Designing a Paperless Laboratory

Robert D. McDowall

Understanding and optimizing the implementation process

This article presents an overview of the design and implementation of a paperless laboratory with case study examples of how to progress toward an electronic environment. Process improvement is the basis for implementing the paperless laboratory.

Introduction

The main drivers are currently business-based: speed of decision making, capacity increases, cost reduction and efficiency gains. Preparation of regulatory dossiers have become the main justifications for electronic working. Regulatory compliance is still important for those laboratories wanting to work electronically within a regulated environment.

Goals of the paperless laboratory

The main goals of implementing a paperless laboratory include:

- *Reduction of paper work*: acquiring and manipulating data electronically is faster than paper-based processes.
- *Increasing efficiency:* Electronic data can be shared more easily and quickly, allowing decisions to be made faster than on paper
- *Speeding sample throughput:* Electronic data acquisition and manipulation allows work to be completed faster and goods to be released to market earlier.
- *Automating regulatory compliance:* 21 CFR Part 11 compliant systems can have the same or better level of compliance, but are generated automatically.
- *Reducing cost:* doing the same work with fewer resources, or more work with the same resources.

Business and regulatory drivers

The drivers for the paperless laboratory are two-fold: regulatory and business. From the regulatory perspective we have:

- *Electronic records and electronic signature regulation (21 CFR Part 11):* the original request from the pharmaceutical industry was for a regulation to allow the use of electronic signatures to take advantage of technology. This gives the legal basis for the use of electronic signatures but the issue is that the underlying process is still paper-based.
- *Electronic submissions:* Allow faster review and approval of dossiers.

With the publication of the Part 11 Scope and Application Guidance by the FDA, the regulatory pressure of 21 CFR Part 11 has abated somewhat. However, the business drivers for working electronically have increased. The pressures are:

- faster time to market with both R&D and manufacturing
- cost reduction: reducing time to release
- efficiency and effectiveness of the analytical laboratory
- speed of decision making

This needs to be delivered by effective, efficient, data repositories, plus effective integration and data transfer between applications that constitute the paperless laboratory for an individual organization.

Issues for the paperless laboratory

Primary issues regarding the implementation of the paperless laboratory are:

- Can we use our existing paper-based process electronically?
- How does a laboratory actually become paperless?
- Do we mean paperless or is it just less paper?
- Do we have the understanding necessary to design an electronic laboratory?
- Can we work electronically?

Line in the sand: Where are we now?

There are a number of applications available that can automate functions in the laboratory:

- laboratory information management systems (LIMS)
- chromatography data systems (CDS) and other instrument data systems
- chemometric and experimental design software
- applications for visualization of data
- statistical analysis applications

The first stage in considering the paperless laboratory is to look at the basic processes and computerized systems: How do they currently operate, and how do they integrate together? A laboratory may have many computerized systems such as chromatography data systems and data systems associ-

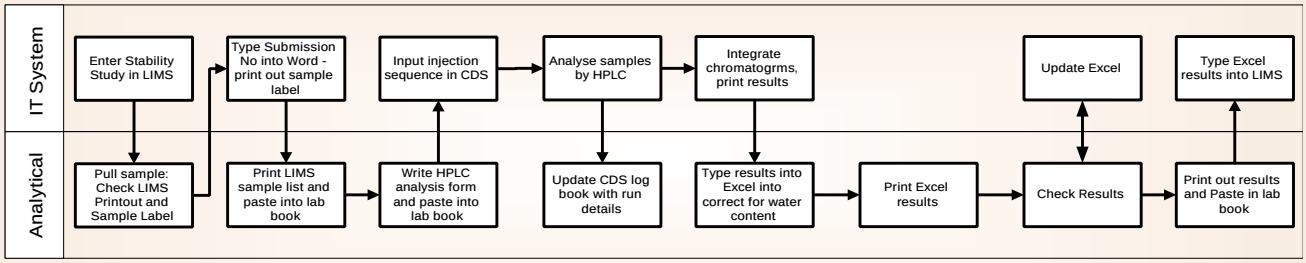

Figure 1: *Cross-functional process map of laboratory and IT systems*

ated with the main analytical techniques such as MS, UV and NIR.

