



LIMS versus QMS

What Are They and Do I Need Both?

WHITE PAPER

A LIMS vs. QMS White Paper for Laboratories
by: Juliann Poff

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If I run a laboratory, do I need one of these or do I need both?

So let us start with a description of the two systems.

A LIMS is a Laboratory Information Management System or sometimes also referred to as a LIS – Laboratory Information System or a LMS – Laboratory Management System.

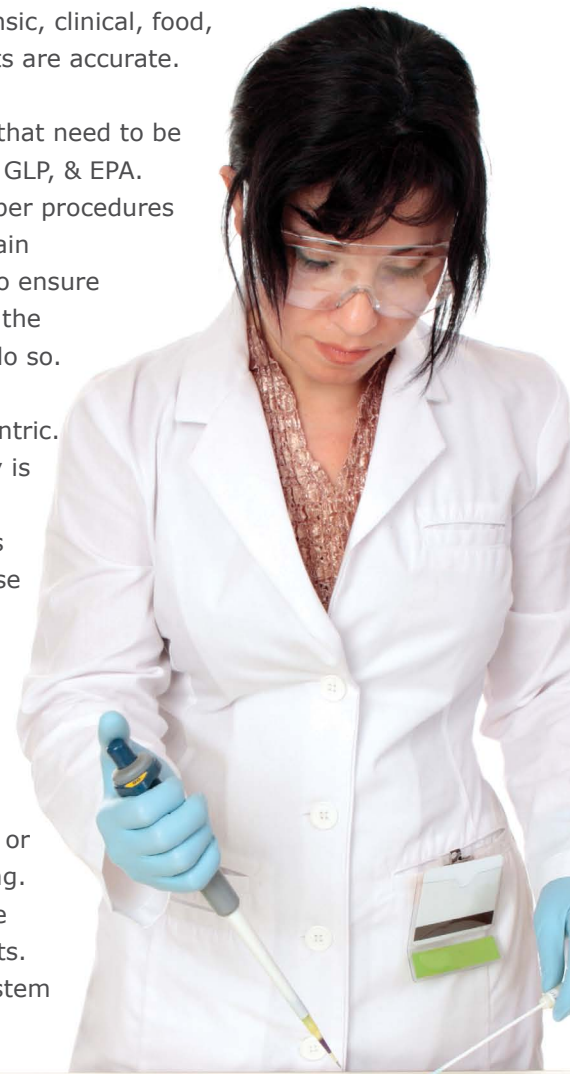
A QMS refers to a Quality Management System or sometimes also referred to as an eQMS – Electronic Quality Management System or a Compliance Management System.

In a laboratory setting, there is a plethora of data that needs to be tracked. Very important work is being completed on a day-to-day basis and a system needs to be able to help a laboratory efficiently capture that sample analytical testing data. It needs to be able to provide traceability for the results, track the items that are used during the testing process back to lot numbers and be able to validate and QA that data to ensure its accuracy. As we know, testing laboratories of all types (environmental, forensic, clinical, food, reference, veterinary, & agriculture) have to routinely prove that their results are accurate.

Also in a laboratory setting there are quality and/or compliance regulations that need to be adhered to, such as ISO 17025, ISO 17020, ISO 15189, FDA, CLIA, NELAC, GLP, & EPA. These regulations are put into place to ensure that a laboratory has the proper procedures in place to tell the laboratory technicians how to perform those tests, maintain documentation on all of the instrumentation in the laboratory, MSD sheets to ensure the safety of the employees, and most importantly, be able to track back to the personnel who performed those tests to ensure that they were qualified to do so.

Day-to-day test data is typically captured into a LIMS, which is very case centric. The information on the high-level quality and management of the laboratory is typically captured into a QMS. LIMS enable you to not only track casework information, but also to report out data and statistics on that casework. This can be extremely helpful when grant funding is used to support a lab because you have to report those numbers back (how many cases worked under a certain grant dollar amount during the first quarter, how many specimens, etc.) This is also used for labs funded by the government since they have to report to legislators how many cases were worked in the previous year as compared to the current year, and how many in each discipline.

Laboratories must remain competitive for jobs and must adhere to a quality or regulatory compliance on a local, state and/or federal level to receive funding. This is where a quality management system comes into play to help manage and protect all of the information pertaining to their compliance requirements. More than just a document management system, a quality management system often allows you the ability to not only manage your documents, track the revision history of a document to know who signed off on it, and when and what changes were made and why, ensure that everyone is using the most current version.



A QMS should also have the capabilities for you to manage and automate both quality and business processes in your laboratory. You would also store your organization chart, your employees' job descriptions, training checklists and proficiency testing results to be able to prove the competency of your employees and their technical aptitude to perform valid tests. In many cases, there are quality records that are not directly related to the casework and laboratories need to have a secure, accessible way to manage this information.

