

Choose the Best Implementation Option for Your LIMS Project To Maximize ROI without Compromising on Functionality

Summary

This article compares the different options that can be used to implement a LIMS solution. It is not intended to be a guide to your requirements or the methodology of requirements gathering. Nor is it intended to act as a project template or planning aid, it simply compares and contrasts the benefits and downsides of the different implementation options available. No assumptions have been made about operating systems, server software or the type of database required for the solution. No conclusions are made about which is the best or worst solution as that depends on many factors. The object of this article does is present the positives and possible negatives of each option.

Introduction

LIMS projects are normally both high profile and of relatively high cost to an organization. This means that Project Managers want to get the best solution at a price within their budget but at the same time making the minimal amount of compromises to the original solution envisaged at the outset of the project. If this balancing act is carried out efficiently then the company will have achieved the best Return on Investment (ROI) possible. Achieving a maximized ROI does not always mean that the system will have 100% of the originally envisaged functionality. There are situations where such a solution could only be obtained by spending beyond the budget or simply has a large cost implication for a relatively small gain in functionality.

The LIMS market space has a high number of commercial vendors. There are over 100 companies who claim to have a "LIMS product" and that does not include software companies that will develop a bespoke solution for you, or the option of developing an in-house solution. Within the vendor community there are a few large companies that cover many different market sectors but there are also, mainly, smaller companies that have developed a niche product to serve a particular market sector. For example there are companies that only provide LIMS solutions for the water and waste water markets, there are also companies that only provide

solutions to specific regional or national markets such as the German speaking markets.

Whatever route you decide to take to implement a LIMS you will need to choose which vendor is best for you. Remember, this is likely to be a long term business relationship as your LIMS solution should give you many years of service. It is also worth remembering that over the period when you are using your LIMS solution the laboratory will also undergo change. The nature of the work will evolve, with luck you will have new instrumentation and possibly expansion of both the volume of work and the people performing it. This means that you will need ongoing support, not just for occasional bugs and the like but also for expansion and updating of the system. A laboratory is not a static situation but it changes and the LIMS solution must keep in step with the changes to work efficiently.

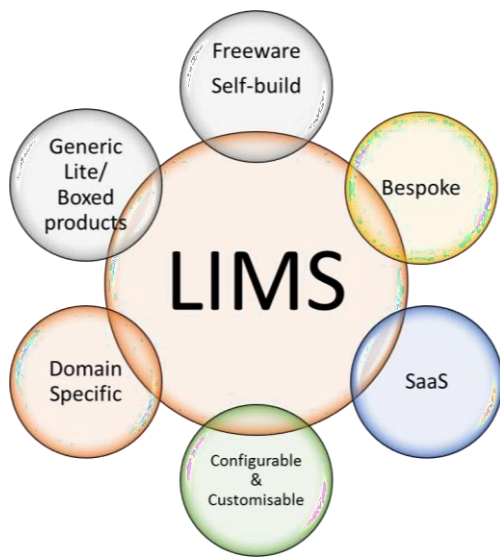


Figure 1 LIMS Implementation Options

A LIMS solution is not a one-off purchase. The system that you buy will be used for a number of years so in addition to the initial cost there will be other, recurring, costs. For example there will be annual support costs if you purchase a system and in Software as a Service (SaaS) solutions there will be regular on-going costs. This is without the costs, buying or leasing, associated with the hardware that will be used to host your system. Another point to consider is if you will have costs associated with the staff managing your solution. The majority of solutions will not need a full-time system administrator but some will incur support costs from internal or third party IT professionals. If you develop an in-house solution you will have on-going costs for the further development of the software and the transfer to more modern operating systems as the older ones become obsolete. You need to be planning for a 10 year lifetime even if that seems quite distant at the present time.

Below are the different options available at present for your LIMS project. They cover everything from building your own solution to buying from a vendor and the recent option of SaaS and managed solutions.

Self-build and freeware solutions

These options are considered together as they tend to be used by people who are trying to develop a very low-cost solution to laboratory management. This is not always the case, sometimes this route is chosen as there is nothing in the market that offers a suitable solution so the only choice is to either self-build or buy a bespoke system. People often will try to use a freeware solution as the starting point for developing their own solution as it can reduce or eliminate the programming element from the development. In the early days of LIMS it was quite usual for a company to develop their own solution. This was often instigated by an employee who developed software as a hobby in smaller organizations. In large companies they often had an IT department and their role was to develop applications for the company to give some strategic advantage or simply because the software was not commercially available. The use of this option is now less widely adopted but has not completely disappeared.

