Questions of Quality

Not Another LIMS Project?

A laboratory information management system (LIMS) can make your laboratory more effective — if it is designed correctly. Many are not.

Happy New Year, it is a lovely day. The sun is shining, the birds are singing — at least those that have not been frozen to death. You are back in the lab, working hard, and the word goes around — a LIMS project is coming your way. Your comfortable way of working with a chromatography data system (if you're lucky) or the pen and laboratory notebook (if not) will be changed forever.

Still, it's like all the other LIMS initiatives in your organization, isn't it: here today, forgotten tomorrow. You've got to look on the bright side. Just think of the fun with the usual laboratory competition of thinking up a new meaning for LIMS:

- Labyrinth of Incompatible Machine and Software
- Lost In Machine Somewhere
- Life Is Made Slower (the system doesn't work)
- Life Is Made Simpler (surprisingly, the system works).

Alternatively, there will be the organization-sponsored Waste of Time Competition — thinking up an "official" name for the project. There are not many rules for this. The name must usually end in "IS" for information system or have LIMS somewhere in the acronym, but above all, the name must imply that the project is leading edge.

For those in some organizations this may sound very familiar. However, many chromatographers won't have much idea of what I'm writing about. A LIMS is something that sounds complex and happens to chromatographers in other companies. Anyway, you're very happy with your current way of working, aren't you? All that paperwork means you don't have to do many chromatographic analyses.

The Warning Lights are Flashing Down in Quality Control

Meanwhile the customers of the laboratory are becoming frustrated. Samples are sent to the chromatography laboratory — and then what? Nothing. The laboratory seems to take an eternity before any results are sent back and the product can be released. (Don't worry — the same scenario can be applied to R&D laboratories — except it takes longer to get the product to the market). Improvements in turnaround time are required; but how can they be achieved?

Meanwhile Back in the Real World...

At *LC•GC International*, we have been doing some homework. During a recent survey of our readers we noticed that the use of LIMS was very low. In response to this, the editor and I planned a series of three "Questions of Quality" articles covering:

- the scope of a system and options available to a laboratory
- the development of the system and problems that can occur
- alternative ways to implement the LIMS.

These three articles aim to form an overview of a LIMS and some of the common pitfalls.

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The principles described in these articles are also applicable to the introduction of complex equipment into a chromatography laboratory. Other examples are robotic systems or HPLC method-development systems. All that is required is a tailoring of the approach to the system in question.

LC•GC International has covered the LIMS topic a number of times in the past. One article, by Jim Stafford and Graham Walter (1), discussed the minicomputer or personal computer (PC)-based LIMS. Today, the distinction between a PC, PC networks, or a minicomputer LIMS is getting smaller and smaller, based on the processor power of PCs and increasing power of networking. The use of client-server computing is being proposed as the way to solve many performance problems. However, initially the most emphasis should be placed on the functions required by the laboratory, rather than on the means of delivering the solution to the user. In plain language, don't be seduced by technology. This was the main message in another article by Graham Martin (2). Here he discussed the need to consider the overall scope and role of the LIMS before considering the technological solution to deliver it. Much of Martin's article is still valid and should be a consideration before a LIMS is purchased. I hope to build on his arguments (2) to give you a better understanding of the role and scope of a LIMS.

Make or Buy?

One question arises early in a LIMS project. Should I make or should I buy a system? In my view, there is no room for argument in today's companies. The answer is to buy — every time. The time taken to build and test an in-house system will probably result in a system that does not match user requirements. Furthermore, the cost of initial and further development and operational support will ensure that such a system will never be cost-effective and the system may not be very robust.

If I buy, which system? If a commercial system is advocated, a logical question arises — which is the best? The answer is quite simple: it is the LIMS that best meets user and organization needs. What you need to do is find the one on the market that best meets your needs. How to approach this will be one of the topics in the next column.

What is a LIMS?

A computer system designed to capture, analyse, report, and manage information and data via a database (3) (American Society for Testing and Materials [ASTM]). This definition is based upon a concept model described in references 4 and 5 and covers the main functions of a system. However, the LIMS model focuses on identifying and visualizing the user functions within the laboratory and less on the strategic siting of a system.

