Questions of Quality

"User" is a Four-Letter Word

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Implementation is one of the most crucial stages of a laboratory information management system (LIMS) project, when risk of failure is greatest. Most fail by not considering the key group of people — the LIMS users.

The Human Element

This is the third Questions of Quality column on LIMS. The first looked at the scope of a system (1) and the second at the system development life cycle (2). This column is the only one of the three that considers the human factors in a LIMS project and concentrates on the users. The human element of a LIMS is overlooked in most installations and these are the projects that fail or are only partially successful.

User Involvement in a LIMS Project

User involvement must begin from the start of the project with inclusion of at least two users on the project team. Remember that the user base will come from inside and outside the laboratory, so chromatographers and laboratory customers should be represented in the project team membership. Their roles should be to ensure that user requirements are included in the new system.

In the words of one of the great LIMS pioneers, Machiavelli, user involvement is very important.

"It must be remembered that there is nothing more difficult to plan, more doubtful of success, nor dangerous to manage, than the creation of a new system.

"For the initiator has the enmity of all who would profit by the preservation of the old institution and merely lukewarm defenders in those who would gain by the new one.

"Thus it arises that on every opportunity to attack reformers, opponents do so with the zeal of partisans, the other only defend them half-heartedly."

This is pretty perceptive for 1513 — it leaves you wondering what he did *after* his mid-afternoon tea break.

Users can make or break a LIMS. The most technologically advanced system can be rejected by users, but a mediocre system can be fully accepted. The difference is management backing and user involvement in the project.

Management leadership and support throughout the whole of the LIMS project are essential and their absence will be a major cause of failure. Wholehearted support for the LIMS will allow a project team to work with authority. Management should also be available to discuss and resolve any problems. In a recent article, I discussed the need for management leadership in more detail and the role of the project manager (3).

Factors for Success

Factors for success in a LIMS project are:

- a worthwhile project, with business and laboratory benefits
- attention to detail in design
- analysis of the users needs
- not being over-ambitious with the first stage of implementation
- thorough system testing
- thorough training of the users
- written objectives with pre-defined success criteria
- implementation of the minimum functions for the first phase of the system.

Factors for Failure

Factors for failure in a LIMS project are:

- a sceptical approach
- no management or user involvement
- replacing an existing system without adding new functions
- inadequate support
- not meeting user expectations
- inability or unwillingness to change ways of working
- complex system design
- long implementation times.

Long implementation times: A major cause of failure is a long implementation time. The average LIMS implementation may be 1.5 years or more. LIMS implementation must be kept short and concentrate on delivering minimum requirements quickly and getting user feedback. A classic quotation, from an article by Ray Dessy, that I used over ten years ago when working on my first LIMS project is:

"Building credibility of the system in users' eyes involves providing simple services that work well initially with the more difficult tasks following later" (4).

This quotation encapsulates risk management, customer and user focus, and the KISS (keep it simple, stupid) principle, and it is as relevant now as it was then. Following a successful first phase, enhancements and upgrades to the LIMS are possible in an environment that is constructive and encourages suggestions. If the users do not demand change from day one, then they are not accepting the system, they are putting up with it.

The target LIMS implementation time for the roll-out of a pilot system for comment, after training the developers, is six months. Delivery of the core system must be complete within 12 months. More complex functions and interfacing with other software applications should come later. To meet this tight time-scale, management *must* (there is no optional *should* here) resource the project professionally or not bother — again, as mentioned in the last column (2), my daughter would welcome your money.

Planning for Implementation

The planning for the implementation of a LIMS should begin from the initial conception of the project. This means deciding in advance what needs to be achieved and then how it is to be done. Planning requires predicting how long it will take to achieve a certain task and considerations should include:

- the scope of the first-stage implementation
- complexity of the LIMS compared with the current ways of working
- changes in working practices required to use the new system
- what new skills do the users need to acquire to use the LIMS
- impact of the system implementation on current work schedules.

Training for Implementation

Training key personnel how to use the system must also be covered. To be meaningful, this must be undertaken after the system has been installed at the user's site and acceptance tests have begun. It is no use training potential users who then have to wait for their LIMS to be delivered so that they can reinforce that training.

How Does This #$?!% Thing Work?

Before contemplating rolling out the LIMS, it is imperative that there is sufficient documentation for the users. When a LIMS is used without modification there may be a case for using the manufacturer's documentation. However, even here there is a case for the laboratory to write its own customized instructions. For systems where there is customization of the functions, specific documentation is needed. Take it from someone who has implemented a LIMS with no user documentation — you need it, or a good disguise, to hide from angry users. Good, well-written documentation is a prerequisite before training of the users.

