LABORATORY INFORMATION MANAGEMENT SYSTEMS (LIMS):

RE-ENGINEERING THE WAY SOUTH AFRICAN TESTING LABORATORIES CONDUCT BUSINESS

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Abstract

A critical objective of a LIMS is the integration of different systems and processes such as the receipt of samples, testing as per the customer's requirements, generating results and certificates of analysis. By consolidating the work of laboratory technicians and speeding up these processes, LIMS can save time and dramatically improve the access of results to analysts and ultimately the customer. A study was conducted to assess the current implementation of LIMS in testing laboratories in South Africa, as part of the business process re engineering of the life science industry using a mixed methodology approach. Of the 328 laboratories that were requested to participate in the survey only 72 (22%) of the laboratories responded, with 66 (92%) agreeing to participate and 8% declining to participate further in the survey. Of the 72 laboratories, 32 completed the questionnaire. The majority of these laboratories (24%) use LIMS for sample management while 20% use LIMS for analyses with calculations, 19% for user reporting, 14% for workflow automation, 11% for quality assurance and control and 36% for instrument connection. When investigating the status of LIMS service providers in the South African market and their strengths and weakness and opportunities for improvement, Lab Ware was the preferred vendor for 36% of the respondents. Cost was mentioned as a weakness of some of the LIMS vendors by half of the respondents in the survey. Just under half of the respondents (46.7%) mentioned costly improvements as a weakness of the LIMS. In analyzing what laboratories thought about the future of LIMS, 58% indicated that they plan to implement LIMS in the cloud, 25% through mobile devices and 17% through tablets. The implementation of a LIMS will meet the objectives of reduced lead times, automation, enhanced productivity, reliable and accurate data, electronic reporting, and integration with other systems such as ERP and CRM.

1. Introduction

Why are Laboratory Information Management Systems (LIMS) becoming a catalyst for and the face of reengineered laboratories today? Is it just a new fad where everything is put on an information system? Is LIMS a necessity for every life science organisation? The laboratory like other business environments depends on and is supported by information technology to reengineer business processes. Technological advances through automation in the laboratory, has warranted a need for automation of its information management together with reduced lead times, accurate certificates of analysis and easy access to information resources. The LIMS is about the way a laboratory monitors and manages the results generated that represents the laboratory's product or service offering. The use of LIMS in combination with automation of laboratory processes such as the use of automated instruments, technological advances in the instrumentation used, and environmental monitoring, has improved the efficiency and quality of the work by reducing the potential for human errors, increasing the throughput of testing and results generated and ensuring that sample tracking processes that are otherwise complicated to perform without error by hand, are achieved[1].

Changes in information management processes with the introduction of systems such as LIMS can create anxiety amongst the laboratory analysts and technicians because they have to adopt and implement new ways of conducting business. These changes are costly, requiring manual and automated systems to be run in parallel in the beginning of the implementation and is often not easily acceptable to those who are directly involved in operating the system. The long-term benefit however is enhanced effectiveness and efficiency which outweighs the initial outlay. A laboratory must be committed to allocate the necessary time and resources to plan, select, and implement a LIMS [2]. The system must however also be implemented in line with the strategic objectives of the organisation.

In the last 10 years, implementation of automated information management systems aimed to meet the requirements of faster turnaround times, reduced human errors and improved efficiency and effectiveness has compelled organisations to face the challenge and embrace the opportunities of transforming the way they conduct business [2] with LIMS being viewed as a catalyst for re engineering laboratory operations.

This study proposes to survey and evaluate the impact re engineering of South African Testing Laboratory's with LIMS has made on productivity, efficiency and effectiveness of the business. The study further proposes to present a framework for successful implementation of a LIMS as part of the re-engineering of laboratory operational processes and continual improvement in the South African Testing Laboratory landscape.

Apart from providing an end to end integration of the laboratory within and across the organizational functions, a LIMS helps increase efficiency and assigns ownership of activities, it helps improve the speed

and accuracy of the workflow process and helps disseminate information faster and accurately to the right analyst and can be used to gain a competitive advantage by customizing the system to reflect and amplify the core competencies which are unique to a particular laboratory and its operating process.

Real, tangible benefit is derived by developing improved products and services and by reducing costs. This requires changes which involve the re-engineering or significant improvement of core business processes. A LIMS can allow these changes to be adopted, but the identification, design and implementation of them is a people orientated process. A LIMS project is much more than specifying the requirements, selecting a package and validating it. The people, business and change management issues all require equal consideration, since these aspects of the project significantly affect the benefit delivered (Broad, 2010). Having implemented a LIMS in the laboratory the researcher also argues for the proper training of staff and their buy in, which is critical to the success of LIMS implementation.

