An Introduction and Guide to Successfully Implementing a LIMS (Laboratory Information Management System)

Ben Tagger

Computer Science Department

University of Wales, Aberystwyth

Aberystwyth, Ceredigion, SY23 4NL

bnt8@aber.ac.uk

Abstract

This paper aims to introduce the technology of LIMS (Laboratory Information Management System). LIMSs have been around for over twenty years, but still remain difficult to implement successfully. This paper will provide a brief introduction of LIMSs followed by a description of some of the existing technologies available to users of today's LIMS. LIMSs projects will rarely fail through technical restrictions, but rather through human inadequacies. The paper will describe some of the pitfalls of LIMS implementation and some of the most likely causes for a failed LIMS project. It will then give a generalised approach for the development of a successful LIMS implementation and finally, a look to the future addressing some of the needs of the LIMS industry.

Categories & Subject Descriptors

C.0 [**Systems Application Architecture**]: System Features − *standards, XML, ASP, web services, development languages.*

General Terms

Management, Design, Reliability, Security, Experimentation, Standardisation.

Keywords

LIMS, Implementation, Knowledge Management, Project Planning, Electronic Laboratory, Automated Process

Structure of the Paper

Section 1 provides an introduction to LIMSs and gives some of the realised benefits that a LIMS has been seen to provide. Sections 2 and 3 provide descriptions of some of the issues raised by the selection and development processes. Section 4 covers the issue of data value and knowledge management. Sections 5 and 6 describe how a LIMS may typically fail, and provide guidelines for implementing a successful LIMS project. Section 7 provides a look at what may be in store for LIMS in the future and section 8 gives a conclusion for the paper.

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1   Introduction

1.1 What is a LIMS?

The modern laboratory exists in an environment that produces a large amount of data. With the advent of new technologies, both the quality and quantity of information is increasing exponentially. This increase of data can cause significant problems and methods are needed to manage it. One such method used is a LIMS [2].

A LIMS provides a way of automating part of the laboratory system. In a traditional laboratory 75% of the total cost comes from manpower. Removing the need for some human interaction can significantly reduce overheads. The primary function of most laboratories is to provide validated information under some sort of time constraint and then based on that information, allow customers to make decisions [12]. Nowadays, traditional record keeping solutions are simply not up to the task. A LIMS can be of great importance in integrating laboratory operations with the laboratory itself. One of the most important aims of a LIMS is the integration of many different subprocesses, bringing together and consolidating the efforts of potentially many individuals and consequently speeding up the whole process.

LIMSs can save considerable amounts of time and dramatically improve the level of data access for all stakeholders of any given project. This is where a LIMS can become extremely beneficial. The sooner the user is notified of a problem, the sooner that problem can be fixed and the less the solution will cost [12, 8, 2]. The ideal LIMS should help provide the documentation to ensure that a laboratory and all of its operations exist in compliance.

LIMSs have been used for over 20 years and the technology has been considerably evolved during this time. This paper will document the current state of the LIMS technology and attempt to identify some of the pitfalls of the current technology.

1.2 Benefits of a LIMS

A LIMS provides benefits for many of the users of a laboratory. However, a LIMS does represent an expense that must be considered. This expense will almost certainly have to be justified by a level of higher management. The following is a brief outline of several of the main benefits identified and realised from current users of LIMSs.[i] [21]

- Information can be obtained with the click of a button rather than having to dig through files.

- Years of data can be kept easily without the need for traditional archiving.

- The improvement of business efficiency.

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[i] Data taken from a survey paper, in which users had been running LabWare LIMS for at least two years.

- Improvement of data quality (all the instruments are integrated).
- Automated log-in, tracking and management.
- Automated customer reports (Turnaround Time, Work Load).
- Automated Integration of Hand-held LIMS devices.
- Automated Quality Control.
- Daily Quality Reports.
- Easily accessible data via the web.

2 Process of Selection

This section endevours to cover some of the issues concerning LIMS's selection. A LIMS is a tool that is not successful for everyone who decides to employ it. There are several reasons for this, but one is without doubt an inherent ignorance of LIMS. Errors in the selection process can have a very significant bearing on the success of a project. The following section aims to identify some of the selection issues, including: vendor selection, portability, customisation, specification, safety, security and reliability.

2.1 LIMS Selection

It is said that a successful LIMS implementation is closely linked to the selection process. Selection and implementation of the LIMS is a complex process [13]. It is very important to select the right product, as this will have a major impact on the success of the LIMS project. The selection process should be thought of as an official part of the LIMS implementation process.

There are reasons for not taking a formal selection process for a LIMS. The most prevalent is that most of the systems today all have about 80% functionality in common. In considering the 'Pareto Principle', it can be shown that it is in fact, the remaining 20% functionality that is of paramount importance [13]. For example, the greatest benefit that a LIMS provides may be in the 20% that you haven't got. When selecting a LIMS, it is important to select one that is the 'best fit' for your requirements. There are obvious problems with selecting ones with less functionality than needed, but at the same time, there is little worth in selecting a LIMS with superfluous functionality just because it is available.