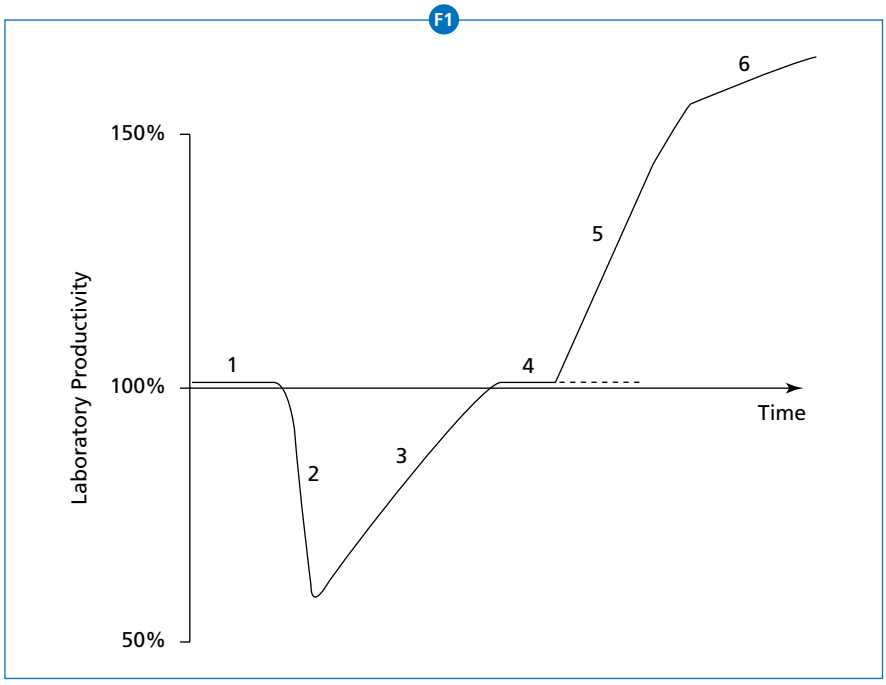

Figure 1: *Impact of a LIMS on laboratory productivity (adapted from Stein, reference 5).*

Impact on Productivity

Stein (5) has shown that the time course of productivity in a LIMS implementation typically follows that in Figure 1. Here, there are six phases during the implementation. If you have not gone through a LIMS implementation, the same time course you follow when you learn to use a computer program can be duplicated.

Pre-LIMS productivity: The productivity of the laboratory before the LIMS is introduced is set at 100%.

Initial drop in productivity: When the system is introduced into the organization, there is an initial drop in productivity. According to Stein, this can range from 10–50%. The drop in productivity begins with the training to use the system. It is important to realize that training is essential and it is not possible to work on high-priority work at the same time. Failing to understand this cardinal rule will result in failure of the LIMS. Chromatographers who are used to a known way of working will revert to it when under pressure to produce results to tight time-scales. It is imperative to allow sufficient time for users to be trained and understand how the LIMS operates.

The extent of the productivity drop can be minimized by the type of implementation style that you choose, but it cannot be eliminated. It is possible to plan the implementation over a longer time period, especially if a drop in productivity is not acceptable. This may be the case in a quality control laboratory, which has a direct impact on the profitability of an organization. However, if the implementation is phased over too long a period, it can lead to disillusionment and rejection of the system, especially if the LIMS results in a stepwise approach to working.

Return to pre-LIMS productivity: It is important for the laboratory to return to the pre-LIMS productivity levels relatively quickly because customer and organization expectations will demand it. The time taken to reach this stage of the implementation will depend on how well the system has been designed, how well tested and how effective the training was, and the level of management support for the system. The time can vary from as short as two weeks to as long as several months.

Plateau at pre-LIMS productivity: This should be a transitory stage for most LIMS projects but a minority of projects will finish here. These are the projects that do not have much vision and/or have been poorly resourced. These projects have not repaid the investment in time, resources, and money.

> THE BENEFITS OF A WELL-DESIGNED SYSTEM SHOULD ALWAYS OUTWEIGH THE TIME SPENT ON TRAINING.

Rapid productivity improvement: After a slow rise in productivity, there is a rapid rise that gives the laboratory and organization the major benefits of the LIMS. This can take 3–6 months to achieve and is usually dependent on the amount of effort you put into using the system. Remember what it was like learning your last computer software package? It takes a long time and then all of a sudden it becomes clear. This is the same effect.

Plateau followed by slower improvements: Most systems will plateau at 50–75% of their expected benefits (5) after the largest benefits have been obtained. What tends to happen now is that smaller benefits may be sought or that enhancements are implemented. These occur more slowly than at the start of the project.