1.1 Redesigning the Business processes in Laboratories

Business process redesign (BPR) is about creating innovative business processes which an organisation can implement to meet the demands of today's information-intensive, global business marketplace. The motivation is usually the realization that processes need to be completed faster with less resources to improve productivity, efficiency and competitiveness [3].

With the economic environment constantly changing, many organisations are increasing their interest in BPR. A study showed that approximately 87% of organisations questioned were either involved in or were intending to implement BPR projects in the future [3]. The BPR process involves investing in many processes to implement activities that produce a service or product offering that is valued by a customer. Process redesign is a programme that can have positive outcomes for change in an organization. When the critical processes are redesigned correctly, BPR has the ability to improve company-wide performance. In order for laboratories in South Africa to be recognized as official testing laboratories by Government, they must be ISO 17025 accredited, and involves continual improvements and redesigned processes.

Information technology (IT) has the potential to give businesses options to redesign processes to develop high-performing organizations. Today organisations are encouraged to adopt high performance cultures. A high performance work culture is where innovation, performance, value-added change and customer satisfaction is valued by all employees and where the team is goal orientated, disciplined and focuses on improving individual, team and organizational performance.

Computers and information management technologies have evolved with time and are touching our lives where we live, play and work. Those of us who work in a laboratory environment are faced with the challenge of how to best apply these information technologies to increase the revenue of the life science organisations we work for to continually improve quality. While creating a culture of quality is a complex,

time consuming and expensive process, a LIMS helps to create a culture that values quality by ensuring data integrity and therefore becomes an essential need of the current business environment of the life science industry in South Africa.

1.2 The need for LIMS in the current business environment of the life sciences industry

Executive and Laboratory Management, and IT professionals often pose the question as to whether they need a LIMS. The LIMS has been recognized as a crucial function in the life sciences environment. Scientific and laboratory testing oriented companies are making major investments in their LIMS solutions to improve productivity and data quality. With mandates to minimize costs while improving safety levels and the quality of their findings, life science organizations are feeling the pressure[4]. One of the major weaknesses of life science organisations is the inability to adapt quickly enough and change the large amount of laboratory information into something meaningful to allow laboratory management to make timely and appropriate business decisions[5].

Currently there are companies that still use manual processes for collecting, analysing and reporting which often involves collating volumes of data taking the scientists away from the bench[5]. Companies that do not integrate data sources across the business run the risk of transcribing data very slowly which is labour intensive and prone to errors. When employees utilize most of their time analysing data they cannot focus on being productive, which leads to loss of valuable employee time and income [5].

As laboratories expand they face the challenge of processing data accurately and quickly and at the same time keep an eye on the competition by making sure they stay ahead by using advanced technologies to improve performance and profits [6]. One area where this is achieved is in the tracking of processes. Having a good understanding of what happens at each step in the value chain, which employee is responsible for each step, and what resources are involved can be helpful in addressing troubleshooting. Incorporating checks at critical control points is a good way to prevent bottlenecks along each step. Competency training, instrument validation, performance monitoring and sample tracking, are examples of some of the processes that should be tracked to contribute to the optimal workflow process in the laboratory.

One of the critical uses of a LIMS is to maintain proper records of samples and the tests required out on them. This occurs at the point of sample receipt in the laboratory and often in a designated sample receiving area that is well controlled. This sample management process assigns sample numbers or bar codes and records details of the sender, condition of samples, types of tests required, the type of matrix received, amongst other information as defined by the laboratory.

Not only does a LIMS support green initiatives of reducing the extensive paper trail, it ensures the control of a sample from receipt to the dissemination of a final result to a customer in the shortest time possible. The researcher has observed that in the business unit she manages with a customer base of over 500 clients in South Africa and abroad, the demand of customers is a lead time of 24-48hrs. LIMS is one of the ways the

laboratory has redesigned its workflow process to meet this objective of a reduced turnaround time. For a laboratory that performs a statutory function, testing for a specific market or industry, invaluable data is generated that is disseminated to that industry or government so that that may gauge the status of the quality of that product in South Africa. Therefore in understanding the fundamentals of a LIMS, the power of this information management tool can be evaluated for use by laboratories.

1.3 The fundamentals of a LIMS

The LIMS is a software-based laboratory information management system that provides applications to support a laboratory's internal and external business processes.