LIMS projects require large amounts of time, commitment and money. Making the wrong choice of selection could result in a failed project. It can therefore be argued that a process with such bearing on the success of the overall project should have a formal selection process.

There are many steps involved in the selection process. One of the most important (and frequently missed) steps in LIMS selection is a method known as WPE (Work Process Evaluation). WPE is used primarily to define the role of LIMS within the organisation. Requirements must be clearly specified, concise and well understood. Once these requirements have been clearly defined, the selection process can enter the 'Purchase Process'. This process should include viability studies:

- What is the state of financial health of the company supplying the products? Will they be around in 2 years when you need to upgrade?
- What are the future plans for the company? Are they planning on shifting business strategies, rendering your purchase obsolete?

It is important to consider such concerns when selecting a product to ensure that the companies' resources are spent wisely.

After the Purchase plan has been approved, a vendor demonstration process should take place. A selection of vendors should be invited to demonstrate a test harness product taking into account the specific requirements. This can help in several ways. Firstly and most obviously, this process aims to identify the most proficient supplier. It can also be used as an information-gathering tool. It is unlikely that one single vendor will have all the answers. The customer can take ideas from all of the vendors and amalgamate them into one single proposal. It gives the customer ideas of what can be done and educates them in what cannot be done. This helps identify problems and possible shortcomings of the project from the beginning. This process also introduces the supplier into the project at an earlier date, which can help speed up and increase the understanding and sharing of a common ideology.

As customisation is an expensive way of achieving a 'correct fit', it is important that a LIMS match your criteria as far as possible with as little need for customisation as possible. The final stage of LIMS selection is the Vendor Audit. It is accepted that the customer is responsible for the system once it has been installed. With this in mind, it is necessary to check that the system has first been engineered properly. It is a chance for the customer to verify that the system fully meets the organisation's criteria and to identify any potential pitfalls. It also provides a platform for the customer to suggest possible improvements or modifications and to establish a working environment with the supplier.

2.2 Portability

The last few years has seen a considerable growth of pocket PCs for use in information management [20]. It appears that the idea of liberation from the confines of a traditional workplace commands a significant appeal. More and more people are working from home, or abroad and are encouraged to do so by their employers. The overheads from 'keeping' employees soon become significant: heating, watering, feeding, desk space, car space, and other facilities (gym, libraries, etc). When these costs are multiplied for thousands of employees, there appears a huge opportunity for saving resources.

It is also increasingly necessary to provide employees with data 'on the go'. It is unfashionable and unpopular nowadays to expect employees to clock in at 9 and out at 5 and sit at their desk for the time between. Today, the productive worker is the busy worker. They should enjoy the freedom to move around. Employees should be mobile, but contactable and still productive. The un-relentless advance of mobile telephony has greatly aided the mobility of employees but their functionality relies totally on the ability to adequately communicate with another worker. Pocket PCs allow a user to directly access and liaise with a system without the need for a middleman. In principle a user can have immediate access to data from anywhere in the world.

It is imperative that laboratory information be available both inside and outside of the lab [20]. This availability of information is critical for improving both the quality of the products and the productivity of the users.

Traditional LIMSs provide basic lab functions, running on PCs. Unfortunately, these PCs are in stationary positions, representing a constraint on productivity. Laptops with wireless connections can be used portably in the place of desktop PCs and are extensively used in companies where employees are encouraged to take their work home. The problem with laptops is that they are

usually large, battery-driven and wireless connectivity is seldom without problems. Laptops are ideal for the transportation of a work platform, but have severe limitations for working 'on the go'.

An increasingly popular method of mobile access to LIMS can be found in the use of handhelds [20]. These small devices are lightweight and can be stored easily in a pocket or a briefcase. Many handhelds have pens, which are used as pointers or as writing implements, which the handheld recognises as words with the use of handwriting-recognition software. The handheld must provide the processing power, resources and functionality demanded by present-day LIMSs. There exists a huge market for these handhelds currently. Indeed, Compaq's iPAQ became its fastest selling product after only 12 months[ii]. These handhelds are not designed to be a replacement for a desktop, rather an extension. They provide docking and synchronising facilities for use with a desktop.

There are essentially two different ways of operating a handheld LIMS [20]. The first is to keep a self-contained environment on the handheld itself. This involves having all of the application and system data residing on the handheld itself. The handheld can work in a standalone environment and is not restrained by network availability. Data is kept on the handheld until the user can get to a PC where it can be uploaded and synchronised with the LIMS. The result of this is that all application data must be physically stored on the handheld itself. This may raise significant resource issues, as there are strict application and size limitations on these devices. Data may only be synchronised with the LIMS at certain points in time. This raises the problem of users submitting conflicting data. There is a danger that data will be lost or over-written and it is likely that a more rigorous CVS will have to be used, representing an overhead with this scenario.

The alternative approach to this method is using an interactive application [20]. This requires the Pocket PC to be connected to the network at all times. This can be achieved by either an IEEE 802.11 broadband wireless network connection or by using a cellular telephone connection (General Packet Radio Service). The Pocket PC may act as a browser to a much larger LIMS elsewhere. In this situation, data is always current as it is constantly being downloaded and uploaded, so as to provide a more vigorous system. The level of computing complexity of the handheld can be greatly reduced, as less software needs to reside on the Pocket PC itself. However, this scenario does rely on being connected to the network at all times. As a result, the system will not function in areas where the network is not available.