A laboratory may appear to be very efficient but, in practice, the way many applications are implemented is poor. Applications are implemented stand-alone with no interface except paper and manual data input; in effect they become islands of automation in an ocean of paper.

Therefore, consider the question: "Can we use our existing process to implement a paperless laboratory?" The simple answer to this question is "NO." Furthermore, the process evolving over time may have additional tasks that do not add any value to the laboratory output and make it very slow and inefficient.

Figure 1 shows a cross-functional process map of the laboratory work and the IT systems used in the process. The laboratory uses a LIMS and a CDS, but as point solutions. The whole process is manual and there must be multiple transcription error checks for all the manually entered data.

The way forward

You must understand your current ways of working (As-Is process) and then redesign and optimise your laboratory process (To Be process) to use IT systems effectively and efficiently.

Therefore, from the As-Is process maps, understand what you do and why you do it. In many instances, it will be due to one or more of the following:

- custom and practice (we have always worked this way)
- evolution over time (we have had new projects or new tasks to do)
- extensive quality checks of products

In essence, you will be looking at a paper-driven process; unlike computer systems, this has infinite flexibility – if you need a new process, new forms can be developed very rapidly and cheaply. However, the operating cost is very high.

The aim is to understand the bottlenecks and hold-ups in the way that the laboratory works. Find, analyze and understand the root causes of these process bottlenecks, as they will help you to challenge and improve the process. The aim is to have:

- electronic data capture
- electronic ways of working
- electronic storage and sharing of data and information

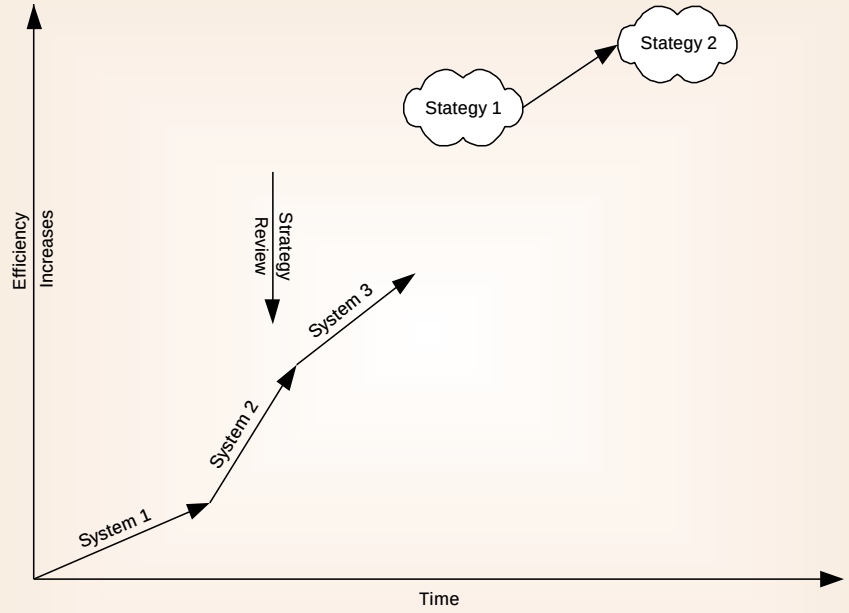

Figure 2: *Paperless laboratory strategy adapts to changing business needs*

- electronic signatures where required by predicate rules

The key message is to ensure that, once data are acquired, they are transferred electronically between systems, not retyped.

Look at your basic laboratory process and design electronic ways of working: see what changes could be made to remove inefficient tasks and to improve speed. Knowledge and interpretation of the applicable regulations to which the laboratory works to is also very important: knowing which records need to be generated, signed and when. Any application used in the paperless laboratory must be technically compliant with 21 CFR Part 11.

