

How a LIMS Can Save Your Laboratory Money and Enhance Data Quality

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Abstract

When surveyed about what the major challenges were facing them in their operation, environmental laboratories shared a short list of common issues. These include meeting turn around times (TAT) and holding times, missed sampling events, certification audits, unprofitable departments, lost time searching for or checking data, and cash flow problems.

These issues can be grouped as two main topics, data quality and costs. In the environmental laboratory these two are intricately linked. Through the use of proper systems and processes a laboratory can produce and manage data of high quality. In today's world, this must be accomplished while working under heavy budget constraints. As a result the laboratory must consider how to achieve high data quality without destroying the budget.

This paper will explore how the proper implementation and use of a Laboratory Information Management System (LIMS) can not only enhance the data quality in a laboratory, but can also offer significant savings in time, money and other resources. These savings happen as a result of automation and better access to the data in the laboratory. Automation is most successfully implemented following a needs assessment and following the guiding principles of Quality Management. Over the years there have been many tools utilized including; TQM (Total Quality Management, BPR (Business Process RE-engineering), PDCA (Plan, Do, Check, Act), Continual Process Improvement, Six Sigma and many others). For the purpose of this paper we will examine the application of Continual Process Improvement.

Topics that will be covered will include LIMS enhancements to Quality Systems, time and resource management, standardization, traceability, and the monetary ramifications upon the laboratory.

Introduction

Customer expectation and the laboratory business environment are changing constantly, to the point that current, efficient processes can rapidly become obsolete. One example is the reporting process. In the past clients were satisfied to receive a report on the analytical results in the mail within a few weeks. Enter the fax machine, which transformed result transmission to the client to days rather than weeks. Once the results were validated and approved they could be printed and faxed directly to the client or multiple individuals that needed to review that information. The next major technological improvement was the Internet and e-mail, where laboratories now have the capability to convert reports to PDF files and e-mail them to clients or through a web enabled Laboratory Information Management System. Customers can actually obtain information in close to real time on the sample status, tests, methods, results, reporting limits and much more. Please see Figure 1 to view an example of a web enabled product called Sample Master[®] LIMS Result Point. Users can access a web site with a user name and password and the site utilizes Secure Socket Layer and encryption via an electronic server certificate.

If a laboratory wants to remain competitive it needs to have a plan to do so and constantly look for area that processes can be improved upon. This is even more important today with fierce competition among laboratories and eroding price schedules. Privatization is the threat to state and federal laboratories, as governments look at ways of reducing costs, if outsourcing is more financially effective that route will be investigated. The good news is that the technology and the tools are becoming increasingly affordable. The cost of computer hardware, personal computers, servers, hubs, networking supplies, software, and Laboratory Information Management Systems (LIMS) are becoming much more affordable than they were 7-10 years ago. The tools that are required by the large laboratories are the same ones that are needed by the smaller ones, and fortunately laboratory automation solutions are scalable. Users can purchase LIMS software in modules, only purchasing the modules that they require, and there are also affordable hardware and network configurations for smaller laboratories.

The term continual process improvement refers to an initiative that involves eliminating steps that do not add value to the final process or the final product which in the case of the laboratory is data or information. This initiative utilizes employees are key stakeholders that are often closest to the creation of the final product and can best identify ways to eliminate waste, prevent delays in reporting or analysis, avoid duplication of effort, and look for ways to reduce errors (such as transcription errors that can occur when laboratory instrumentation is not integrated with a LIMS and users are manually re-entering data into spreadsheets or reports). Not only does this initiative prevent waste, to save money and resources, but it also servers to focus employees on the most critical part of any business, watching the bottom line and provides an avenue for creativity. Continual Process Improvement is not just for employees intimately involved in the final delivery of the end product, rather is it a way of doing business for the entire organization. The same principles apply to management which must also actively seek out opportunities for improvement across the organization. Table 1 defines the principles of Continual Process Improvement.

In a hypothetical example, let's apply these principles to a typical analytical laboratory that is operating in a municipal setting with eroding budget, requests for higher levels of service with no increase in staff, the possibility of Privatization, and increases in regulatory requirements. The first step is to *define the problem* and attempt to solve one problem at a time. In our hypothetical meeting, one problem that was well defined was meeting turnaround times, due to the significant interaction with paperwork and manual QC checks, the time that was required from the time a sample was logged into the laboratory to the time that it was reported to be from 9 to 14 days. This was determined by *documenting the process*, creating a flow diagram and measuring the time between each step. Next the automation team formalized the problem that they were trying to solve; they *developed an objective statement*. The laboratory needs to automate its sample login process and reporting process to provide the higher level of service required to compete with Privatization. This will be done by selecting a Laboratory Information Management System (LIMS), examining the use of bar-coded labels, and barcode scanners on the next 2 months and implementing a new system within 3-5 months.

