www.digitala.demon.co.uk					
	Nottinghamshire	☎ 0115 940 0705					
	NG4 3AT	🖷 0115 940 0976					
		🖧 webmaster@digitala.demon.co.uk					
Instem Life Science Systems Ltd	Walton Industrial Estate	Mr Neil Donaldson	yes	£5m - £10m	variable	yes	yes
	STONE	www.instem-lss.co.uk					
	Staffordshire	☎ 01785 825600					
	ST15 0LT	🖷 01785 812 460					

Company	Address	Contact details	LIMS in UK	Turnover in UK	Systems installed in UK	ISO 9000	TickIT
Thermo Lab Systems	1 St. George's Court	Mr Richard Travers	yes	$40m (worldwide)	c200	ISO 9001	yes
	Hanover Business Park						
	ALTRINCHAM	www.LabSystems .com					
	Cheshire						
	WA14 5TP	☎ 0161 942 3000					
		0161 942 3001					
Labdata Management Ltd	44-46 Lower Bridgeman Street	Mr Elian Winstanley	yes	£450k	3	not yet	no
	BOLTON						
	Lancs	www.starlims.com					
	BL2 1DG						
		☎ 01204 392 492					
		01204 392592					
LabLogic Systems	St. Johns House	Mr Richard Brown	yes	not available	not available	ISO 9001	yes
	131 Psalter Lane	www.lablogic.com					
	SHEFFIELD	☎ 0114 250 0419					
	South Yorkshiore	0114 250 0291					
	S11 8UX	Solutions@lablogic.com					
LabSys. Ltd	The Old Rectory	Mr David Parsons	yes	£ 500k	3	yes	yes
	GLOUCESTER						
	Gloucestershire	www.labsys.ie					
	GL2 0RX	☎ 07000 155 551					
		07000 255 52					
		David.parsons@labsys.ie					

Company	Address	Contact details	LIMS in UK	Turnover in UK	Systems installed in UK	ISO 9000	TickIT
LabVantage Solutions	Instron House	Mr Graham Wilson	yes	£2.5m	35	no	no
	Coronation Road						
	HIGH WYCOMBE	www.lims.com					
	Buckinghamshire						
	HP12 3SY	☎ 01494 456 450					
		01494 456 454					
		europe@lims.com					
LabWare Europe	The Old School House	Mr John Gabathuler	yes	$20m worldwide	35	ISO 9001	no
	Knutsford Road						
	HOLMES CHAPEL	www.labware.com					
	Cheshire						
	CW4 7DE	☎ 01477 539 000					
		01477 544 910					
		info@labware.com					
P E Biosystems	7 Kingsland Grange	Mr Peter Boogaard	yes	not available	not available	no	yes
	Woolston						
	WARRINGTON	www.pebiosystems.com					
	Cheshire						
	WA17SR	☎ 01925 825650					
		01925 282502					

Company	Address	Contact details	LIMS in UK	Turnover in UK	Systems installed in UK	ISO 9000	TickIT
Quality Systems International (UK)	The Lodge	Mr Clive Collier	yes	£2m	30-35	no	no
	Station Road						
	CHINNOR	www.qsius.com					
	Oxon						
	OX9 4HA	☎ 01844 351 212					
		01844 353 544					
		sales@qsiuk.com					
Visual Automation Ltd	Stopford Building	Dr Patrick Courtney	yes	not available	not available	no	no
	Oxford Road						
	MANCHESTER						
	M13 9PT	☎ 0161 275 5164					
		0161 275 5145					
		pc@svl.smb.man.ac.uk					
		www.wiau.man.ac.uk/Val					

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APPENDIX 9

The Consultants

Company	Address	Contact details	No Consultants	Manufacturer Loyalty	Quality System
AUTOSCRIBE	Unit 9 Moor Place Farm	Mr J Boother	5	Autoscribe	ISO 9001
	Plough Lane Bramshill				
	Nr HOOK	www.autoscribe.co.uk			
	Hampshire				
	RG27 0RF	☎ 0118 932 6196			
		01734 885604			
		matrix@autoscribe.co.uk			
BM COMPUTING LTD	35 The Ogilvie Building	Mr Brian Murray	1	Independent	no
	77 Dee Street				
	Aberdeen				
	Scotland				
	AB11 6FF	☎ 01224 572308			
BENSON ASSOCIATES	8 Academy Gardens	Mr Ken Leider		Independent	
	Gainford				
	DARLINGTON				
	County Durham				
	DL2 3EU	☎ 01325 730773			
BLAZE SYSTEMS	29 Harvard Road		4	Blaze Systems	no
	ISLEWORTH	www.blazesystems.com			
	Middlesex				
	TW7 4PA	☎ 020 8580 1992			
		020 8560 5865			