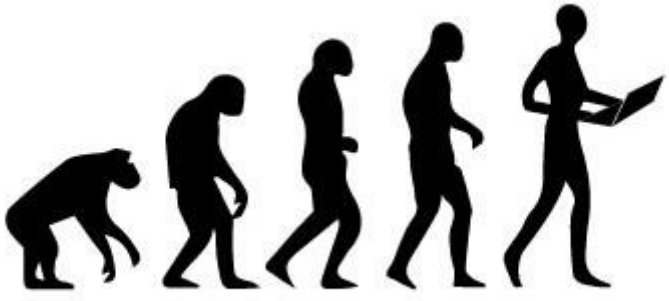

Figure.1. A light-hearted illustration to depict the evolution of a LIMS [7].

With the emergence of LIMS in the 1980s assigning laboratory functions to a centralized computer, productivity and functionality improved. As technology advances and work flow changes, the need for application specific features emerged [7]. This initiated the development of second generation LIMS which was possible by using third-party commercial relational databases through the use of minicomputers and by the early 1990s the first client/server configuration was developed using a PC combined with the security of a minicomputer [7]. Functionality "appeared" quicker by splitting the data processing between several clients and the main database server. Fourth generation LIMS was developed by the mid-1990s which allows distributing client/server functions over a network to optimise processing and sharing capabilities and in 1996, the internet advanced and initiated the first web-enabled and wireless computing features for LIMS [7]. Now a LIMS is packed with full functionality for laboratories to immediately benefit from increased productivity after implementation.

These characteristics of a LIMS have improved over time from simple sample tracking to an enterprise resource planning tool that manages multiple facets of laboratory informatics [8]. LIMS products have been growing beyond their original intention of sample management to include data management, mining , and analysis, and electronic laboratory notebook (ELN) integration [8].

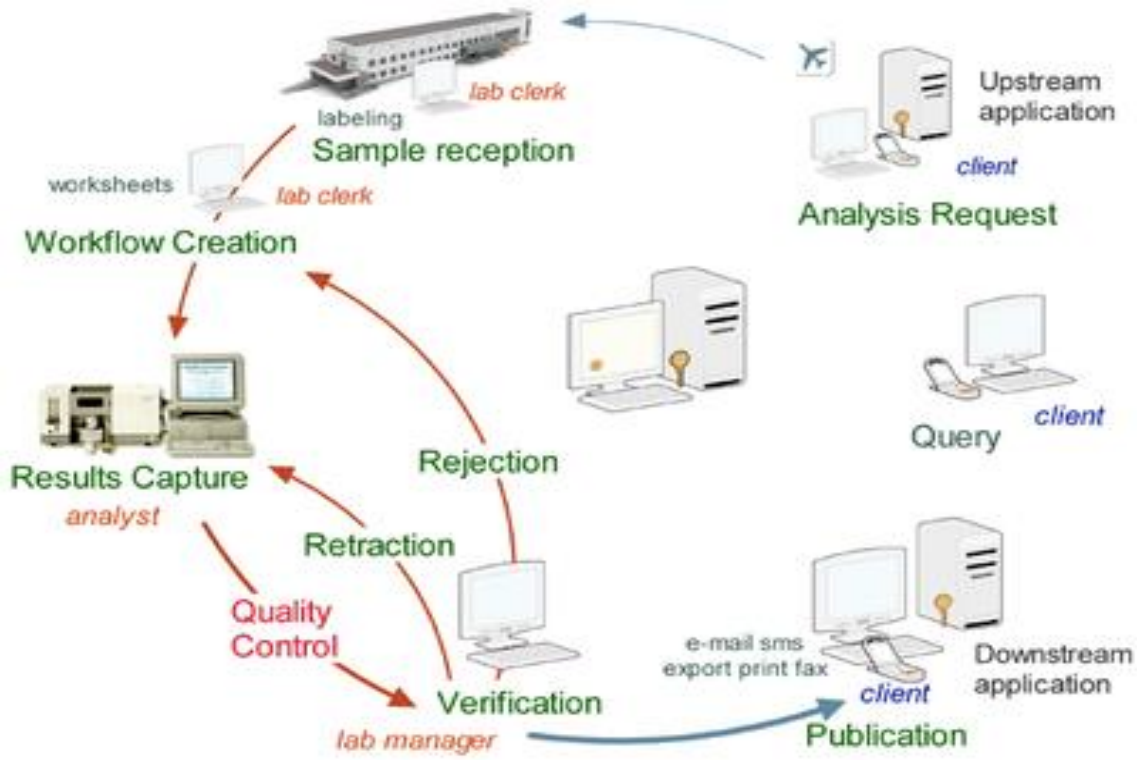

Figure 2. A schematic illustration of a typical LIMS integrated into the sample receipt, analysis and generation of certificates of analysis for the client. [9].