There are limitations to the Pocket PC. It cannot yet be used as a replacement for a desktop system, as there still exists the tradeoff between the portability (weight and size) and the functionality. As mentioned before, the handheld is best thought of as an augmentation to a LIMS. There are three principle limitations of Pocket PC LIMS. The first is the screen size of the device. These are small and often limited in resolution by the very dimension constraints that keep the handheld 'hand-held'. The second limitation is the entry method. Keyboards must possess a single key for each character and so take up a large amount of space. Handwriting-recognition software has come far in the last few years but is still far from perfect. The third limitation is wireless coverage. Wireless networking can be significantly less expensive due to the fact that the cost involved in wiring is practically

eliminated. However, in wireless networks, there will exist 'holes' in the network, where the handheld will lose reception from the LIMS.

2.3 Customisation

LIMS can save vast amounts of time and dramatically improve productivity within the workplace [1]. However, inevitably no two laboratories are going to be the same. Work practices, management structure, strategy, expectations, human involvement, are all going to differ. How can a LIMS be produced so as to satisfy this gantry of differing criteria? The answer is simple. It cannot. The solution is to provide the users with a LIMS, which they themselves can customise and alter to their own ends. This removes the need for the LIMS developer to include specific functionality, rather provide the means for LIMS users to provide their own. As a result, the overall potential functionality for the system is greatly increased.

One point to note is that customisation does not simply involve passing on a shell of a working program to a customer. It may involve extensive testing and analysis of the stakeholder's requirements. User feedback can help a developer produce a new, more efficient process, automating as many activities as possible.

What can be customised?

The most important need for customisation is the user interface of a system. If a LIMS is to improve productivity, it must provide an easy-to-use, specifically designed front-end for its users. The user interface must be intuitive, flexible and robust. There must be specific screens for various parts of the system and this should reflect the specificity of the system's domain. This is no different to many other areas of system design. The average Microsoft Word™ user will only ever use 15-20% of the functionality of the application. The determination of exactly which 15-20% is to be used is the hard part and this is where the power of customisation can be applied. By allowing the user to determine which parts they are going to need, avoids the need for a proverbial 'finger in the air' guestimate.

Whole screens can be redesigned (possibly from scratch), making them more intuitive and specific for the individual applications. Unnecessary fields, selections, and choices can be removed. Important areas can be highlighted. The user can drill-down or drill-up menus to the desired level of detail. As a consequence, users will not see functions that they do not need and will not have access to data or functions that are irrelevant to their job. The largest drain on productivity manifests in the communication of a desire of a user to a system. Improving the user interface will have the greatest effect on productivity, as it is the tool that provides the most interaction with the user. The more a system can reduce the amount of typing, clicking and thinking, the greater the improvement to productivity.

Customisation can occur in terms of the type and functionality of instrumentation that is to be used. Some instruments may be passive. Others may require user input and require bi-directional communication to provide feedback. Aspects of the project such as these can be provided and integrated into the LIMS from the start.

Laboratory systems are primarily concerned with the collection and analysis of data. A database (RDBMS) seems the most sensible way to manage this plethora of data. However, it is extremely unlikely that any two unrelated laboratories will have the same structure of data. Therefore, a level of customisation is needed to give the customer the freedom to present the data in the

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[ii] This may be the reason why we haven't seen the name-change of this particular product to HP iPAQ.

most beneficial way for them. This is also applies to areas such as data-entry systems, where a generic form is totally unsuitable.

How can you customise?

There are two main ways of providing customisation to a LIMS. The first is to include a scripting language with the LIMS. LIL (Laboratory Interface Language) from LabManager is an embedded high-level language with which the user can write their own methods and routines to automate repetitive tasks [1]. With a language, such as LIL, users can combine parts of the system, utilising available additional functions supplied with LIL. This approach is not unique to LabManager. Most LIMS developers provide some sort of scripting language in order to allow the user to customise, develop, and progress their laboratory system.

Another means of customizing a LIMS is to provide a packaged customised LIMS to the customer right from the start. This is usually advantageous for laboratories conducting research on fairly generic subjects. For example, consider the problem of integrating molecular genetics analysis capabilities into a LIMS. gtLIMS is a pre-customised LIMS that specializes in this area [6]. gtLIMS contains the basic building blocks found in a normal LIMS. However, additional features have been added in order to create gtLIMS[iii] and make it more specialised to its target domain.

2.4 LIMS Specification

One of the great problems with LIMS selection is the huge variety of vendors from which to consider services. Many of these vendors offer services and products that are not compatible with other similar products from the same domain. It is important to invest in products that are valuable and are not going to become redundant in the future.

To date, a set of standards regarding the development of a LIMS has yet to be produced. It is possible that this is one of the essential pieces of the puzzle still to be put into place. Standards allow universal acceptance of a product and also promote a facilitated development curve. The absence of standards can often put the brakes on a potentially successful technology. Often, the discussion on appropriate standards can take so long that the demand for the product has diminished when an agreement is struck. This is true for network technologies more than any.

