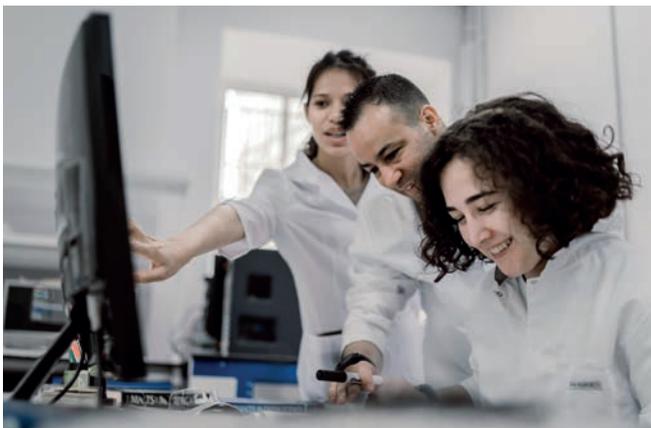


## Creating a Business Case for Laboratory Information Management Software

LIMS<sup>4</sup>U

Dr Phil Williams, LIMS4U

Many laboratories start out using paper-based data management, based around laboratory notebooks, and instrument result sheets. This solution does not scale well and soon the burden of managing paper-based data can overwhelm the laboratory manager. The data is heavily siloed, making it difficult to audit, compare, merge or search. Add to this errors introduced when data is manually transcribed from instruments to result sheets, spreadsheets are used for complex calculations and data manipulation, and final reports manually produced, it is easy to see why paper-based systems are time consuming and error prone. One typical study [1] of manual transcription errors in laboratory data found an error rate of 8.8%. The use of spreadsheets for intermediate calculations has been shown to be just as bad, with another study [2] showing that 88% of spreadsheets had a least one error built into the formulae or underlying data.



Errors are just one enemy of laboratory data when it's held in multiple notebooks and spreadsheets. The time taken to find data stored in multiple filing cabinets and hard drives means that laboratory managers can waste days creating monthly reports and compiling data for a customer or regulatory audit.

Automation provides a way of eliminating many of these costly errors as well as saving time and resources. Laboratory Information Management Systems (LIMS) hold all laboratory data in a single database, helping to break down data silos in at least two ways. Firstly, as the data is stored digitally it can more easily be searched and utilised, for example to analyse cross batch variation in a manufacturing process. Secondly it can be cross-referenced and combined with data from other sources to provide business intelligence and insights for the whole organisation.

While the benefits of a LIMS are well documented the stumbling block for many laboratory managers is successfully justifying the costs. Experience has shown that there are, in fact, many ways

of justifying a LIMS investment which can vary depending on the type of laboratory, organisation or business area.

Three common ways of justifying the cost, however, are:

- The time saved in entering, transcribing and correcting laboratory data
- The time saved creating certificates of analysis and management, or customer reports
- Improved data quality that can eliminate costs associated with product recalls or poor audit findings

### Eliminating Transcription and Manual Processes

Justifying costs from laboratory data automation boils down to a time and motion study of each process in the laboratory and the savings that could be made by using a LIMS. The time saved in receiving samples by automatically assigning required tests, printing bar code readable labels and scheduling work to be done. The time saved in sample preparation by ensuring correct procedures are followed using an automated workflow manager or laboratory execution system. Time saved and errors eliminated by automating result capture from instrumentation. Time saved during data validation and approval by having all the information in one readily available place. Time saved by automating the creation and dispatch of certificates of analysis, invoicing, and billing functions.