Company	Address	Contact details	No Consultants	Manufacturer Loyalty	Quality System
BOVIS TANVEC LTD	Alexandria Court	Mr Mark Hale	18	Independent	ISO 9000
	Larrs Road				
	CHEADLE	www.boistanvec.com			
	Cheshire				
	SK8 2JY	☎ 0161 495 6600			
CITY SOFTWARE CONSULTANTS LTD	Bucklersbury House	Mr Cliff Tucker	9	Independent	no
	2 Queen Victoria Street				
	LONDON				
	EC4N 8NH				
		☎ 020 7329 9944			
		020 8554 0600			
		cscltd@ibm.net			
DAVID BURNS MANAGEMENT & TECHNICAL CONSULTANTS	Kingsway, Fore Street Seaton, Devon EX12 2AD	Mr David Burns	6	Independent	No
		www.davidburns.co.uk			
		☎ 01460 234180			
		01460 234170			
		davbur@compuserve.com			
DIGITAL ANALYSIS LTD	Carlton Business and Technology Centre	Mr Mike Elphick	2	Independent	
	Units 15-16 Station Road, Carlton				
	NOTTINGHAM	www.digitala.demon.co.uk			
	Nottinghamshire				
	NG4 3AT	☎ 0115 940 0705			
		0115 940 0976			
		webmaster@digitala.demon.co.uk			

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Company	Address	Contact details	No Consultants	Manufacturer Loyalty	Quality System
DIGITAL APPLICATIONS INTERNATIONAL	Axtell House	Mr Graham Else	10	Independent	ISO 9001, Tickit
	24 Warwick Street				
	LONDON	www.dai.co.uk			
	W1R 5RB	☎ 01923 816877			
EUTECH	PO Box 43	Ms Melanie Snelham	1 to 5	ICI	no
	Brunner House				
	NORTHWICH	www.eutech.com			
	Cheshire				
	CW8 4FN	☎ 01606 705248			
		enquiries@eutech.com			
FELTHAM ASSOCIATES LTD	Carlton House, Kibworth Hall Park	Dr Kevin Feltham	5	Independent	ISO 9001
	Kibworth Harcourt				
	Leicester	www.fal.org.uk			
	LE8 0PE				
		☎ 0116 279 3232			
		0116 279 2473			
		kfeltham@btinternet.com			
HELP WALES	University of Glamorgan	Mr Luke Brown	pool of 7000 in Wales	Independent	ISO 9000 IiP
	PONTYPRIDD				
	Wales	www.help.co.uk			
	CF37 1DL				
		☎ 01443 482751			

Company	Address	Contact details	No Consultants	Manufacturer Loyalty	Quality System
INFOSHARE LTD	40 Laburnham Road	Mr John Mole	3	Independent	ISO 9000
	MAIDENHEAD	www.demon.co.uk/microft			
	Berkshire				
	SL6 4DE	☎ 020 8541 0111			
LAB VANTAGE SOLUTIONS LTD	Instron House	Mr Graham Wilson	15	Labvantage	will be ISO 2000
	Coronation Road				
	HIGH WYCOMBE	www.labvantage.com			
	Buckinghamshire				
	HP12 3SY	☎ 01494 456 450			
		01494 456 454			
LABWARE EUROPE LTD	The Old School House	Mr Stephen Broad	14	Labware	ISO 9001
	Knutsford Road	www.labware.com			
	Holmes Chapel, Cheshire	☎ 01477 533733			
	CW4 7DE	01477 539000			
		infoEU@Labware.com			
MI SERVICES GROUP	Chapter House	Mr Christain Oram	6	Independent	ISO 9001 & TicKet
	St Catherine's Court				
	HYTON RIVERSIDE	www.mi-services.co.uk			
	Sunderland				
	SR5 3XS	☎ 0191 516 3020			

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Company	Address	Contact details	No Consultants	Manufacturer Loyalty	Quality System
PATHFINDER LABORATORY SYSTEMS	Unit 8, St. George's Court	Mr Javier Tejero	9	Thermo LabSystems	no
	Hanover Business Park				
	ALTRINCHAM	www.LabSystems.com			
	Cheshire	☎ 0161 942 3000			
	WA14 5TP	0161 942 3001			
		info@labsystems.com			
PHARMA PRO CONSULTANTS	Wessex Ho	Mr Paul Butler	30	Independent	no
	Upper Market Street				
	EASTLEIGH	☎ 023 8057 6779			
	Hampshire	023 8090 9762			
	SO50 9FD				
RTS ENABLING TECHNOLOGY	North bank Industrial Park	Mr Neil Head	5	Thurnall	no
	Irlam	www.enabletech.com			
	MANCHESTER	☎ 0161 777 2000			
	M44 5AY				
SCIENCE INFO THEORISTS AND ANALYSTS	7A Westward Road	Mr Rufus Abraham	9	Independent	ISO 9000
	Hedge End	☎ 01489 782305			
	SOUTHAMPTON				
	Hampshire				
	SO30 4NP				