Localised standards are emerging such as LECIS (Laboratory Equipment Control Interface Specification) [15]. This technology is concerned with providing a specification to provide a robust standard for communicating between equipment from different controllers and platforms. The problem is that developers are inherently more concerned with improving their core capabilities rather than their interfaces and engineering standard. This can often result in poorly designed device interfaces, which can be very inconvenient for implementers. LECIS aims to define the interactions between the devices and the controllers in order to achieve some level of operation. The degree of flexibility pushes LECIS into more of a specification-type category although in 1999, LECIS was balloted through ASTM and has become standard E1989-98.

Such standards are important so that equipment can interact directly with the controllers, a standard specified by the industry rather than by the individual user. Specifications such as LECIS are sorely needed in an industry that contains so much variety and incompatibility. However, more are needed in order to improve the LIMS development process.

2.5 Safety, Security and Reliability

There are many aspects to consider when choosing a LIMS and there are indeed many reasons for selecting particular LIMS vendors. Although financial reasons are often of paramount importance, other issues must be taken into account. This section covers safety, security and reliability and how these characteristics manifest within a LIMS.

For a LIMS to exhibit these three attributes, it is necessary to look closely at two important areas; the LIMS implementation programming language and the LIM operating system [18]. The programming language should be capable of defensive programming. Functions such as exception handling, variable typing and garbage collection should be present in a viable LIMS programming language. The OS should be completely robust. It should monitor and regulate all resources under its control, ensuring that they are not being illegally accessed, maliciously or otherwise. The system must be secure at all points. This means considering dual processor machines, uninterruptible power supplies, network clusters, and hot-swappable components.

Most systems today supply some kind of user ID and password security feature. This is notoriously fragile, as many users tend to lose, share or even write their passwords down. There are various "sniffing" devices, which enable wrongdoers to commit impersonation attacks. Encouraging people to keep their passwords safe and to change them often can reduce the chances of an attack such as this. In addition, there are various biometric devices for authentication such as fingerprint, voice print, retina scans and so on.

Arguably, the most valuable part of a LIMS is the data. It is important that the data can be authenticated so that its credibility can be weighed. This process of authentication can be achieved with the use of digital signatures. Digital signatures can be used to prove the origin and sender of a piece of data, reassuring the recipient that the data is valid and has not been tampered[iv] with. Although it is extremely difficult to prevent packages of sensitive data being intercepted and compromised, encryption methods and protocols can help protect the data from unauthorised access.

3   The Development Process

The following section describes some of the tools that are often used in a LIMS's implementations. This section is by no means exhaustive but endevours to cover some of the basic points of development, such as: development languages, XML, ASPs and web services.

3.1 Development Languages for LIMS

One of the most important aspects to consider when developing a LIMS is the database technology to be used. The database technologies have not significantly changed over the past few years, so it is reasonable to suggest that the ones around today will be around tomorrow. Most LIMS support relational SQL (Structured Query Language) databases such as Oracle, whilst the newer systems are expanding into the object-oriented technology. This has been supported by the object alternative to SQL, namely OQL (Object Query Language, surprisingly). The hugely popular

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iii A complete description of gtLIMS is not within the scope of this document. Please refer to the referenced paper.

iv A discrepancy in the digital signature of the electronic data would indicate to the recipient that the data had been tampered with.

object-oriented programming languages Java and C++ have reinforced this object-oriented approach. While most vendors develop their LIMS on the Windows platform, those who have employed a multi-platform approach have done so largely influenced by Java's JVM (Java Virtual Machine) [18]. This allows the same source code to be used on many different platforms, by providing a platform-specific runtime environment for the code rather than the code itself being platform-specific.

Selecting the right language to implement the LIMS is a difficult process. Many aspects must be considered; functionality, readability, portability, maintainability, support, tools, etc [18]. Currently, Java is one of the most flexible and widespread programming languages available. As well as providing platform-independent software development, Java enjoys a plethora of support, including distributed computing, networking, and enterprise technology. Standard and non-standard APIs and other support tools are emerging all the time, making Java an extremely strong contender.

3.2 XML in a LIMS

XML (eXtensible Markup Language) provides a flexible way of creating a common data format to facilitate the sharing and distribution of information on-line. XML provides a means for obtaining and supplying information about things in a standard way. For example, authors can allow browsers to present information inline with the user's requirements, rather than a standard HTML page. Compared to traditional closely coupled interface methods, XML-based systems can be loosely coupled, which are more maintainable and less expensive [4].

XML fits in nicely with the idea of distributed computing with the use of peer-to-peer message passing [17, 18]. In such a system, there are no slave-master relationships, rather each individual system creates, responds to and deals with its own packages. This has two main benefits. Firstly, the peer-to-peer architecture helps to keep the network protocol as generic as possible – systems can learn where neighbours are, rather than having an explicit hierarchical structure. Secondly, a peer-to-peer messaging system will survive if one machine fails. Each system will simply re-route the packages through a different route.