A LIMS has two targets: This column focuses on the impact that a LIMS should make on both a laboratory and an organization but rarely does. To be effective a system should deliver benefit to both the laboratory environment and the organization. But how should this be designed?

A LIMS is unlike any other piece of laboratory automation equipment available to the analytical chemist. It can provide benefits both within the laboratory and outside it. Thus a LIMS has two targets:

- the laboratory — the information generator
- the organization — the information user.

The problem is how to site and implement a system so that it hits both targets effectively.

Figure 1 shows an outline of the functions that a LIMS should undertake. The diagram shows a LIMS sited at the interface between a laboratory and an organization. Samples are generated in the organization and logged into the LIMS; the samples are analysed within the laboratory. The data produced during analysis are reduced within the LIMS environment to information that is transmitted back into the organization. Figure 1 represents the ideal siting of the LIMS, where both the organization and the laboratory benefit. The line dividing the organization and the laboratory show the system is of equal benefit to both.

However, there are two other implementations that are possible with a LIMS, which result in different positions of the interface between the laboratory and organization. Figure 2 shows the more common implementation. This is probably typical of the majority of implementations of LIMS in the 1980s. The main functions performed by the system are the same as previously but the emphasis of the implementation is different. The boundary between the organization and the laboratory has been moved up and the benefit of the LIMS is almost exclusively given to the laboratory with little payback for the organization. In this instance, the LIMS is a toy for the laboratory that few others are allowed to play with. The system is built from the bottom up but with no consideration for anyone outside the laboratory.

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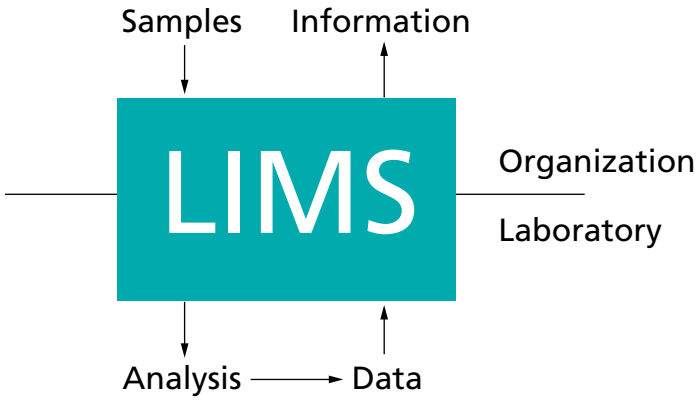

Figure 1: *The ideal implementation of a LIMS. The interface between the laboratory and the organization shows that the LIMS benefits both.*

The rarest alternative implementation is presented in Figure 3. This is the top-down approach, in which senior management or, worse, the information technology (IT) group, has decided that a LIMS will be implemented for the benefit of the organization. There has been little consideration for the laboratory. The analysis and data-gathering functions of a LIMS have been ignored, which allows the chromatographers the latitude and the excuse to develop their own alternative local processing solutions. This system requires additional work by the staff to ensure its success in addition to the normal analytical function. The likelihood of failure with such a system is much higher than with the other two forms of implementation. However, due to the attention paid by senior management to the LIMS, it will take longer to fail and be more costly than any other failure.

As can be seen when comparing the three alternatives, there is a balance to be found between the needs of the organization and the laboratory. The interface between the two must be carefully defined; however, the initial implementation should be towards the analytical laboratory, the information generator. Automating the information generator is a key critical success factor for the whole LIMS project.

Scope of a LIMS

Where does a laboratory begin and end? How can you plan a LIMS to achieve the ideal system shown in Figure 1? We need to consider two factors:

- the types of LIMS possible
- the scope of a LIMS.

The Types of LIMS

Following on from the scope discussions above, three types of LIMS can be defined:

- an operational LIMS
- a logistic LIMS
- a strategic LIMS (6,7).

An operational LIMS: This is a basic system that automates analytical processes in the laboratory. This increases the efficiency of a laboratory but the impact is only local. A computer system in this category would normally be concerned with the operation control of a laboratory and would automate functions such as sample entry, work list generation, and report preparation. Another way of looking at this system is that it is usually the automation of the status quo. Such a system is probably typified in Figure 2.

A logistic LIMS: In addition to the functions of an operational LIMS, a logistic LIMS provides users, especially managers, with the information necessary to undertake their work. Such systems generate control information. Ultimately, this information improves the effectiveness of a laboratory.