Company	Address	Contact details	No Consultants	Manufacturer Loyalty	Quality System
SCIMCON	Newmarket Road	Mr Trevor De Silva	4	Independent	ISO 17025 GLP UKAS
	FORDHAM	www.scimcon.com			
	Cambridgeshire	☎ 01638 720500			
	CB7 5WW	01638 724200			
		tdesilva@scimcon.com			
SMILE LTD	9 Nightingale Grove	Mr Adrian Carter	1	Independent	no
	SHEPTON MALLET	☎ 01749 345420			
	Somerset				
	BA4 5PZ				
UNIVERSITY OF GLAMORGAN		Mr Malcolm Thomas	2	Independent	IiP
	Wales	☎ 01443 482110			
	CF37 1DL				
VITIMPEX CO LTD	56 Gloucester Road	Mr Michael Vitkay	not available	Independent	no
	BAGSHOT	☎ 01276 474498			
	Surrey				
	GU19 5LT				

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APPENDIX 10

Demo Checklist

For response columns use:

1. Not available
2. Not demonstrated. Custom at separately quoted price.
3. Demonstrated. Optional feature at separately quoted price.
4. Demonstrated. Standard feature and within quoted price.

For priority column use:

1 - unimportant, 4 - mandatory.

Notes should be added for further explanation as required.

Ref. No.	Description	Priority	Response System A	Response System B	Response System C
1	**General**				
1.1	System must allow concurrent operation of multiple database groups e.g. for use in separate departments, active/archive/test etc.				
1.2	An active/complete sample data-base structure must be possible.				
1.3	System configurable by the non-programmer and without use of special languages				
1.4	Fully searchable event logging				
1.5	Web enabled.				
1.6	Multi-site operation for global enterprise.				
2	**User Access**				
2.1	Multi-level security access system.				
2.2	Ability to define specific menus for each individual user and/or class of user				
2.3	It must be possible to restrict user access in the following ways:- a) by location e.g. access to own data only b) by function c) by type of authority e.g. read/write/delete d) by screen e) by field/button on each accessible screen				
2.4	User name and password access control consistent with above.				
2.5	In multiple database system user's authority should be separately set for each database.				
2.6	Time-out function with times individually set for each user and/or class of user				

Ref. No.	Description	Priority	Response System A	Response System B	Response System C
2.7	Confirmation of user i.d. and password should be enforced for selected critical operations by the system.				
3	**Sample/work Registration**				
3.1	System must support the following types of registration:- a) single sample b) single sample with copy feature c) batch registration d) batch registration with copy feature e) registration templates				
3.2	System must allow sequential and automatic allocation of sample/work numbers				
3.3	System must allow a separate automatic and sequential batch number for situations when batches of samples are submitted				
3.4	When work is divided into different categories (e.g. QC/Research) the system must allow an unlimited number of parallel automatic sample/work numbering systems without the use of multiple databases				
3.5	Data relating to sample/work submitters and products to be picked from pre-defined lists				
3.6	Ability to view details of sub-mitters and products from the registration screen should be provided.				
3.7	Pre-defined lists available for editing from the registration screen i.e. without exiting registration, for users with an appropriate user authority. All editing to be audit trailed.				
3.8	Data for other fields on registra-tion screen to be picked from pre-defined lists as required				
3.9	Fields to have masking to ensure that correct format of data is entered.				
3.10	System should support date fields which should allow date calculations				
3.11	System should support short form date calculations e.g. CD + 5 to represent turnaround time of current date plus 5 days.				
3.12	System should allow fields to be populated automatically by defining a default value within the system which can be over-typed by a user with suitable authority.				

Ref. No.	Description	Priority	Response System A	Response System B	Response System C
3.13	Bar-code support should be provided				
3.14	Reports e.g. worksheets, and labels to be automatically generated from the registration screen				
3.15	Easy on-screen configuration to get the best fit for a particular user or work type				
3.16	Each user to have the option of their own design of registration screen				
3.17	For user or work specific screens the displayed lists should be filtered automatically to fit the relevant user/work requirements.				
3.18	When a product is selected from a pre-defined list at registration a default test list, appropriate to the given product, should be automatically assigned.				
3.19	If a product is an unknown a default test list should be assigned by selecting, e.g. Unknown Liquid, Unknown Solid etc.				
3.20	Users with appropriate authority should have the ability to modify the assigned test list including the addition and deletion of tests with full audit trailing.				
3.21	Certain tests to be made compulsory with no allowance for editing.				
3.22	System should allow the allocation of test limits for each individual sample as it is registered. These limits to be in addition to any test related limits e.g. detection ranges, pH 0 to 14 etc, and product related limits e.g product specification.				
3.23	All details of a test should be available for viewing from the registration screen. This should include historical versions of the test and appropriate audit trail.				
3.24	Test methods should be available for viewing from the registration screen.				
3.25	A notepad facility should be available at sample registration. All notes to be stamped with date, time and user i.d.				
3.26	Standard text/templates stored in external files should be easily transferable into the notepad.				
3.27	System should also allow the allocation of standard phrases to buttons, for example, on the notes dialogue in order to minimise repeated typing of frequently used text.				
3.28	There must be a means of locking access to previously entered notes.				
3.29	Screen configuration tools should allow the number, position and type of fields to be specified for the registration screen.				