The appeal of the XML interface is its ease of development, maintainability and potential for reuse. The XML interface can aid a LIMS in situations such as job and sample submission, LIMS data archiving and the integration of two LIMS in different labs. It is this transfer to and from different laboratories that XML provides the biggest benefits. Transferring the data in a secure and recognisable format constitutes one of the largest challenges for a current lab. There are often isolated areas of a typical laboratory, each of which must be successfully integrated to exploit fully the laboratory's total potential [17]. This problem is further exacerbated due to there being so many different vendors, offering products that lack the standards for exchanging information between them.

With XML, systems can pass tagged data to each other without having to know how the other system is organised. The system can be expanded, trimmed, or reused without any further need to provide additional or differing functionality.

For example, in a LIMS, each XML file could represent one job. Users can customise this file with their own job descriptions as well as including static data structures (lists, etc.). Consider the development of an ELN (Electronic Laboratory Notebook). The ELN must be able to liaise with the other components of the laboratory, one component being the LIMS. Within the ELN, the user submits experiments to be analysed by the LIMS and then the results are required back at the ELN. In such a situation, XML capabilities can simply be added to both the ELN and the LIMS, providing a successful means of communication between the two.

ASPs and Web Services are closely linked to one another and are as much a part of the development process as the selection process. It may be important to select vendors that have provided means for ASP integration. Conversely, it may become a development issue as whether and where ASPs and web services are used within the LIMS.

3.3 ASP for a LIMS

Of all the 'buzzwords' in use today, ASP (Application Service Provider) is one of the largest and most promising. It was predicted that ASPs would revolutionise the face of the industry, changing how systems are implemented and managed. However in spite of this, ASP has failed to produce more than a few decent examples of its use [11]. Hugely optimistic forecasts were made about the future ASP market but with the end of the dot-com boom, it now seems that these are unattainable in light of the industries' self-mistrust. The other problem with ASP is that there is a general lack of clarity and understanding in what is actually offered. In spite of this, there are indications that ASP has a successful future.

Over the past 7 years, science-based organisations have been looking to outsource their IT operations in order to achieve a business focus on their core competencies. This does raise the question of security. In particular, pharmaceutical companies are reluctant to employ third parties to manage their systems as regulatory and security issues are paramount.

ASP provides a way of using software applications without the need to buy expensive licenses, machines, and support. Functionality of the applications is rented out to the organisation, possibly on a pro rata basis. System maintenance, backup, and recovery are all provided for by the supplier as the source program normally resides with them rather than with the customers. All the functionality of the application is held somewhere else and the customers are only shown a front-end. A lot of money can be saved in various areas such as implementation, installation, upgrading, maintenance, security and support. In modern day businesses, up to 80% of the total cost of system will come from these types of costs, greatly outweighing the initial expense of the actual hardware and software. One of the drawbacks with ASPs is that it requires a totally radical new way of strategising an organisation's attitude to software purchasing. There is no slow, baby-stepping into an ASP scenario. It must be done all at once with no middle ground. This requires some degree of faith, which can be lacking when there is so much at stake. One huge concern within the LIMS domain (as well as any other security-conscious organisation) is that data is held off-site by a third party. This can raise considerable security issues as well as legality concerns in some cases as information must be passed back and forth continuously. However, confidence in the security of the Internet and the communication abilities of the Internet is growing all the time and rightly so.

There are considerable advantages in considering ASPs. In the IT sector today, there exists more competent competition than ever before. The pressure to develop quality products in the shortest time possible is an extremely prevalent occurrence [11]. ASPs can significantly reduce the time taken to achieve an operational status. Installation, configuration and implementation can all be completed at a greatly increased rate, reducing the time needed to

prepare the equipment for development. ASPs should be thought of favourably, especially with regards to tightly scheduled projects. There is no need to spend time choosing and purchasing hardware and software systems. With ASPs, the experience is already there. There is constant available support providing instant resolvement. The other benefit of using an ASP is the assurance that it provides. The total risk taken by the customer is reduced when compared to that of purchasing a whole new system. Many suppliers will have an insurance clause, indicating their responsibility for any loss incurred due to a failure in their system.

ASPs can work within the LIMS environment but first, a solid, reliable service must be offered, providing peace of mind to customers. Once this is achieved, ASPs could represent a considerable step forward for LIMS.

3.4 Web Services

A web service is effectively an application or application logic that can be accessed through the Internet. Companies pay rent in return for the use of services held on a third party's web-server. By using the standard Internet protocols (HTML and XML amongst others), the web application can pass and receive messages from the user. The ASP (Application Service Provider) may have many customers using the same web service and so the web applications are written with strict specifications in order to allow different users access to similar business methods. Companies can add value and functionality to their services as and when the customers require it [10].

Laboratories can have many different data management tools and needs. These may include LIMSs and ELNs, measuring and analysis machinery, as well as the more logistic areas such as human resources, time planning, and accounting. The vast majority of these tools can either benefit by using or beneficially become a web service. Web technologies such as XML and SOAP (Simple Object Access Protocol[v]) and the current omnipresence of the Internet have made this kind out application outsourcing technically possible, but there are various hurdles to overcome before a complete success can be made through web servicing [5].