A strategic LIMS: The purpose of a strategic LIMS is to integrate information and applications from different functional areas. From this information it may be possible to reshape operations. A strategic LIMS has the greatest impact on the business by increasing the competitiveness of the laboratory.

The System Scope

The system scope possible in a LIMS covers six areas:

- laboratory operations
- monitoring and controlling operations
- laboratory management
- reporting and communications
- analytical decision making
- organizational integration (6,7).

Combined, these areas define the maximum scope of a LIMS. The functions performed by each are outlined in Table 1 but a detailed discussion of the functions is beyond this column; references 6 and 7 have more information.

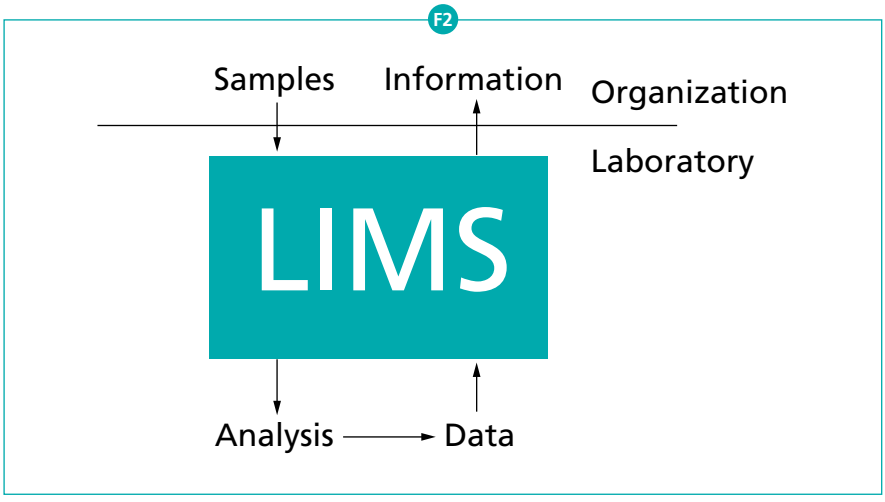

Figure 2: *A bottom-up implementation of a LIMS. The laboratory benefits but the organization does not.*

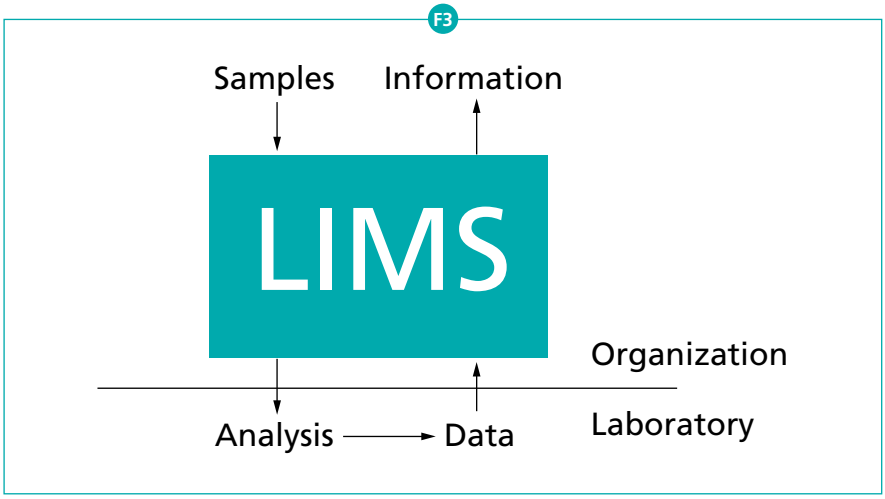

Figure 3: *A top-down implementation of a LIMS. The emphasis is on the organization, allowing the laboratory staff to develop their own data-handling solutions independently of the LIMS.*

The LIMS Matrix

We are now in a position to develop a tool to visualize the full functional scope that a LIMS could take. By simply taking the system scope and plotting it against the three types of system, we produce the LIMS matrix. This takes the form of a 3 by 6 matrix, as shown in Figure 4.

Laboratory operation, monitoring and control, and laboratory management are concerned with functions inside the laboratory. Organizational functions are represented as reporting and communications, analytical decision making, and organizational integration.