Ref. No.	Description	Priority	Response System A	Response System B	Response System C
3.30	Fields available for use in a registration screen should include text, numeric, date, logical and notes.				
3.31	Buttons on the registration screen should be configurable e.g. definition of the function the button activates.				
4	**Sample Receipt**				
4.1	A sample receipt function must be provided with the system. Some work is pre-registered prior to the availability of the samples. The receipt function is needed to track arrival of samples.				
4.2	Sample receipt must allow single sample, multiple sample, batch sample and global sample receipt.				
4.3	Sample receipt should be an automatic status level in the system.				
5	**Sample Preparation**				
5.1	A sample preparation function must be provided with the system. This will be used to indicate that samples must complete the preparation stage before they are ready for testing.				
5.2	Sample preparation must allow single sample, multiple sample, batch sample and global sample preparation.				
5.3	Sample preparation should be an automatic status level in the system.				
6	**Work Scheduling/Work Allocation**				
6.1	System must allow the creation of worklists and worksheets.				
6.2	Worklists/worksheets to be available by test, instrument, resource, and laboratory as a minimum.				
6.3	Worklists to be available for downloading to an instrument system.				
6.4	System should allow assign-ment of samples and/or tests to resources e.g. people, labs, instruments, etc., to enable the tracking of workload.				
6.5	Chain of custody audit trail giving track of time, date and 'owner' of sample should be provided.				
7	**Result Entry**				
	System should allow:-				
7.1	Result entry by sample – entry of any/all test results for a single sample				
7.2	Result entry by test – entry of results for one test type for multiple samples.				

Ref. No.	Description	Priority	Response System A	Response System B	Response System C
7.3	Multi-sample, multi-test result entry (spreadsheet style) should be provided with non-applicable tests automatically greyed out.				
7.4	Viewing of results previously entered using same selection criteria as for selection of samples for result entry.				
7.5	Viewing of test status.				
7.6	Scheduling of re-test from result entry screen				
7.7	Option of forcing entry of reason for re-test.				
7.8	Out of limits results to be high-lighted whether the limits are associated with a sample, test or product.				
7.9	System to allow unlimited number of limits that can be associated with the product, test and/or sample				
7.10	The use of a wide range of calculations – similar to those available in Microsoft Excel, for example.				
7.11	Cross-test calculations.				
7.12	The following result types should be available:- 7) static text b) numeric/calculated numeric 7) short text 7) long text 7) menu selection f) date/time g) sample field (any field/s populated in the registration screen h) linked (allows viewing of information from a third party package e.g. chromatogram)				
7.13	Result validation				
7.14	Sample approval/completion				
7.15	Result entry to be audit trailed at the component level i.e. time/date/operator i.d. This is important where one “test” may consist of many components, the results for each component being entered by different users at different times.				
7.16	A Test to consist of any combination of result types as listed in 7.12				
7.17	Result import from a variety of sources including files and instruments.				

Ref. No.	Description	Priority	Response System A	Response System B	Response System C
8	**Static Data Tables**				
8.1	System should include static tables for:- a) security b) users c) sample submitters/customers d) products/samples/unknowns e) test definitions f) laboratory resources g) instruments h) workstations				
8.2	Full version control should be provided for all specified tables				
8.3	Full auditing should be provided for all specified tables				
8.4	System should allow user definable screens for all static tables				
8.5	System should allow multiple views of any static table with views listed separately on the appropriate menu. This will be needed to split, e.g. submitters of research samples from submitters of QC samples.				
9	**System Configuration**				
9.1	System should offer a variety of tools for system configuration that require no programming expertise.				
9.2	Screen configuration should provide:- a) ability to define an unlimited number of screens including multiple screens per function b) drag and drop techniques for field/button positioning c) use of a variety of different Windows controls including, but not limited to, bit map images, check boxes, combo boxes, edit boxes, etc. d) dynamic sizing of fields and buttons e) specification of tabbing order f) definition of “jumps” g) simple method of specifying control identity				