All these projects, big and small, use valuable resources. Resource usage can be high and, in smaller organizations, can result in project timescales slipping due to lack of available resources. In many cases the true cost of the initial development is not known as the resources are not always tracked effectively. These systems are created by people with software programming skills, although they do not always adhere to good coding standards, but one issue with this approach is that the same people do not have the skill or inclination, in some cases, to provide good documentation for their solutions. As the solution is a one-off then the documentation is important, particularly a few years later when the original people have moved on and there are new lab staff to train.

In many cases the major issue is not the initial development but the on-going support required. In a large organization when the project is deemed complete the people who have been involved move on to new projects. This means they are less available to help with problems when they arise. It also means that a new team is often formed to take on future developments and enhancements, they do not have the same knowledge of the original software. In smaller organizations where a very small team, possibly even a single person, is involved they may well move on due to promotion or even leave the company. In this case the question is who supports the system? In both cases, unless steps are taken, the future viability of the solution may be in question. There are cases where a solution becomes obsolete within a very short timescale leaving the organization in a very difficult situation, particularly if they discover a bug or want additional functionality added to the software.

In general this type of system is initially often a very good fit to the labs specific requirements. However, over time, if there has been a lack of on-going resources available for the system, the functionality reduces as the lab evolves. The system often requires flexibility and, sometimes, imagination, by staff to be used for new processes and practices in the lab. In some cases scalability may be an issue, particularly if the system becomes much larger than originally envisaged. In such case the platform that the original system used may be inappropriate for a system of such increased size.

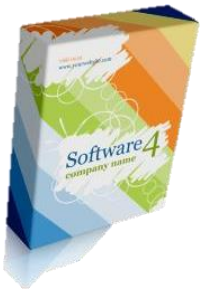


Figure 2 : Boxed Products

Generic, Lite and Out of the Box solutions

These solutions are grouped together as in most cases they will offer a partial solution for a partial price. They may well be able to cover between 60 and 70% of your requirements. The main point about this type of solution is that it is, by its nature,

Always a compromise as you are buying a generalized solution. You may have to change some of your working practices and the ways that you record data to match the way in which the system works. Some of these changes may well be beneficial but others may mean that staff need to get used to doing things in a slightly different way.

An issue that may become a problem later is what happens in the future. How does the vendor handle product enhancements are they dictated by the type of laboratory that has the most installations of the software. If that happens to be, for example, pharmaceutical labs and you are an environmental analysis lab that could be problematic. Also check to see if there is a limit on the number of users as that could limit your expansion of the system if you want to roll it out to other labs. Some vendors have a limit on the number of concurrent user licenses that their "Lite" or out-of-the-box solution can accommodate. They may also limit the total number of fields that can be used in the configuration. Mostly these restrictions are due to limitations of the database used.

The positive point about this type of solution is that it can be relatively low cost to purchase. If you go down this route check carefully to determine the match between system functionality and your own requirements, both current and potentially future requirements. Another positive with this type of solution is that it can be a good starting point. If you have little or no experience of LIMS then this can be a useful route to take as it gives you the opportunity to work with a system to understand and define your specific requirements. After using the "standard" system for three to six months you can perform a "gap analysis" to determine what functionality is missing from the system that you would like to be included. This approach will, of course, only work if the vendor offers upgrading the package as part of their service. If

there is no such upgrade path then you are probably unlikely to be able to take this type of work on yourselves or even have a third party do it for you. This means that you have to be satisfied with the standard solution, if it works for you that is fine. If not then you may need to choose an alternative product or re-think your approach.

Bespoke solutions

A bespoke system can be required in certain situations. If there are no vendors who can offer you a solution to your requirements then you may consider the bespoke option. You may however find that one of the existing vendors is interested in working with you, often in partnership, to develop a solution for your specific application area. If the vendor has the opportunity to sell a number of similar systems to yours then they may consider it



Figure 3: Bespoke Software

Commercially viable to create the solution. That way you get your solution and the vendor gains experience in this specific sector to help implement other similar systems in the future.

However, if nothing exists that you feel you can use then you may well consider the bespoke option. The positive factor in taking this route is that you should be able to get 100% of your requirements. Remember that whilst you can get 100% of your requirements some of the functionality you have defined may be expensive to build into the software. It could be more cost effective to achieve a 90% or even 95% solution and make considerable cost savings. A good vendor should give you these options.