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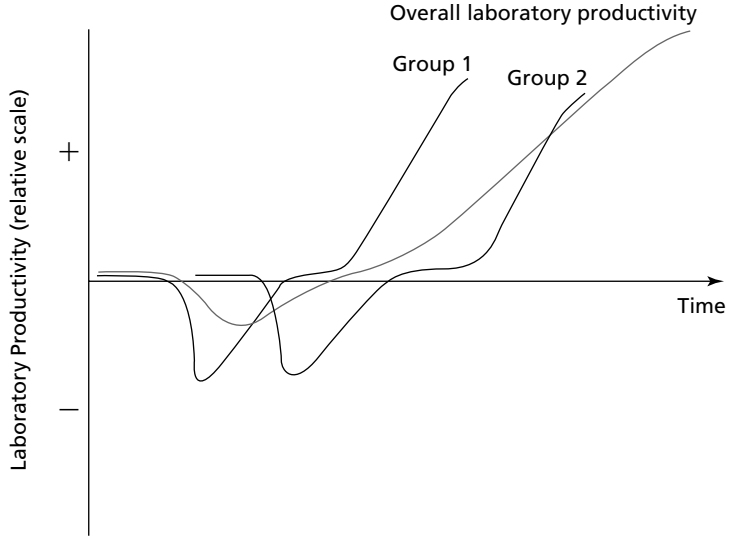

Figure 2: *Strategy to reduce the impact of a LIMS implementation on laboratory productivity, by using two individual groups (1 and 2 on the graph) for* selected use *implementation.*

Styles of Implementation

Graham Murkitt (6) has described three modes of implementation for a LIMS:

- total immersion
- parallel operation
- selected use.

Regardless of which method is chosen, the learning curve for a LIMS is usually long, requiring much training and understanding, but the benefits of a well-designed system should always outweigh the time spent on training.

Total immersion: This is the introduction of the LIMS on a set date, with everybody using the new system (i.e., stop the old way of working and use the LIMS). It is a bold manner of implementation and requires 100% confidence gained from previously validating the LIMS, as well as total commitment on the behalf of the laboratory management and users.

This approach is merited when the new and old working practices differ radically. Implementation in this manner is best suited to periods of calm, allowing prompt attention to problems as and when they arise, with support staff to deal with them. A major problem with this style is that if a serious error occurs with the LIMS, it can cause all laboratory work to stop. Training of all users may be a bottleneck. The question is: how many laboratories have calm periods? Certainly none of the ones I have worked in.

Parallel operation: As the name suggests, this involves running both the old and new systems to allow cross-checking and confirmation of data. It should be borne in mind that this will only be applicable to certain tasks when the data from the two systems are comparable. If the data differ, you have the added problem of determining which are correct. Usually this can be resolved if the old way of working is taken as the benchmark, against which the LIMS results can be compared. The advantage of this approach is that if the LIMS has problems, you can still produce results with the old procedures. Because of the burden on resources of this style of implementation (i.e., duplicating the work), a time limit should be set, after which only the LIMS should be used. The problem with resources has caused some laboratories to cut the parallel running before the date for completion.

Selected use: In this style of implementation, only a selected group will work on the LIMS at one time. Nonetheless, this cautious approach is a real test of the system, with the advantage of allowing prompt attention to any problems as they arise. The system manager can help resolve any problems quickly and efficiently. From the organization's perspective, this style of implementation does not result in major disruption in laboratory operations.

The first group to use the LIMS in this style should be sympathetic and understanding; this means that if there are any problems, the group will not destroy the credibility of the system.

Implementation Strategy

With the information from the impact of a LIMS on productivity and the implementation styles, what strategies are there for implementing a LIMS? Given the fall in productivity while learning to use the LIMS, what is the best approach to take?

Most laboratories are usually very busy and my preferred approach to LIMS implementation is *selected use*. Here, as mentioned above, a small group (3–6 staff) is trained to use the LIMS. As only a small group of chromatographers is learning to use the system, the laboratory productivity is not affected very much. As the first group is getting used to the system, a second group starts to learn how to use the LIMS. Overall, the laboratory productivity does not fall dramatically, as shown in Figure 2. You can see the effect of the individual groups learning to use the LIMS and the bold line shows the overall laboratory productivity.

The choice of implementation style and strategy is yours; with the information in these three LIMS columns,
you can plan a LIMS project more effectively.

References

(1) R.D. McDowall, *LC·GC International* **9**(1), 21–26 (1996).
(2) R.D. McDowall, *LC·GC International* **9**(4), 202–213 (1996).
(3) R.D. McDowall, *Analysis Europa* August, 33–34 (1995).
(4) R.E. Dessy, *Analytical Chemistry* **56,** 725A–731A (1984).
(5) R.R. Stein, Chemometrics and Intelligent Laboratory Systems, Laboratory Information Management, **13,** 15–36 (1991).
(6) G.S. Murkitt in *Laboratory Information Management Systems: Concepts, Integration and Implementation*, R.D. McDowall, Ed. (Sigma Press, Wilmslow, Cheshire, UK, 1987) pp. 67–73.