Ref. No.	Description	Priority	Response System A	Response System B	Response System C
	h) simple method of specifying function of a button i) choice of font/size for screen text j) revision history for all screen definitions				
9.3	Menu configuration should provide:- a) ability to define multi-level menus b) ability to define different menus for different users c) ability to use terminology suitable for the application				
9.4	List configuration should provide a simple means of defining lists, e.g. as used in combo boxes.				
9.5	Terminolgy configuration should allow the use of terms suitable for the application to include, for example:- a) menu items b) static text on screens c) text on buttons d) error messages e) help files				
9.6	API - to allow authorised users to link externally developed programmes.				
10	**Reporting**				
10.1	System should support any reporting tool that complies with ODBC standards.				
10.2	Reporting must be down to test component level.				
10.3	Automatic report numbering should be provided.				
10.4	Event triggered reporting - reports generated by status change, for example - should be included.				

Ref. No.	Description	Priority	Response System A	Response System B	Response System C
11	**Options**				
11.1	Instrument Calibration and Maintenance - should include: a) instrument inventory management b) scheduling of instrument calibration intervals c) checking of calibration results against pre-set limits d) scheduling of maintenance/ inspection intervals				
	e) recording of non-routine occurrences f) monitoring of instrument status				
11.2	Training Records Management - should include: a) record of details of training courses b) assignment of users to courses c) attendance records d) facility for tracking changes in course details e) automatic scheduling of refresher courses f) course evaluation g) full screen configurability				
11.3	Frequency Testing - should include: a) ability to specify testing frequency for each test on a substance/product b) ability to force tests for the first 'n' samples of a new substance/product c) facility for full testing auto- matically if a specified time period has elapsed since the last sample of a particular substance/ product.				

Ref. No.	Description	Priority	Response System A	Response System B	Response System C
11.4	Stability Study Management - should include: a) highly configurable screens and menus b) full protocol design c) storage inventory calculation prediction and monitoring d) sample location management e) flexible study and batch inter-relationships f) configurable review and approval systems g) use of study templates h) condition cycling i) storage operation management including auditing of container placement, moves, relocation, staging, pulls and scrapping j) automated or manual regis-tration of samples into LIMS.				

The above checklist has been kindly supplied by Autoscribe Ltd.

APPENDIX 11

CASE STUDIES

A.11.1 APPLICATION: LIFE SCIENCES

Laboratory	Aventis CropScience
Field	Plant Metabolism Laboratories
LIMS	Thermo LabSystems

Background

Aventis CropScience (previously Rhône-Poulenc Agriculture Ltd, Ongar, Essex) is part of Aventis SA, which produces a wide range of agrochemical products. In 1997 it successfully adopted an information management suite in its plant metabolism laboratories.

Arrangements prior to LIMS installation

Approximately 10 years ago, the decision was taken to move R&D from the use of Excel spreadsheets onto a commercially supplied Laboratory Information Management System. These were previously, effectively "a series of linked spreadsheets which were unreliable and prone to errors".

SampleManager LIMS from Thermo LabSystems was the corporate specification. Jack Gibson, IS Specialist, comments: "The standard functionality provided and ability to further customise provided in SampleManager gave a solution that most closely fitted in with our laboratory processes."

Ten years ago the Aventis CropScience site used only mainframe computers across its operations, with very few PCs. The requirement for IT support has changed dramatically since that time, since there is now approximately one PC per person on site, and the IS delivery team has to support a wide range of software and hardware.

Situation after system installation

Aventis CropScience took the corporate decision some time ago to phase out their VAXs on the sites and move onto Windows NT servers. As part of the move onto NT, the R&D SampleManager LIMS had to be upgraded onto v4.0 for Windows NT.

In a study, samples of soils, water and compound are subjected to numerous tests which give rise to many results and calculations, all of which must be compiled into reports that are sent to agencies such as the FDA (US) (Food & Drugs Administration) and EPA (US) (Environmental Protection Agency).

Lessons learned by the laboratory

Each Aventis CropScience site had a different schedule to go live on the LIMS, Ongar originally went live with SampleManager v2.62 in 1997. A small project team was formed to integrate the standard lab processes into the SampleManager environment and specialist contractors were brought in to transfer the necessary data and customise the system to fit user needs.

These study dossiers form an important part of compound registration and must adhere to strict rules laid down by these agencies and GLP. SampleManager v4.0 allows full item login and tracking, result entry, instrument data capture, auditing and reporting, all of which are essential to fulfil regulatory requirements.

Item processes are more automated and much manual data entry has been replaced by electronic data capture, avoiding errors and increasing faith in the system.

The length of time spent on a study has been cut by an average of 25% per study and the time the Quality Assurance department has had to spend validating each study has fallen by 75% allowing more studies to be conducted in a year.