If nothing exists already then this is essentially a one-off software package. Some software developers may have had experience of similar projects before so it is worth trying to seek out this type of vendor. Of course, even companies with experience may well have only produced a few systems so their experience will probably less than a specific LIMS vendor. Specific LIMS vendors are likely to have much more knowledge of laboratories and how they work. This means they may be able to suggest functionality that you have not put in your requirements, simply because they have had other clients request it.

When you are negotiating the contract remember to include the process for on-going enhancements and also for support. Will the vendor have a formal enhancement program or will it just be a case of them building enhancements on request? Similarly, how are they going to deal with support and bug fixing?

SaaS and managed solutions

A topic for LIMS meetings and similar events in the last two or three years has been the continued rise of cloud computing and Software as a Service (SaaS). The real questions are how this can be adopted by companies using LIMS. There are two options a managed solution or a pay-as-you-go option where usage determines cost. In both cases the system resides either on a remote server or a cloud server. A



Figure 43: SaaS Model

Managed service or SaaS solution may well be a specific configuration of the software to meet your specific needs or it may be an out-of-the-box type product that you use and your data is stored remotely, both are available. The benefit is that you no longer need your own hardware to host the system, you rent space and the service from the vendor. The pay-as-you-go option takes this a stage further as you own nothing, you use the vendor's software as and when you need it. One of the Advantages of this type of approach is that you can expand (and contract) your system very easily without the cost of capital equipment or, in some cases, additional software.

Other industries have gone down this path already and are some way ahead of the LIMS market. However, the pharmaceutical industry is one of the industries that have been in the LIMS market for many years and they have specific issues including data traceability, security and validation. They are required to use validated systems to ensure their data has not been altered or tampered within any way. The point here is that the pharmaceutical company is responsible for compliance and if they have a supplier who does not or cannot adhere to the regulatory guidelines it is still the pharmaceutical company that is responsible. This, naturally, makes them want to be sure that this type of approach is watertight and that there is no possibility of compliance issues arising. In many ways it will probably be the, currently, less regulated industries that adopt this type of solution and as more experience and confidence can be demonstrated then the pharmaceutical and similar industries will have the confidence to go down this route.

The issue of costs also needs investigation so that you fully understand the on-going costs of this type of solution. Initial costs may look attractive but you need to determine the total lifetime costs of the solution, including how much costs increase with larger sample numbers and therefore larger databases and storage requirements.

Configurable and customizable solutions

This sector is where the majority of vendors can currently be found. They have a wide range of products with a diverse range of functionality. This covers systems that are client/server based and also web-based solutions. The first point to make is that the words customizable and configurable tend to be used interchangeably and what some vendors call configurable others call customizable (and it is not just vendors who do this, customer's fall into the same trap).

Purists will often define configurable as a system that has objects with properties that can be defined without using computer programming and that customization generally requires computer programs to be changed or extra code to be written.



Many of the vendors offering a customized/configured solution also offer customer training to allow system administrators and similar people to do their own updating. This can be extremely useful to keep your solution in step with changes in the lab environment. It is also true that some of the systems that vendors call configurable/customizable are almost bespoke systems and use an integrated development environment. This type of development environment requires a highly trained person for it to be used effectively. You should be aware of how the configuration/customization is done, preferably by asking for a demonstration or even by attending a customer training course before you buy.

The second point is that 100% configuration is very difficult because the vendor is never quite sure what a customer's requirements might involve. In effect they need to plan for unknown and unrequested functionality to be incorporated into their solution. Some of this functionality may be requested by more than one customer and these items are likely to be added to the configurable product in normal development cycles. A truly configurable solution could mean that you are buying functionality that you may never require, but can you be sure what you will need in the future?

In most cases vendors using both approaches have a "core" of software that is the same for all applications. Some will then have a second layer that will provide the general functionality that is required by a specific laboratory type, for example an environmental analysis lab, a contract testing lab or a pharmaceutical analytical lab. This gives the "core" software the look and feel of the specific lab type but it does not give the complete functional requirements of a specific lab. That is where the customization and configuration comes in. These systems with the general functionality of a specific lab type are often used for "proof of concept" or "gap analysis" exercises. They allow you to understand what a general solution can do and what you need to add to that solution to give you the functionality that you require.

Generally configurable and customizable solutions are scalable and can change as the labs requirements change over time. The ability to update functionality over time cannot be over stressed. Labs always change over time due to new instruments, new analyses and analytical techniques, changes in legislation and even mergers and takeovers. This means that flexibility and re-configuration or further customization are essential features if the system is to remain in step with these changes.