The following example [3] illustrates the times savings achieved by a specialty chemicals manufacturer in just one part of their lab process. Prior to implementing the LIMS all work was held in individual lab notebooks. To release each batch, the laboratory manager had to access the QC chemist's paper notebook to

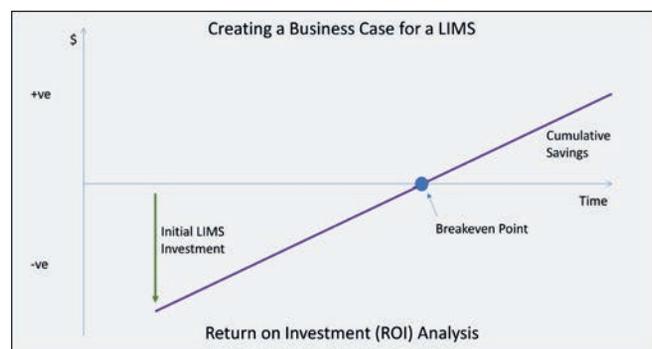
view the test results, calculations, and observations before they could create a certificate of analysis. This process was time consuming and had the knock-on effect of holding up the product in the reactor vessels meaning they would be idle and unproductive for 2-3 hours. Using a LIMS to streamline the process resulted in significant efficiency gains across not only the laboratory but the whole production plant, vastly reducing production idle time.

This example shows how laboratory efficiency gains and cost savings achieved through the use of LIMS can benefit not just the laboratory but the entire organisation.

## Automation of Data Analysis Improves Report Efficiency

Some of the biggest paybacks, and cost savings, can come from digitising your data and having it all in one easily accessible place. Gone are the days of pulling data from multiple spreadsheets for a customer audit, or manually creating a report full of statistics for the monthly management meeting. Having all the data in one database means managers can create a monthly report showing the required laboratory statistics, throughput, and profitability, and run it at the touch of a button. This can reduce an arduous task taking several hours, even days, down to seconds and free up valuable resources to do something more creative with their skills.

A manufacturer of medical devices needed a LIMS to help manage their biobank of clinical samples and the data associated with it [4]. The goal was to have a readily searchable database for easier data recall and manipulation and better management of the samples. The improved automation of the new LIMS, which now manages the clinical biobank, clinical trials activities, and the laboratory testing activities, as well as all the associated data and information has created efficiency savings and freed up valuable managerial time from the manual creation of monthly management reports. This in itself is a significant justification for the costs.



## The Cost of Manual Audit Processes, and Product Recall

Regulated businesses are often audited by customers or the regulatory authority to ensure compliance. Finding and preparing data for such audits can take considerable preparation time when done manually, as can finding additional information during a live audit. These audits can also be extremely stressful for the people involved. When all data is held in one database

pulling the appropriate information becomes much simpler and faster, often resulting in a quicker audit and a more positive outcome. In the worst scenario of a product recall, being able to instantly trace which constituents are in each production batch allows manufacturers to quickly identify suspect products for recall. This can not only save lives, but early recall can dramatically reduce the complexity of finding the products in the supply chain and the overall recall costs.

## Creating the Cost Justification

A major part of the cost justification for a LIMS is a matter of identifying which manual processes cost you most in terms of man hours, and estimating the time saved through automation. For example, logging received samples, creating labels, and routing the samples to the appropriate testing areas within the lab may be estimated to take 6 minutes per sample when done manually but 2 minutes per sample when automated, saving 4 minutes per sample. If the laboratory processes 300 samples per week the time saved will be  $300 \times 4 = 20$  hours per week. In a similar way, if the monthly report took two days to create manually and is now automated then a saving of 2 days per month can be estimated.

Looking through each process in the laboratory, and estimating the time saved through LIMS automation, will result in an overall cost saving in man hours. By deducting from this the cost of a LIMS, (licensing and implementation costs), as well as ongoing annual support, the overall return-on-investment (ROI) of implementing the system can be calculated.

The key is that the cost of implementing a LIMS will be offset by the reduced costs achieved through automation. After working through the costs and savings for the project you will identify the breakeven point, the point in time (measured in months or years) when the time saved through automation outweighs the cost of LIMS implementation. This provides a solid financial business case for your LIMS project that management can believe in and support.

## More Information

A more detailed paper covering these points and including worked examples, can be requested from the author to help justify your next LIMS project. Please email the author Dr Phil Williams at [phil@lims4u.co.uk](mailto:phil@lims4u.co.uk) or visit 'LIMS4U' on LinkedIn. Phil has over 37 years' experience in Lab automation. He founded LIMS4U in 2020 and offers LIMS marketing services primarily via LinkedIn.



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