Jack Gibson said: "Where the SampleManager LIMS base product could not fulfil certain study requirements, specialist contractors were brought in to write custom code to fill the gaps, but this customisation was requirement was kept to a minimum. Our intention is to only use and continue with standard LIMS upgrades from Thermo LabSystems. This approach reduces maintenance costs and eases future upgrades."

Thoughts of the LIMS vendor

There is a formal training program in place within Aventis CropScience and the company is certified Investors in People (IIP). The organisation's commitment to development and training meant that the installation of Thermo LabSystems' SampleManager progressed in parallel with the staff training course. This allowed the customer to develop its applicable knowledge of the operating system in line with the implementation and usage of the LIMS. For the vendor, the customer commitment to training allowed the implementation to run smoothly.

By attending courses to develop their knowledge, Aventis CropScience find that they never have gaps in their knowledge of how the LIMS can work for the business.

Conclusion

The planned approach of Aventis CropScience to its upgrades has allowed both Thermo LabSystems and Aventis to ensure that the LIMS implementation continues to meet the changing needs of the customer. By keeping its focus upon training, Aventis has kept its staff up-to-date on the current IT applications it uses, as well as allowing it to plan its upgrades in controlled manner. Aventis CropScience has seamlessly adapted to modern IT usage on its site whilst maintaining a modern LIMS from Thermo LabSystems that continues to meet its needs.

A.11.2 APPLICATION: ANALYTICAL CHEMISTRY AND IMMUNOASSAY

Laboratory	The Horseracing Forensic Laboratory Ltd
Field	Drug Detection
LIMS	Thermo LabSystems

Background

HFL is a research-based company, located in Cambridgeshire. It is owned by the Horserace Betting Levy Board and was originally established to provide for drug detection services for racing and equestrian authorities, including the Jockey Club of Great Britain.

HFL specialises in separation science, analytical chemistry (especially mass spectrometry), drug metabolism and immunoassay techniques. Services include comprehensive screening for drugs prohibited by sporting authorities, analysis of medicines, testing meat for veterinary drug residues, pharmacokinetics and metabolism studies, stability studies, GCMS, LCMS and LC-MSMS services.

HFL's forensic services are used for routine screening and counter analysis by racing and equestrian authorities worldwide. It is the designated laboratory for the Federation Equestre Internationale's (FEI) medication control programme in Europe and also provides drug detection services to the National Greyhound Racing Club. The varied workload of the scientists adds to HFL's ability to recognise new drugs, and track doping trends worldwide. HFL's experience of prohibited substances has led to the development of a unique library of chromatographic and mass spectral characteristics of drug metabolites.

Legal Implications

As a forensic laboratory, the results of HFL's work are likely to be subjected to legal scrutiny. It is therefore of paramount importance that all the analytical procedures and working practises employed at HFL are carried out with a high level of control.

To support its chain of custody requirement, items are collected at the racetrack under controlled conditions and delivered to the laboratory in tamper evident collection bottles. Following inspection on arrival, the bar-coded items are processed through the highly automated laboratory. It is essential to maintain rigorous item tracking procedures. The quality of the analytical results produced by HFL's state of the art laboratory technology is assured by stringent internal auditing practices, and a quality system accredited by UKAS and GLP.

Situation After System Installation

For management and collation of its item information and data, HFL specified its first LIMS over 10 years ago, and the system went live in 1990. The LIMS was originally commissioned to replace the laboratory's manual systems, to reduce the 'paper mountains' as well as improving efficiency of working, eliminate human and other transcription errors, and improve both the quality and the integrity of data.

Requirements for the LIMS included: utilisation of barcodes, automatic data transfer and result entry, as well as meeting the constraints of the forensic environment (such as chain of custody and multi-level result review).

Upgrades

Having projected a five-year lifetime for the original LIMS, in June 1994, an internal group was formed to assess the requirements for a new system. There was a need to justify the replacement of the LIMS, and to identify the options for replacement. Having run a LIMS for more than 10 years, HFL is an "experienced" LIMS user, and took the opportunity to consider the longer term needs of its replacement system. HFL's new LIMS had to be flexible so that the business rules could be changed easily without needing to re-customise the system. The LIMS had to meet all previous requirements, as well as new definitions laid out for:

- Customer Services
- Future Development
- Company Stability

Two LIMS vendors were finally shortlisted, both with systems which seemed to meet the needs. Of those, Thermo LabSystems was selected, because it addressed both HFL's product and corporate considerations.

HFL signed a contract with Thermo LabSystems to contribute to the development of a LIMS, Nautilus. This has been developed by Thermo LabSystems, with users such as HFL involved throughout the development process; known as Joint Application Development (JAD) and HFL (plus other users who participated in the programme) were known as JAD partners.