The larger vendors in this sector have large customer bases and this can mean that they have extensive experience of implementing solutions. In some cases this may be across multiple lab types but in others it may be limited to one or two specific lab types. They are often able to help potential customers in areas such as requirements gathering and system specifications due to their past experience. One area where this can be

particularly useful is being able to offer alternative approaches to achieve similar or the same functionality, this can lead to cost savings.

As with all solutions there is an element of balancing the costs against functionality and it may be that some of the functionality that you have defined is costly to implement. If this is indeed the case then you may want to look at alternative approaches or even to ask yourself if you really need that specific functionality operating in a very specific manner. If you want a 100% fit then you may be moving into the same area as the bespoke systems with their associated costs.

Agaram Technologies' solution

Agaram Technologies LIMS is one of the leading configurable/customizable solutions available in today's market. Currently all of the major vendors fall into this category although some are client/server based and others web-based with a few being available on both platforms. Using Agaram's range of lab software products will illustrate the type of functionality available and the way in which additional modules or complimentary products can be integrated together to give a more comprehensive solution. Products like [Qualis LIMS](#) can be configured to give a complete single vendor integrated laboratory information and data management solution. A LIMS is not a complete answer to information and data management in the lab. A LIMS generally will handle sample management, test allocation, result entry, comparison against specifications, reporting and assist in the general management of the lab. The general management of the lab is often overlooked as LIMS functionality but this is a significant role. It includes the ability to quickly analyze sample throughput, sample turnaround times, number of samples analyzed per customer, number of samples not meeting specification etc. The data extracted from the database can, in many cases, be exported into third party packages for statistical analysis and similar tasks.

In the case of [Qualis LIMS](#) the core software can be configured to meet the general requirements of many different lab types. This is achieved by using plug-in modules, domain apps, that will give the general characteristics of, for example, a pharmaceutical LIMS, contract lab LIMS or a clinical research lab. This means that the same core software is used in all solutions, so it is well tried and tested. Different vendors have their own solution to creating application specific products but, in general, they involve adding a "skin" over the core software to create a generalized solution for a specific industry. From this stage configuration/customization is used to add the additional functionality requested by the customer.

A number of the LIMS solutions available have a range of additional modules that can be integrated into the main LIMS product or used alongside it. The range of modules available varies from vendor to vendor but in

many cases they is a growing portfolio created to meet the requirements of specific areas of functionality such as instrument calibration and maintenance management. Using Qualis to illustrate the range of modules that can be integrated into your LIMS solution includes the following.

- Chemical and standards inventory management
- Work quote and invoicing module
- Instrument calibration and maintenance management (mostly known as ICMS)
- Staff competency register and training module
- Stability study protocol management
- Document management

However, all of the above information is associated with just the LIMS solution. A fully integrated lab information and data management solution needs to cover more than this as a LIMS really only manages the samples, results and reporting. It is also important to be able to handle instrument data output including the raw data, meta-data, methods (SOPs), specifications etc.

To achieve a fully integrated lab information and data management solution Agaram Technologies have developed three additional products that can be used as stand-alone products or integrated with the Qualis LIMS software to create a more comprehensive solution. The products are the [Logilab Electronic Lab Notebook \(ELN\)](#), the [Logilab Scientific Data Management Solution \(SDMS\)](#) and the Quality Management Suite (QMS).

Briefly [Logilab ELN](#) has two main functions, instrument interfacing and laboratory method execution. Instrument interfacing enables users to transfer the output from pc and non-pc based instruments to LIMS (both Agaram's Qualis and other vendors LIMS) and other third party applications such as ERP and MRP software packages. Using a range of parsers LogiLab ELN can extract data from RS232, TCP/IP and file based outputs. Using its LIMS mapping tool it can then transfer the data to the LIMS or other software. The laboratory method execution uses lab sheets, similar to an Excel spreadsheet, to collect instrument data and manual inputs into a single document. You can then perform calculations to produce a final report for result transfer to LIMS. The sheet can be configured to produce a stepwise process for recording data in a fixed order, ensuring that all of the data is collected and is traceable for future auditing. Even the most straightforward analysis normally involves a number of weighing and measuring steps. These are all recorded on a version controlled lab sheet that can be checked and approved before results are committed to the database. LogiLab uses audit trailing to ensure that the solution meets the requirements of regulatory guidelines such as 21 CFR Part 11.