Laboratories are not only required to prove that their day-to-day case information is captured accurately, but that their procedures are being followed, that there is a way to prove they are being followed, and that their employees are competent to perform those tests. Any question of impropriety can be costly, not only in money, but in the form of lawsuits for questionable samples as well as the loss of time and earned revenue to earn back that respect and credibility to the laboratory. Sometimes these labs cannot recover at all, causing loss of services to that community along with the loss of jobs.

If this information is not being controlled by a laboratory information management system and a quality management system, it can leave your laboratory vulnerable. Employees could delete test results and/or procedures inadvertently, use wrong versions of procedures and put your laboratory and its results in jeopardy. In many laboratories, deadly consequences are the result of inaccurate results.

In most laboratories, the same individuals who are asked to administer their quality management system often have the task of also performing the tests themselves. They need their systems to help the organization become more efficient and help build a culture of quality in their organization while helping them allocate their time more effectively.

Laboratories are typically audited annually by third-party auditors that represent various quality or government organizations. Audits can be very time consuming and stressful. Having both of these systems in place during an audit is beneficial. During an audit you are going to be asked to provide a master controlled document list along with all of the current standards and their associated standard operating procedures. These are housed and controlled in your quality management system. You will also be asked to show examples of analytical work as well as reports or certificates of results and these are housed and controlled in your laboratory information management system. The efficiencies gained by having both types of systems will allow you to be better prepared at all times and reduce your time to audit. The actual audit will run more smoothly and allow you to focus on continual improvement for your laboratory instead of the auditors having to review and write up findings on the inefficiencies and/or inaccuracies in your work.

Now that you understand the benefits of having a LIMS and a QMS, you have to make your business case to go to senior management to get approval to procure these tools for your laboratory. They are going to ask you, "how many types of software does one lab need?" They will argue that "you only need one type for each capability." That is somewhat true. Some software may be able to do some portion of the other. For example, some LIMS may have a document management portion to their software while a corresponding QMS has workflow capabilities to track samples. However, individual expertise in their LIMS and QMS space leaves the cross over portions typically lacking and often times better left to the portions of the processes that their expertise is known for. Laboratory information management systems do casework really well and quality management systems do quality really well. We have seen laboratories in the news over the years lose their accreditation due to not following procedures or not having the proper checks and balances in place. This has cost them a lot of money, loss of jobs, and years of time to earn their credibility back. So it is worth paying the money to get these systems and processes up and running on the front end to eliminate the heart ache and pain in the end.

Both of these systems are an integral part of the overall quality of your laboratory, so do not try to cut corners. "They both do different things, so buy both" says Jenna Oakes-Smith from the St. Louis Metropolitan Police Department Crime Laboratory LIMS Administrator and Clint Thomason, Quality Manager with the Colorado Bureau of Investigation.



Thank you...

A special note of thanks needs to be given to all of those that helped contribute to this paper. They are:

William Pingpank, VP of Client Services, Ethosoft, Inc. (X-Lims)

John Kucek, Managing Director of Georgia at Computer Aid, Inc. (USA LIMS)

Clint Thomason, Quality Manager at Colorado Bureau of Investigation

Kris Akins, Program Assistant, Texas A&M Veterinary Medical Diagnostic Laboratory

Cullynn Winn, QA and Safety Manager, Texas A&M Veterinary Medical Diagnostic Laboratory

Jenna Oakes- Smith, LIMS/Lenel Administrator, St. Louis Metropolitan Police Department Laboratory Division

Susie Honza, Forensic Consultant/Trainer, Qualtrax, Inc.

About the Author

Juliann Poff has been with Qualtrax for 10 years. In addition to her duties as Inside Sales/Channel Development Manager, she also serves as a member of the Internal Audit Team for their parent company CCS-Inc., sister subsidiary FoxGuard Solutions, Inc. and Qualtrax, Inc. auditing to their ISO 9001:2008 accreditation. Juliann has served as the Quality Improvement Team Administrator when rolling out the Crosby quality methodology to the organization and she has participated in and led several quality improvement teams. Previous to Qualtrax, Juliann served as the Site Coordinator and Document Control Administrator for a Fortune 500 Manufacturing company helping to manage their ISO 9001 and ISO 14001 accreditation. Juliann is an active member of her community serving in leadership roles in several community service organizations and recently graduated with her MBA. Juliann enjoys learning about the compliance industry and matching up prospects with Qualtrax to help continually improve those organizations.

About Qualtrax

Qualtrax, Inc., a wholly owned subsidiary of CCS-Inc., provides compliance software that enables electronic document and process management. Qualtrax focuses on heavily regulated industries where compliance with standards such as ISO 17025, ASCLD/LAB, SQF, BRC, FDA 21 CFR Part 11, and others presents challenges to organizations. Qualtrax greatly simplifies document management, workflow tracking, and business and manufacturing process control. Qualtrax provides the tools needed to manage internal and external audits and ultimately enables organization to effectively manage regulatory challenges. To learn more, please visit the Qualtrax website at www.qualtrax.com.



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