After *analyzing data*, the flow diagrams and process description bottlenecks were discussed and identified. It became clear that the problem was multifactorial. Some of the bottlenecks identified were related to problems with an incomplete or illegible chain of custody form, lost samples, analysts not being aware that samples were ready for analysis, and finally manually reporting. Manual reporting was performed by tying results into Word templates which often suffered from transcription errors. These transcription errors cost the laboratory in terms of data quality, repeat work, and delays. The team came up with *several solutions*, these included acquiring automation tools, such as label printers with bar-coding to better track samples throughout the laboratory. With the creation of report templates, reporting will be much quicker, as will data review and release, with an increase in data quality. Another significant enhancement will be allowing clients to view their sample data once it has been validated and approved via the Internet. LIMS systems can be integrated with a web server to allow clients rapid access to results. The advantage is that the laboratories that are embracing new technology will be able to offer clients higher levels of services, allowing them to meet the stated objective of rapid access to analytical results. Additional advantages include the ability to link pdf result reports to the web site, so that if clients lose a copy of their reports, they can download them 24/7 without contacting the laboratory.

An additional benefit of a computerized LIMS is the ability to enforce Quality Assurance and regulatory goals. An integrated LIMS will allow for the specification of required methods, QC samples, holding times, and even sample condition checks at login. This helps the laboratory integrate the regulatory requirements into their processes. An integrated LIMS will also allow the laboratory to better communicate, generate worklists to alert analysts as to what tests need to be performed that day and expedite the generation of reports, dramatically reducing reporting times.

The next phase of the Continual Process calls for *testing the proposed solution* in a "test environment". Typically the laboratory will operate the manual system in conjunction with the automated LIMS until they are confident that the output of both systems is equivalent in terms of output, this period is often referred to as "parallel testing". Since the problem currently being worked on in this example is the turnaround times, they are compared for the two systems. It should be noted that with the switch from manual typing of Word templates to report templates that are automatically populated from the LIMS, the time savings for greatly reducing turnaround times are accompanied by enhanced data quality as transcription errors are greatly reduced. The time for the report generation with the automated LIMS can be within hours or even minutes of the final approval of the analytical results.

The overall laboratory process was improved and reports are able to be generated in hours rather than weeks. Consider that the laboratory also implemented bar-coding on a single workstation to test it out, but the sample volume made the bar-coding too cumbersome and it was abandoned since it was not a "best solution". The laboratory's next step was to *implement the best solutions*. The best solutions are those that eliminate duplications, enhance quality, reduce the cost of each analysis and have a rapid return on investment (ROI). The laboratory should continue to *track progress* and monitor the performance of each automation enhancement, by charting laboratory turnaround times, examine the number of reports generated from the LIMS versus the number that can be created manually. The tracking of this kind of performance data can also be automated within a computerized LIMS. Create control charts and Pareto charts so that the progress can be monitored and fine-tuned. Once the *results are recoded* the laboratory can examine specific cost savings and time savings by perhaps decreasing unnecessary steps in the sample analysis process. The team should also create new flow diagrams after the automation steps and LIMS have been implemented to see how the flow has been altered.

Finally, the laboratory should *share the project information* with the rest of the laboratory, with an explanation of the thought process on each improvement item and how the process improvement creates an on-going winning situation for employees, customers and stake holders. Those organizations that work to streamline processes, increase efficiency, and productivity will be able to reward employees and ensure the organization's economic health today and into the future.

Conclusions

To remain competitive in the ever changing laboratory landscape organizations must embrace the principles of continual improvement to reduce waste and function more effectively. Employees are constantly being asked to do more with fewer and fewer resources; Continual Process Improvement is the key. This process must involve each member of the organization for the process to be successful.

Laboratories that effectively manage change and implement Continual Process Improvement can realize substantial cost savings through enhanced data quality, laboratory safety (through training and record keeping), improved customer satisfaction, reduction in turnaround times, and elimination of waste and duplication of efforts.

Figure 1. Captured screen image of Sample Master[®] Pro LIMS Result Point web application that allows clients to access their laboratory data 24/7 via a secure web site.

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Table 1. Ten principles of Continual Process Improvement as applied to the analytical laboratory.

No.	Principle Objective	Description
1	Define Problem	Basically a simple statement of the problem that the laboratory is trying to solve.
2	Document Your Process	Create a flow diagram of current operations and examine it for bottlenecks, opportunities for improvement, duplication of effort or any other waste.
3	Develop an Objective Statement	The statement should be a summary of the team's findings and include a Gantt chart with measurable goals.
4	Analyze Data	Try to examine the data with an eye on a cause and effect type of relationship, and then determine the root cause of the problem.
5	Develop Several Solutions	Assemble a team to brainstorm in coming up with creative solutions to the problem, evaluate solutions to select the best one.
6	Test Your Solutions	Implement your solution in a test environment and measure the results before you roll-out any changes laboratory-wide.
7	Implement Best Solution	Solutions are evaluated on the basis of ROI (return on investment), resource investment, customer value and cost.
8	Track Your Progress	When the best solution has been implemented it is important not to stop there, but to fine tune the process based on feedback from statistical measurements such as Pareto charts.
9	Record the Results	Document the new process with flow charts and evaluate the cost savings as well as process improvements.
10	Present the Results	Share the results with the rest of the laboratory so that they can also participate if possible and demonstrate a climate of employee empowerment, enhanced shareholder value and increased customer satisfaction.

For additional information on performing a laboratory needs assessment or LIMS automation, please contact Accelerated Technology Laboratories, Inc. at 800.565.LIMS (5467) or visit ATL on the Internet at <u>www.atlab.com</u>.