As a JAD partner, HFL had to provide at least one Ambassador user together with a number of Advisor users for nearly two years of development. Each Ambassador user has to be committed to the Nautilus JAD project for at least 60% of their job.

Trevor De Silva was an 'Ambassador' user at HFL. He said: "Some new innovations were built into Nautilus specifically at our request, and now feature in the final product. One of these is a 'rack' system which mimics our item handling racks and auto-sampler trays. This new feature of LIMS works very well for us, and mirrors the way we work."

Nautilus has been designed with a Microsoft Office user interface and has instrument integration incorporated into the LIMS, so it can connect and extract laboratory data directly and straightforwardly from most instruments.

HFL is both a UKAS and GLP laboratory, so there were specifications that the LIMS had to meet, and which Nautilus met.

Lessons learned by The Laboratory

The lesson learnt from HFL's initial investment into LIMS was that LIMS systems do work. Typically, effort was required to make the system meet the laboratory's immediate needs and the working practices also changed to fit in with the new automated routines associated with using a LIMS.

As a result of two successful LIMS implementations completed over a 10-year period, HFL has increasingly offered its expertise in LIMS, live in its laboratory, to other laboratories considering purchase of a LIMS. This service is now so successful that HFL, has introduced a new division SCIMCON specifically to offer consultancy in LIMS!

Thoughts of the Lims Vendor

The fact that HFL became a JAD partner to develop Nautilus LIMS meant that more frequent and timely feedback was given to the software development team, to ensure that HFL's needs were satisfied. The input of HFL to the JAD process also meant that the final developed Nautilus software had satisfactorily completed the traditional 'beta test programmes' in record time.

HFL's necessity to track 'Racks' of test tubes throughout the laboratory was initially forecast to be a custom solution just for their laboratory, but after discussions about general market needs, Thermo LabSystems built this facility into the application itself. As rack functionality has been subsumed into the application, HFL got a fully supported solution with little customisation, a direct benefit when upgrading to a newer version of NAUTILUS. Better still, all NAUTILUS customers of Thermo LabSystems (JAD partners & new clients) can utilise the Rack functionality directly, which is an additional selling point for the product.

HFL already had practical experience of LIMS, and therefore the customer project team was already familiar with their own requirements. This approach makes the job much more clear for the supplier.

Conclusion

Both Thermo LabSystems and HFL committed large amounts of time (point 54) to the successful development of Nautilus. The final system eradicated many of the training issues that a typical LIMS application brings, since the user interface of Nautilus is so familiar to the new LIMS users (NAUTILUS is just like using Windows 95). Because they are used to Explorer, the laboratory team found the LIMS very straightforward.

Both Thermo LabSystems and HFL have gained new business out of their collaboration - Thermo LabSystems in terms of a product that meets market needs and HFL with a new business division offering IT expertise to other like-minded laboratories. Trevor De Silva's team has contributed enormously to the finished product and is therefore delighted with the result: "NAUTILUS contains as many of our core requirements as we could have hoped for."

A.11.3 APPLICATION: METALLURGY

Laboratory	London & Scandinavian Metallurgical Company
Field	Products for the Metals industries
LIMS	QSI

Background

London & Scandinavian Metallurgical Company (LSM) manufactures specialist products for the metals industries including aluminium, steel, welding and superalloys. It is also involved in a range of other activities including abrasives, hard facing materials and polishes for glass.

Arrangements prior to LIMS installation

When the laboratory began, in 1992, to develop external business it found some strain on the information management and Certificate of Analysis (COA) operations. This was managed by a mainframe computer augmented by a paper-based system.

"We had looked at various LIMS years ago but were not particularly impressed by any of them" said Paul Hurditch (Laboratory Administrator at LSM). "This time it quickly became apparent that they had evolved into very powerful, sophisticated systems."

On the manufacturing side, LSM has a wide purchasing operation which is constantly sourcing materials from around the world. Their R&D department is similarly active, so one of the important criteria was for fast test results. The firm decided on a 32 bit system that could communicate with the manufacturing system and the rest of our company's database.

Hurditch said "It had to operate the same database for both external and internal customers whilst offering guaranteed confidentiality, going well beyond a basic password system."

The firm studied vendors and available systems for nearly eighteen months. They drew up a shortlist of nine and chose four to ask for demonstrations. Further evaluation reduced this to two.

The final choice was WinLIMS 4 from QSI. Initially, LSM ordered a 12 screen system. For added confidentiality, there was another field of security in the system which effectively split the database in two; internal accounts and external accounts. Entry into the latter, outside of the designated user group, is a complex and heavily validated procedure requiring written permission from the customer in most instances.

Situation after system installation

There was no transfer of existing data, which was kept live on the old system, and the company decided to go "big bang" with the new LIMS: "I couldn't have faced telling the staff that they had to keep parallel records for six months" said the manager.