[LogiLab SDMS](#) is a generic software designed to handle scientific instrument data from any analytical instrument, providing data management with access control. The system will perform periodic data capture and backups, it also manages data restoration. The data collected is stored as flat files on an FTP server with an

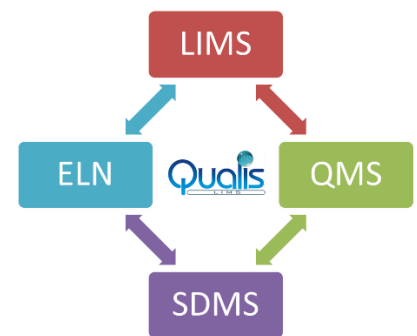
encrypted file name. Data access and viewing are controlled through user access rights providing data security. The meta-data entered by users is sent to a centralized database server. All data generated from instruments and any other source in laboratory operations is captured and stored centrally. Secured storage with version control of all documents including SOPs, manuals and MSDS can be achieved with SDMS. Controlled data access enables data to be made available to specific users, ensuring that data security is maintained at all times. A powerful search engine gives easy access to large amounts of data.

The Quality Management Suite (QMS) is used to manage all aspects of quality from non-conformances and concessions to corrective and preventive actions, document control and training/competency records. Its main purpose is to ensure that quality is maintained at the highest level and that any issues are followed through and resolved.

When all of these products are integrated together they provide a complete information and data management solution for the laboratory. However, this type of integration will require the services of the vendor. Even a stand-alone LIMS will require a services element which will be supplied by the customer in a self-build system but by the vendor or a third party in all other cases. The level of services required will vary depending on which model you choose to implement but will also vary with your specific requirements. Services must be available from pre-project throughout the lifetime of the solution, so that you

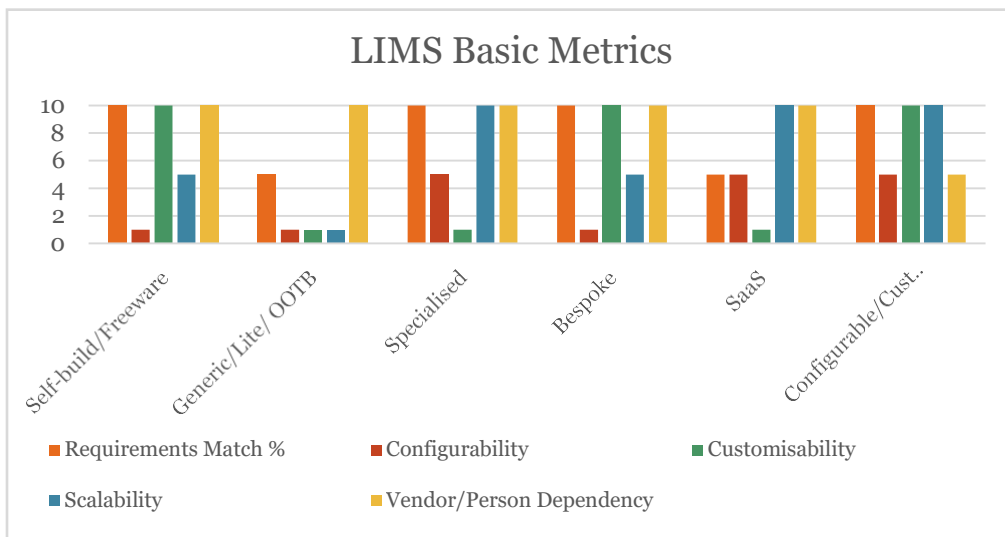
get support at the requirements gathering stage, at implementation and then support for the lifetime of the solution. You can, for example, use third party consultants to give an independent assessment of your requirements. However, be aware that this type of consultant needs to have extensive knowledge of a number of products so they are not unintentionally giving a biased viewpoint towards a single solution. Also be aware that the consultant will only be there for a limited time and they do not have to live with the solution they recommend so make sure that you brief them fully and that you are happy with the functionality of the solution they suggest.