One major issue is trust. The leap of allowing an organisation's sensitive data to be held off-site is a very large one. It is very difficult to place the destiny and future of your business in anyone's hands other than your own [5]. An organisation must be confident that the system will not go down, that it will be secure and safe. In some cases, the option of web services will not be a viable one, due to the nature of the data or the level of importance of the operation. At the moment, safety-critical applications are not suitable for outsourcing given the level of importance, but there are many organisations operating in a non-safety-critical environment that would consider their operations as important. So, are web services suitable for them?

As always, it is necessary to weigh the advantages against the potential hazards. It is reasonable to assume that the supplier will have more specific knowledge and therefore be more proficient at handling the same service than the client. It is the shifting of responsibility that unnerves many customers.

4   Value of Data

Data is unarguably the most important factor of any laboratory.

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[v] A protocol defining how XML represents data.

However, the possession of data alone is not sufficient. An understanding of the data is needed for the data to become knowledge. This section discusses the importance of knowledge and the difference it can make to an organisation.

Knowledge Management and the ELN

Knowledge management is the term given to the process incorporating people and information together in order to acquire, organise, store and distribute information to the greatest effect [19]. It is a process that many organisations have recently strived to get to grips with in order to compete effectively in the modern industry. Competent knowledge management can be regarded as an asset in many ways. Companies with market worth values greater than their own book values can often attribute this discrepancy to the intellectual capital of the workforce. Pharmaceutical companies can often have market values many times greater than their book values and this can be seen as an organisation's potential for becoming more valuable in the future. This was demonstrated in the peak of the dot-com boom, where IT-based companies were valued at huge multiples of their actual worth. Although that is an exaggerated situation, it shows knowledge to have a considerable effect on the worth of an organisation. It is therefore in the interests of the company to maximize the value of its intellectual capital.

Knowledge management is not as easy to implement, as it may at first seem. There is a difference between information and knowledge. The transition of information to knowledge requires the application of a number of human qualities such as experience, intelligence, intuition, talent and more. It is not enough to simply possess data. The data must be understood and the knowledge required to apply it needs to be present. Only then does it become knowledge itself.

A tool to aid the knowledge management process is the simple lab book. Traditional lab books have some considerable limitations. Firstly, paper takes up a lot of space. Lab books are often locked away in cabinets and access to lab books is difficult. Finding the correct book is often difficult, as comprehensive indexes seldom exist. People's handwriting can be variable and sometimes illegible. Paper notebooks are difficult to back up and are therefore prone to being destroyed accidentally (or maliciously).

Many of the limitations mentioned above have been addressed over the years by information technology and through the use of computers. Computers are ideal tools for storing, backing up and allowing access to data. As the name suggests, ELNs (Electronic Laboratory Notebooks) provide a computerised version of a traditional lab notebook [19]. However, an ELN does have drawbacks. Lab books have to deal with every kind of experiment imaginable and so there is a difficulty in defining a generic experiment process. Realistically however, there still exist legislations enforcing the length of time and medium of laboratory records. It is important to note that the ELN is not an alternative to a LIMS. The ELN adds value by complementing the LIMS, which is still the hub of laboratory, and the whole system aims to deliver the right information to the right people at the right time. This combination aims to aid the knowledge management process, exploiting the information of an organisation to the full.

5   Why a LIMS may fail

There are many reasons why the implementation of a LIMS may fail. Surprisingly, the reasons are seldom technology-based; moreover the LIMS projects are more likely to fail due to human

shortcomings [3]. A large number of systems will fail to meet the user's initial expectations and this can often be due to the lack of a proficient user requirements specification [12]. The reason is obvious. How can a system meet expectations when those expectations have not been clearly specified? The absence of adequate requirements makes the system difficult to evaluate and validate[vi]. A LIMS cannot solve problems if those problems have yet to be identified [16], moreover the success of the project will normally rely on the understanding of the business needs and the problems that arise from them.

One of the problematic attitudes towards LIMS is the expectation that it will provide a total laboratory solution [9]. People think (or hope) that a LIMS will solve all of their laboratory needs without the need for any input on their part. As with most things in life, there is no such thing as a free lunch and LIMS implementation is no exception. It is necessary to first ascertain exactly what is needed and then examine what a LIMS can offer. It is not a bad move to push technology to the limits, but it is imperative to know what the limits are so that they can be worked around.

The lack of strategy and vision, which incorporates having a decent requirements specification, is one of the biggest reasons why a LIMS may fail [12]. There is a very real need for serious strategic planning. It is important to discuss and analyse completely the limitations of LIMS as well as the benefits and establish clearly how the LIMS is going to fit into the current laboratory situation. Shortcomings in this area can produce problems such as missed business opportunities, duplicating business efforts, and losing sight of the overall business direction. This could have expensive consequences as the system may require retrospective integration of functionality, which should have been present from the start.