After a two or three week implementation study, during which time QSI spent a week on the premises, LSM began beta-testing WinLIMS before going live on the big day. It was decided to customise the batch item booking out screens, the filing system and the way that information was extracted for invoicing. This was a relatively small amount of deviation from the basic system, say QSI.

QSI has developed a single generic interface program for WinLIMS which enables users to create an unlimited number of instrument interfaces without custom programming. Data can therefore be transmitted into the LIMS database by a wide range of analytical instruments including pH meters, ICP, elemental analysers, laser particle size analysers and the full range of modern instrumentation. LSM have XRF and ICP hooked into the system though soon all relevant instrumentation will be on line.

Lessons learned by the laboratory

Clive Collier, Managing Director of QSI UK said of the LSM System: "Confidentiality was necessarily a major issue with this LIMS and we were able to develop an extra layer of security on top of what we believe is already an extremely secure system. LSM entered with what was a new 32 bit system, which they helped beta test, so we also gained valuable input from them."

A.11.4 APPLICATION: METROLOGY

Laboratory:	National Physical Laboratory
Field	National Standards Laboratory
LIMS:	Autoscribe

Background

The National Physical Laboratory (NPL) is the United Kingdom's national standards laboratory. NPL provides contract research and measurement services to government and industry, and is the largest applied physics organisation in the UK, working on measurement issues across the physical sciences.

NPL manages the majority of the UK's measurement research programmes, and also offers a wide range of commercial services; applying scientific skills to industrial measurement problems. LIMS was installed to help process these commercial measurement services.

Arrangements Prior To Lims Installation

Each scientific area had its own test-work processing system, some paper based and some computerised.

The benefits of a new LIMS were discussed back in 1994. As a result the Optical Radiation Measurement (ORM) Group decided to develop a LIMS for its own area. An 'off the shelf' system was purchased, which had key laboratory functions and the ability to configure menus and screens written into the software. This allowed great flexibility to configure the system in house. After a couple of years of configuration, this system went live and worked well.

Even at this stage LIMS was being used at NPL in an unusual way, as a contract management and test-work processing system rather than for entering results and producing certificates. However, the potential was always there to use the system for generating reports and inputting technical data.

Work began on a corporate system in 1998, the whole project being handled in house with an experienced System Developer being brought in. It was based on the same package as above because it had met the needs of the ORM Group so well and was compatible with other corporate databases.

In fact the underlying software had improved greatly and so it was decided to start again to create one centralised system, rather than making developmental changes based on the ORM system. A corporate LIMS could offer a unified corporate image and better customer services. Customers would only need to quote a single reference number. From a quality perspective LIMS would make it easier to conform to UKAS and ISO9001 requirements, and it would be more time-cost efficient with less repeat transcription errors and a growing database of customers. Also, it offered the benefits of electronic invoicing and future financial, marketing and quality reporting on inputted data.

Situation after System Installation

Initially corporate LIMS was developed around one scientific area and rolled out to that area, so that major problems could be resolved. At the same time the scientists were sold the idea of a LIMS and the software was installed. It was then ready to be rolled out to individual areas one at a time, however this was to involve quite major developmental changes to allow for new requirements. The cyclic process became develop, test, use, review and develop.

A team of 'Super-Users' was set up with technical and measurement service backgrounds, to oversee the changes and to ensure a controlled development that addressed, as far as possible, the needs of all. They were responsible for setting up the descriptions of individual measurements on LIMS, and acted as a support line to Users. Training was an important part of the rollout process and each new User was put through a formal in-house training course and given guidance notes. There was a short period of parallel running before each area went live.

Changes were introduced through a Change Control system. LIMS was "frozen" and new releases were phased in after Super-Users had discussed the most pressing requirements. Users were made aware of any changes in advance, not only to ensure that they would benefit from them, but also because it was easy to get confused by a system that was constantly being developed.

Lessons Learned by the Laboratory

It took two and half years to configure the corporate system, partly because it was used in a different way to the "off the shelf" LIMS, and system functions had to be significantly altered, but also because NPL LIMS developed and grew around the needs of the Users.

The rollout process took longer than expected with the final areas going live some 12 months after the first area. This was mainly because the opportunity was taken to reassess the business needs of the laboratory in terms of best working practices, finance and quality, and also re-organisational changes to identify key Users.

Good communication between the scientific Users and the LIMS project team was fundamental to the successful rollout of such a centralised system. The different needs of each scientific area had to be met and problems quickly dealt with.

It was much harder to rollout LIMS to areas unused to similar automated electronic software packages, as working practices had to be changed and the benefits of the system had to be made clearer. However, confidence in the system has grown as the areas have gone live for themselves, and there is optimism for the future benefits of LIMS.