Finally, a few words about the implementation stage of the project. Whatever solution you have chosen it is crucial to have sufficient resources available at this stage to make it go smoothly. It is also worth stressing that the resources are supplied by the vendor and by you. The vendor will expect you to have sufficient resources available for testing and also data entry. The testing must be rigorous and should test as much of the solution as possible with good, clear, feedback being given to the vendor's technical team. However, the area that is often overlooked is the data entry stage. When you are implementing a system it will need a lot of data to be entered such as tests, specifications, customers, details of analysts and instruments. Some of this may be done by transferring data from a previous system or other electronic sources but even then the information must be checked in the new system to ensure that it has transferred successfully with no mistakes. Also ensure that a

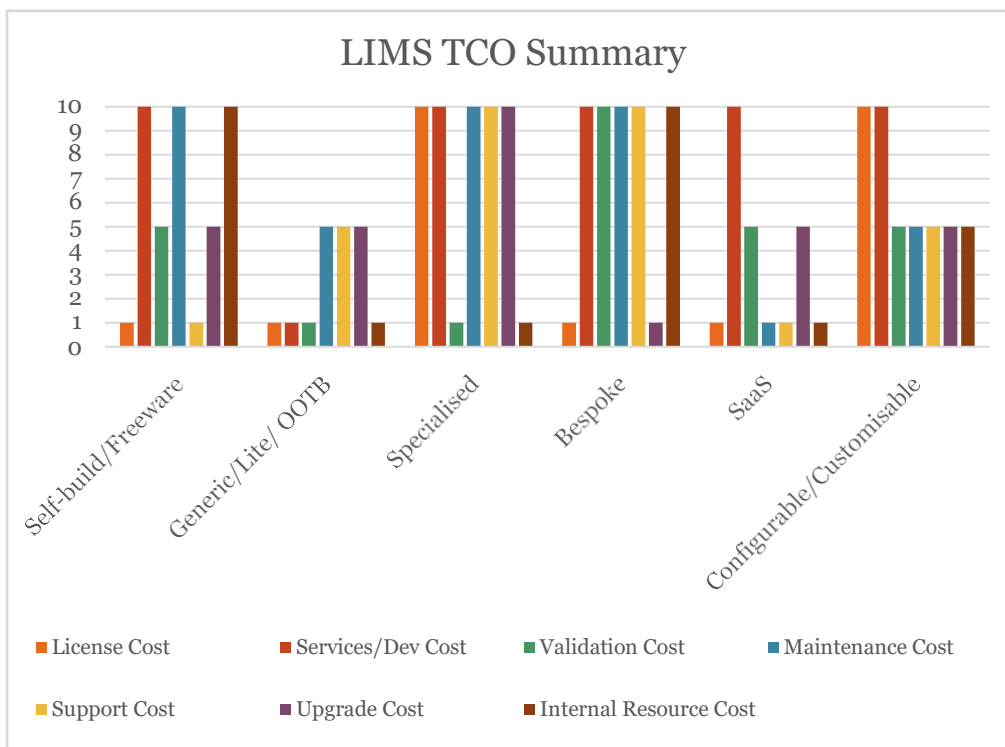


representative of the vendors team are available and, preferably, on-site at key points of the implementation. Ideally they should be on-site for the majority of the time in complex implementations.

Agaram Technologies use an on-site/off-shore model to give a presence on-site but do much of the configuration work off-site. As the price of off-shore resources is much less than on-site resources the customer benefits from on-site staff to ensure the smooth implementation but also benefits from a much lower cost for the solution as the majority of the work is off-shored to their Indian HQ. This results in an enhanced ROI due to the offshore/onsite implementation model.



Rating	Score
01	Low
05	Medium
10	High



Rating	Score
01	Low
05	Medium
10	High

Conclusions

- Currently the largest proportion of LIMS solutions are customizable/configurable model. However, some options such as SaaS are only just starting to become viable options so the balance may change.
- The best option for you is what suits you best, both in terms of functionality and type of solution.
- A LIMS purchase is always a balance of budget vs functionality. Do not expect to get a 100% match to your requirements from a low cost solution even though it will help manage your lab.
- You may aim for a 100% match to requirements but be aware that the last 5 or 10% of functionality can be the most difficult and costly to deliver.
- Most LIMS projects can be split into phases for the implementation. This can be a better route to adopt as you can, for example, implement it for a single lab before rolling it out to other labs or sites. It also allows people using the system to become familiar with it and may lead to some additional functionality being suggested for later phases.
- Expandability and enhancements are important for the future. Labs are constantly changing in their scope, purpose and size so any solution must be flexible enough to take in the changes to ensure that the system and the day-to-day lab processes stay in-step with each other.
- Do not fall into the trap of becoming "LIMS centric" an integrated information and data management solution is more than a LIMS. LIMS is part of the total integrated solution.
- Concentrate on maximizing your ROI without compromising on the major functionality of your required system. Base your ROI calculations on lifetime costs calculated over a 10 year period.