One thing to be clear about from the start is the reason for introducing a LIMS into the laboratory. It is important not to merely jump onto the bandwagon without clearly establishing the reasons for doing so. LIMSs can be thought of as tools for speeding up processes in the laboratory. Saying that a LIMS will improve laboratory management is a fallacy often used to sway naïve senior management [12]. Managing a successful laboratory is much more complicated than that. It is necessary for organisations to ask themselves the basic questions [9]: What is needed? Why is it needed? How will it help? Where will we be at the end? How will we know if it has worked?

An important piece of the jigsaw resides in the selection of a LIMS. Unfortunately, one problem generally leads to many others so when a project fails, it may be difficult to accurately pinpoint exclusively what caused the project to fail. For example, if a clear objective is not held as the reason for implementing the LIMS, then errors may appear in the selection of the appropriate LIMS. As LIMS projects typically require such large amounts of time, money and effort, making the wrong choice of LIMS can often lead to a failed project [13]. LIMS selection is a complex process and deserves much consideration. Selecting the right product will have a major effect on the success of the project.

Implementation of a LIMS project requires a good degree of integration dealing both with the various parts of the LIMS and with the existing system. The problem of integration is further exacerbated by the lack of standardisation that exists between the vendors of today's LIMS. This lack of standardisation must be adequately addressed, causing the overall investment involved in integrating a LIMS to be quite high. As a result, there is a tendency to overlook or skim over this important part of the process, or at the very least, there is management pressure to keep this part of an already expensive system to a minimum.

There are many more factors affecting the success of a LIMS project, some more trivial than others. Mostly, failure can be attributed to people focusing on the wrong areas. Typically, there is a lot of emphasis on the technological side although this is seldom the case for failure. Organisations that map out clearly their needs and address the problem of integrating the LIMS successfully into their own system, taking into account the various needs and relationships of the users stand a far better chance of success.

6   Guidelines for a Successful LIMS implementation

There are three principle protagonists involved in the development of a LIMS [3]: the project sponsor, the project owner and the project manager. The project sponsor can be thought of the investor of the project, usually a section of higher management. The project owner represents the actual customer, responsible for formulating the requirements of the system based on the end users. The project owner is also responsible for the overall delivery of the LIMS. Finally, the project manager has the responsibility of the implementing the LIMS project, within the time and cost restraints supplied.

The first thing that the project owner should do is to clearly and concisely define the problem. It is important that the project owner always keep one eye on the business risk associated with project so that the project can be kept realistic. In an attempt to develop the problem further, the project owner should then liaise with the various departments within the organisation that will be affected by the LIMS. By pooling this range of opinions and concerns, the project owner can emerge with a wide range of possible solutions for the problem in hand. A process of comparison between the conceived solutions can then take place, in which the project owner must weigh up all the advice and support from all areas of the project and attempt to balance them against the perceived business risk involved.

The project owner should then take steps to identify the projected state of the laboratory before, during and after LIMS implementation. This is an important step to take, as it is the overall aim of the project to improve the laboratory environment. The project owner must have a clear understanding of how the laboratory is to progress both during and after the integration of the LIMS. A financially and economically viable way of completing the project must be established at this point. If a realistic way forward cannot be found at this point, this indicates that the project will probably not work under the existing format. It is better to establish this sooner rather than later.

Success in the above areas will depend on several factors [3]:

- The experience and competence of the project owner. Is this their first LIMS? Are they adequately qualified? Are they motivated?

- The nature of the LIMS project. Is it a replacement or an extension? If so, it may be easier (or sometimes harder) to implement.

[vi] FDA defines the process of validation as "the act of providing, to all concerned, the evidence that the system does what it purports to do"

- The extent to which the existing business practice must be altered to accommodate the LIMS. This is linked to the level of management cooperation offered.

It is important that the project owner fully understands the consequences and effects that the new LIMS will have on the existing business structure. There must be a clear idea of how the old laboratory will migrate to the proposed system. Employees are notoriously difficult in embracing change and this is something that the project owner must deal with. An area that is invariably overlooked is the preparing and training of the personnel that are to use the new LIMS. This is an important area, as it will encourage a swifter and more painless migration from the old system.

There are few laboratories that would not benefit from a LIMS, but clear reasons still need to be established. This must be taken into account in order to produce a sensible approach to the problem and to result in a cost benefit argument. This cost benefit argument can be used for gaining investment from the project sponsor and other stakeholders. The benefits of a LIMS are likely to be mostly longer term ones, but some short term ones as well should make the overall proposition more attractive.

A URS (User Requirements Specification) can help this process [16]. The URS describes what the company wants to do and is written by the people who will use the proposed system. This will include the project owner, laboratory personnel, IT support, and possibly some Quality Assurance people. The URS will form the basis of the validation process. The URS should be clear, concise and testable and it should also help group together ideas and align a consistent business strategy. It is also a useful document to supply to the project sponsor. The project sponsor will want the problem to be presented clearly so that some important factors can be established. Is it viable? Is it possible and realistic? What are the risks? Can it be profitable? Is the project owner competent enough and adequately motivated?