LIMS offer an increasing amount of integration with laboratory instruments and applications (Figure 2). The increase in data being generated in laboratories and business demands with profitability being prioritised, LIMS suppliers have to focus on how the LIMS they offer can manage data exchanges, on how an instrument's input and output data is managed, how remote sample collection data is imported and exported, and how mobile technology integrates with the LIMS [10].

1.4 The importance of this study

It has become evident through the years that accuracy and turnaround times in a laboratory are critical to its credibility and are key value propositions to give it a competitive edge. Customers are prepared to pay premium for an accurate and reliable service. The LIMS is an effective way to allow for validation of data captured detecting errors. The ISO 17025 accreditation or quality assurance process of each laboratory allows for improvement in the quality and reliability of data generated. LIMS can be a useful tool that could give a laboratory its value proposition over other laboratories, saving time and money. Laboratories work differently and design their processes to meet their needs therefore a LIMS must be aligned to the laboratory workflow and must be able to address future improvements in laboratory's internal business processes. A LIMS implementation involves the evaluation, monitoring and modification to ensure improved laboratory processes. Having reviewed the relevant literature, it is clear that finding the right LIMS to meet the specific needs of laboratories is critical in order for the successful implementation.

As technology advances, South Africa needs to keep up in order to compete in global markets. Life Science organisations are under pressure to redesign their laboratory testing processes to comply to international standards in order to penetrate EU markets. From the researchers own experience of an EU audit of a laboratory that is an assignee of the Department of Agriculture, Fisheries and Forestry, one of their findings reported to the international community three years ago, was the absence of a LIMS in the statutory laboratory. Therefore the implementation of a LIMS as part of the redesign efforts will hold South African testing laboratories in good stead. South Africa's long term investments in agricultural science and technology will facilitate future competitiveness of the commercial sector and ensure sustained market access. The bio-economy strategy (the "Farmer to Pharma Value Chain"), National Development Plan, Food Security Policy framework and the Food Security Implementation Plan provide the roadmap for future economic growth, national food security and international trade. Life science organizations are cognizant of these developments, and need to be assertive in its approach, and be forward looking by redesigning business processes and position themselves against this background.

2. Methodology

A mixed method research approach was adopted in this study using primary and secondary data and a questionnaire posed to the listed accredited testing laboratories on the SANAS database to explore the implementation of the LIMS in South African testing laboratories. A framework for successful implementation of LIMS that could be used by testing laboratories in business process re-engineering to improve productivity and efficiencies was then formulated.

3. Results and Discussion

The study focused on the categories of customization, vendor service, staff use and customer satisfaction of LIMS. With respect to the demographics of the participants that responded, 62% of the laboratories are based in Gauteng, 14% in Kwazulu Natal and 7% from the Western Cape. No laboratories from the Northern Cape participated in the survey.

Of the laboratories that responded to the survey 58% of the laboratories have a LIMS in place, 30% are not planning to implement a LIMS, and while 12% indicated that they plan to implement a LIMS in the future. Every organization has its own barriers that may prevent it from implementing a LIMS from costs, to organisational priorities and strategies. It is recommended that a proper needs analysis be conducted by laboratories, including research on the LIMS and its benefits and weaknesses before deciding if a LIMS will be worth the investment and fit for purpose. In some instances external stakeholders demand that the laboratory have a LIMS in place which leaves the laboratory with no choice.

The majority of the laboratories (24%) that responded use LIMS for sample management while 20% use LIMS for analyses with calculations, 19% for user reporting, 14% for workflow automation, 11% for quality assurance and control and 10% for instrument connection. With respect to instrument interfacing with

LIMS only 50% of the laboratories that responded have integrated instruments to LIMS. One area of concern is the perception that the process of linking systems is complex. Integration requires support from the vendor, but is encouraged by the author because it reduces the chances of errors and the time taken to generate the certificate of analysis, having a positive impact on productivity and efficiencies in the laboratory.

In addressing the objective of evaluating the preferred LIMS vendor service providers Lab Ware was the preferred vendor for the majority of respondents. Cost was mentioned as a weakness of some of the LIMS vendors by half of the respondents. Costly improvements, a lack of technical support and costly maintenance plans of their vendors were further drawbacks of the systems. LIMS projects require time, top management support and money.