The matrix can be used to plan and visualize a system. It can also be used to justify the functions to be developed on a cell-by-cell basis.

It should be emphasized that not every LIMS will be developed to the full extent of the matrix. There will, inevitably, be some duplication with other computer applications within the organization. Therefore, the aim is to develop the matrix based on business objectives and a good financial justification to make the system pay for itself in a reasonable time. One way to do this, and make economical use of resources, is to link the implementation of the LIMS with existing applications to provide the functionality described in the matrix.

The purpose of the matrix is to allow a cost-effective LIMS to be designed and implemented. Furthermore, being able to visualize the overall scope allows definitive boundaries to be drawn and prevents creeping functionality inherent in so many systems. The matrix allows the full vision of an implementation that is achievable over time to be designed and phased.

Properly designed, a logistic or strategic LIMS will achieve the correct balance shown in Figure 1. However, too great an emphasis on the benefits to the organization at the start of the project is likely to produce the system shown in Figure 3. It is my view that the minimum an organization should aim at is a logistic LIMS. However, to achieve this level it is necessary to start small and expand out of the analytical laboratory.

The next article in this trilogy will look at the life cycle of a system.

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Table 1: The functional scope of a LIMS (for details of functions, see references 8 and 9).

Functional Area	Scope
Laboratory Operations (LO)	To automate and structure work. To automate the basic laboratory operations such as sample entry, work list generation, and results entry. To rationalize work.
Monitoring and Control (MC)	To evaluate performance. To monitor and control the laboratory operations by such processes as approving results, the use of quality control schemes, and the checking of transcription errors. To provide standards, measures, and information for performance evaluation and feedback.
Laboratory Management (LM)	To support intellectual processes. To organize and manage the laboratory functions and operations. To plan projects and work.
Reporting and Communications (RC)	To augment human communication. To provide the means to transmit results or reports and communicate with the laboratory's clients.
Analytical Decision Making (AD)	To aid and speed decision making. To provide quality information in a timely manner and the right format to make decisions. To support processes in production, development, or research.
Organizational Integration (OI)	To facilitate intra- and inter-organization transactions. To integrate with other functional groups in the corporation and between organizations.

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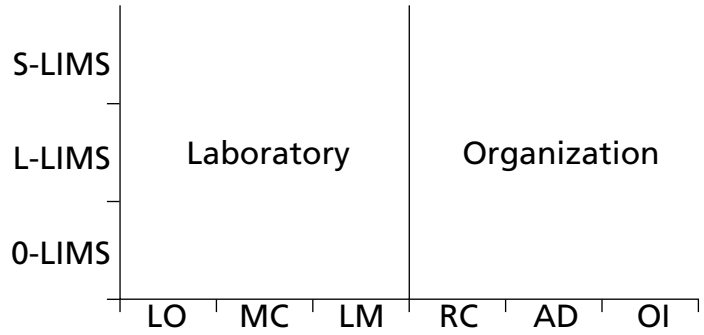

Figure 4: *An outline of a LIMS matrix. S-LIMS, L-LIMS, and O-LIMS are strategic, logistic, and operational versions of a LIMS. The horizontal axis functions are laboratory operations (LO), monitoring and control (MC), laboratory management (LM), reporting and communications (RC), analytical decision making (AD), and organizational integration (OI).*

References

(1) J Stafford and G Walter, *LC•GC Int.* **5**(5)**,** 8–10 (1992).

(2) G Martin, *LC•GC Int.* **5**(7)**,** 8–9 (1992).

(3) *Standard Guide for Laboratory Information Management Systems (LIMS),* E5178, ASTM, Philadelphia, Pennsylvania, USA, 1993.

(4) R.D. McDowall and D.C. Mattes, *Analytical Chemistry* **62,** 1069A–1076A (1990).

(5) D.C. Mattes and R.D. McDowall, *Scientific Computing and Automation (Europe)*, E.J. Karjalainen, Ed. (Elsevier, Amsterdam, The Netherlands, 1990), p. 301–305.

(6) R.D. McDowall, *Analytical Chemistry* **65** 896A–901A (1993).

(7) R.D. McDowall, *Laboratory Automation and Information Management* **31** 57–64 (1995).