It is at this point that the project owner should appoint the project manager. Naturally, the project manager should be chosen on the grounds of their suitability. If the project is technology-centered, then a technically capable project manager should be considered. The project manager is responsible for the delivery of the project. There should be three main areas of concern, which should be balanced at all times: cost, time, and quality. The project manager works closely with the project owner to ensure that these factors are kept in check. Occasionally in small projects, one person occupies both the role of project owner and project manager. This can often lead to a conflict of interests. Traditionally, the project owner is primarily concerned with quality at the expense of cost and time. There is an obvious benefit to having two people for these tasks. For example, the project owner can give the project manager changes to the requirements and the project manager can return a revised time and cost. In this way, the equilibrium between time, cost and quality can be kept balanced.

During the course of any project, there are naturally going to be conflicts and disagreements. It is up to the project owner, with the help of the project manager, to resolve these and move the project forward. At the same time, there must be an understanding as to where these conflicts arise. The project manager should continue to support the project owner throughout the implementation and integration of the LIMS. It is a good idea to form an appropriate alternate implementation strategy with the aim to anticipate possible problems and downfalls. As always, it is best to expect the worst to prevent being halted by it.

7   A Look to the Future

Although LIMS can be shown to be advantageous to the running of a modern laboratory, there are many problems and issues that must be addressed in order to ensure a successful project. Almost all laboratories could benefit from a LIMS but for many such a system is prohibitively expensive. LIMS's implementation requires a colossal amount of time, effort and money. The failing of a LIMS project is an all too often occurrence and results in a great waste of resources, probably including a 'forced career move' of several of the responsible parties. Therefore, it is important to get it right and first time round. Both the expense involved and the high possibility of failure can deter the more modest organisations from attempting a LIMS implementation. Even for the more lucrative companies, of which there are many in the pharmaceutical industry, a LIMS implementation can not be without hindrances. The shear scope of vendor variety can make the important LIMS selection process complex and confusing. The degree of difference between vendors is largely the result of the lack of specifications for building a LIMS and this often leads to serious compatibility problems. For the LIMS technology to progress in a beneficial and well-engineered way, these problems must be addressed.

One step forward could come from the introduction of a standardised way of implementing a LIMS. Standards must be unambiguous, clear and concise. They provide an encapsulation of the most appropriate way of performing a process in order to avoid repetition of previous mistakes. Standards provide a clear way of performing a process. They also allow one person to carry on with another's work, as all the work should be standardised. Specifications and standards can be used to guide a project owner through a successful LIMS implementation. By introducing standards and specifications, vendors will be forced to provide compatible components. In turn, this will help drive the price of LIMSs down for the consumer, increasing competition amongst the LIMS providers. It will become easier to weigh up the differences between different vendors and give the customers the ability to 'pick and choose' rather than being limited to only one company's products. By providing a standardised process that will actually result in a successful LIMS implementation, the possibility of failure will be reduced (not eliminated). This will open the door for the more meagre companies that could not before consider a LIMS. Now that the risk of failure is lower, a LIMS can be seen as a more solid investment.

There is a difficulty arising from attempting to standardise the LIMS development process. Laboratories are largely centred on experimentation. By definition, experiments are original and novel. This makes it very hard to define standards for them. How do you define a standard for something that can be so varied? It is said that it is this variety of laboratory function that has so far hindered the standardising of processes in the laboratory. However, if the experimentation process is treated more like a process, rather than attempting to consider all possible experiments, then a more accessible ideology of a laboratory can be achieved. For example, an experiment can be thought of as having some basic components[vii]: Analysis, Planning, Implementation, Observation, Validation and Conclusion. When

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[vii] These are only the very basic ideas of an experiment. Obviously, some experiments will have differing components.

considered in this way, it seems plausible to construct some kind of standardised process, at the very least fitting around the experiment process.

Typically, standards take a very long time to be produced. This length of time is rightly needed so as to get the standards absolutely correct. However, with an industry that is changing so quickly, standards can often appear too late and consequently, are useless. Generally, standards do not work well with industries and technologies that are changing at a very quick pace.

Good software engineers are inherently lazy and try at all costs to refrain from being innovative. Innovation takes time and is pointless when a solution already exists. Patterns are a tool used by developers to avoid having to re-invent certain solutions. A thorough set of patterns, for use with a LIMS, could significantly increase productivity, speed up implementation, and help reduce the amount of innovation required when developing a LIMS.

8   Conclusion

Implementing a LIMS is an extremely expensive process, one which must be improved considerably if it is to become more widely available. There exist many technologies of which to take advantage, some of which are described here in this paper. However, there are very prominent risks involved in the implementation of a LIMS. A high failure rate can deter many laboratories from attempting such a project. There are various ways to reduce this risk of failure but none of the afore-mentioned processes provide a total, ideal solution. The guidelines for successfully implementing a LIMS are useful but are by no means complete. What may work for one business may be totally unsuitable for another.

The process of experimentation is so varied that any form of automation seems optimistic. However, a LIMS can work, they have been shown to work and they have been shown to be very profitable when employed correctly. It is necessary that, before committing to any particular LIMS, the consumer sits down and reads all the facts. They should be aware of all the possible pitfalls (those already identified) and how to avoid them. A LIMS is a subject that, if tackled correctly, can yield astonishing results.

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