It is recommended that the motivation to purchase a LIMS must be made in the context of affordability, fit for purpose, productivity and efficiency. The laboratory management team must do needs analysis, present projections of returns on investment both tangible and intangible and present a proper business plan for the selection, implementation and evaluation of the LIMS to Executive Management. This would also ensure buy in by the team and reassure them that business processes are re engineered to improved productivity and not make analysts redundant.

To ensure that costs are contained, a budget for implementation for LIMS must be approved by Top Management timeously (a year in advance is preferable). Requesting an unbudgeted approval from management may create the impression of poor planning and lack of confidence by Top Management that the investment could result in returns.

The two most important decision making factors for the respondents in choice of a vendor were service and support, and customization. Every laboratory has its own workflow processes, different types of instruments for system integration, different formats of certificate of analysis, varying throughput per day and different levels of competencies with respect to information technology and management. Customization is critical for the success of implementation of a LIMS. It is recommended that the organisation pay for a monthly maintenance plan to ensure upgrades are made without additional costs, but more importantly a service level agreement should be in place to ensure that the vendor continues to provide after sales support.

The faster turnaround times and easy access to data were the benefits that most of the respondents experienced with LIMS implementation in their laboratories. Many customers rely on a fast turnaround time and are often prepared to pay premium for same day results from laboratories. A laboratory that offers this service will be able to attract more business. Respondents were also confident to refer LIMS to other organisations, based on their own experiences of the information system in their environments. The author recommends that laboratories profile their implementation of LIMS on their websites, through workshops

and conferences, because a LIMS is also viewed as a paperless tool and a ‘green’ initiative which can contribute to the corporate social responsibility (CSR) of the organisation.

The author reviewed the literature on the basic requirements for selection and implementation and formulated a framework making recommendations along each step (Fig 3). By following the six steps of project definition, functional requirements, functional design, implementation, system integration and system evaluation, it is envisaged that laboratories will be able to implement a LIMS that will meet the objectives of faster turnaround times, automation, increased productivity, higher quality of data, electronic reporting, and integration with other enterprise databases.

4. Conclusion

This study proposed to survey and evaluate the impact re engineering of South African Testing Laboratory’s with LIMS has made on productivity, efficiency and effectiveness of the business. Through the online survey of SANAS accredited testing laboratories in South Africa, the study attempted to assess the current implementation of LIMS in testing laboratories as part of the business process re engineering of the life science industry. The study further proposed to present a framework for successful implementation of a LIMS as part of the re-engineering of laboratory operational processes and continual improvement in the South African Testing Laboratory landscape. By determining the impact of LIMS on sustainability, profitability and efficiencies the study aimed to provide guidance to laboratories considering the adoption of this informatics system to improve accuracy, reliability and validity of laboratory testing results, especially when decisions on human and animal health are impacted by speedy and accurate results obtained from these facilities.

In the South African laboratory testing environment, LIMS is emerging as a tool to implement automation of data and information. South African laboratories that have responded to the survey have embraced the technology, acknowledged its strategic benefits in improving productivity, efficiency and effectiveness and are looking to continually improve the system to service its customers with reliable, valid and accurate results.

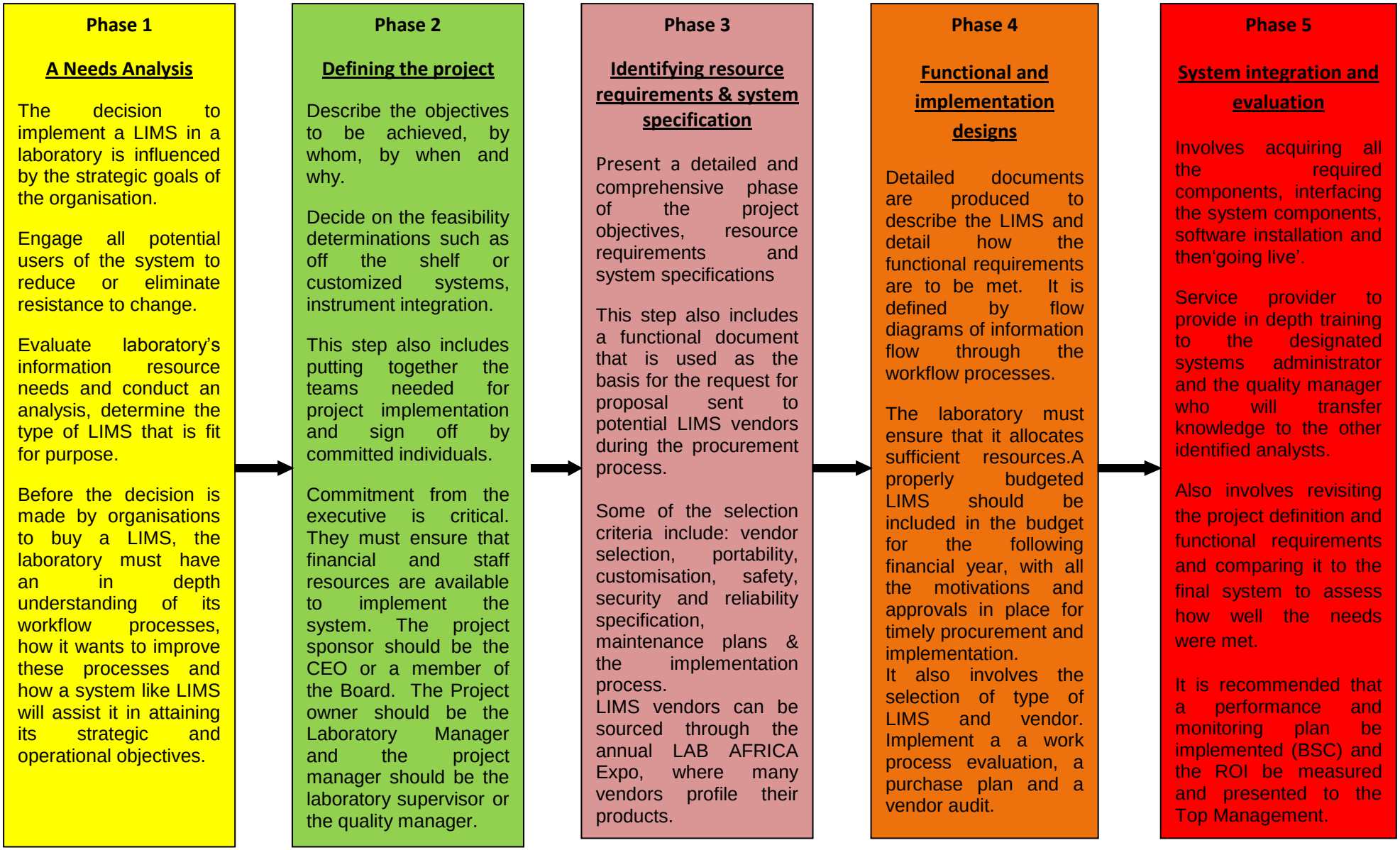

Figure 3. A proposed framework for a LIMS selection and implementation

References

1. Voegele, C., Tavtigian, S.V., de Silva, D., Cuber, S., Thomas, A., Le Calvez-Kelm, F. 2007. ‘ A Laboratory Information Management System (LIMS) for a high throughput genetic platform aimed at candidate gene mutation screening’, *Bioinformatics*, 23(18): 2504-2506
2. Avery, G., McGee, C. & Falk, S. 2000. ‘ Implementing LIMS : A How to Guide’, Analytical Chemistry, A: 57-62.
3. Attaran, M. 2004. ‘Exploring the relationship between information technology and business process reengineering’, *Information & Management* ,41:585–596
4. Nogueira, A., Chawla, V., Lau, K., Eastman, J. 2014.’ Industry outlook: LIMS Master Data Management in the Life Sciences industry, IGate White Paper
5. Shah, K. 2009. ‘Elevating laboratory informatics to assist decision making’, *PharmTech*.com, 21(5).
6. Paszko, C., Pugsley, C. 2000. ‘Consideration in selecting a laboratory information management system (LIMS)’, Accelerated Technology Laboratories, September.
7. Webster, T. 2013. The Evolution of LIMS [online]. Available from **http://www.broughtonsoftware.com/blog/the-evolution-of-lims** [Accessed 19 June 2015].
8. Roebuck, K. 2013. *LIMS Laboratory Information Management System: High impact strategies –what you need to know: definitions, adoptions, Impact, benefits, maturity, vendors*. Emereo Publishing.
9. **http://www.bikalabs.com/images/diagrams/limsflow0902/image_preview** [Accessed 19 April 2015].
10. How Do I Find the Right LIMS — And How Much Will It Cost? 2011. *Laboratory Informatics Institute, Inc.*