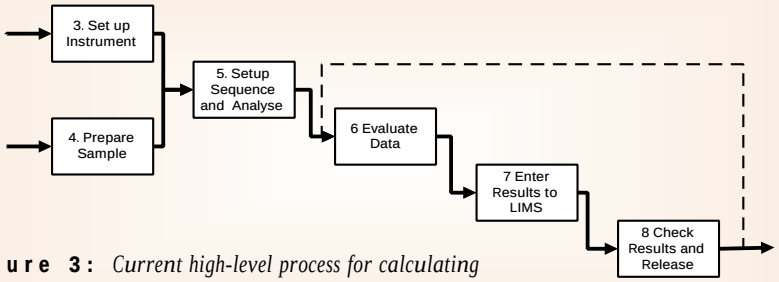

Figure 3: *Current high-level process for calculating chromatographic results in the LIMS*

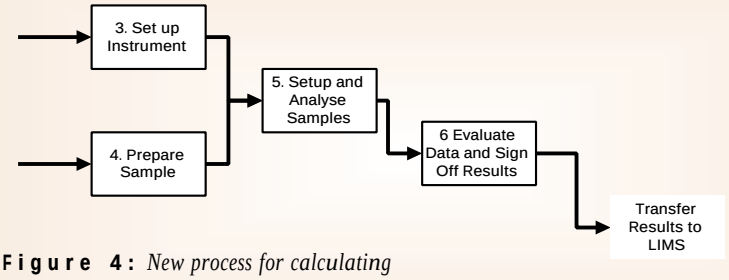

Figure 4: *New process for calculating chromatographic results in the CDS*

Strategy for a paperless laboratory

Overall strategy

In designing a paperless laboratory, it is important to realize that it will take several years to fully implement. Therefore, it is important to have an automation strategy for the laboratory that is aligned with the business objectives of the organization. This strategy needs to be reviewed and revised on a regular basis for a number of reasons:

- checking the alignment with the organization's business objectives
- implementation of individual systems and their integration with the current
- introduction of new technologies and systems that may impact the overall direction of the laboratory strategy

Figure 2 illustrates the dynamic nature of the planning process. The first laboratory strategy is formulated and two systems are implemented to move the laboratory to the vision outlined by Strategy 1. A review of the business and available technologies and applications requires that the strategy is updated, thus System 3 is implemented with Strategy 2 as the new target. Never forget that the laboratory environment is dynamic and changing.

Justifying and implementing systems

There will be a number of individual applications that will be implemented and integrated to the paperless operation. There are LIMS, CDS and other instrument data systems, electronic laboratory notebooks, scientific data management systems and experimental design applications.

The approach that should be taken for the overall strategy must be:

- Each application must be self-justified and implemented with a quick return on investment.
- It automates the underlying analytical process efficiently.
- It interfaces with existing systems to leverage enhanced business benefits.

Implementing steps toward the paperless laboratory requires the active involvement and co-operation of the analytical scientists, quality assurance and laboratory management. A paperless laboratory requires radical changes in working practices not only within the laboratory but also outside of it – this requires communication, effective management support and effective change management.

Table 1: *The Main Critical Success Factors for Implementation of a Paperless Laboratory*

Critical Success Factor (CSF)	Issues to Consider to Achieve Success
Senior Management Support	• Provide a clear vision of where laboratory is going with periodic revisions • Budget support over 3-5 years • (Later) Track record of cost-effective application implementations • Frequent liaison and feedback • Support of the initiative in public and in private
Involvement of Laboratory Management	• Initial assessment of laboratory process and use of existing IT solutions • Develop initial strategy for paperless laboratory and phased implementation • Review and revise strategy on periodic (annual?) basis • Incorporate learning points from previous implementations into forward plans
Evolution not Revolution	• Build on the current strengths and ways of working • Change the laboratory incrementally with every application
Change Management Program	• The current skill set at the start of the strategy may not be what is required in the paperless laboratory • Acquire or retrain staff with these new skills • Many people do not like change: the program will need to explain the new processes and ways of working and encourage staff to use them
Financial Justification	• Each application must be justified individually • Include incremental IT improvement where necessary • Leverage benefits from existing applications where appropriate
Proactive Management of Project Risk	• Projects in the strategy will have common risks and individual risks that will need to be managed to ensure that the project is delivered successfully • See R.D. McDowall paper on risk management (*JALA* 2004)
Organizational Maturity to Use Technology	• How is IT used in the organization? • How successful is the organization in implementing IT systems? • Assess current maturity to use electronic workflow?
Project Resources Available with Correct Skill Mix	• Analytical staff will be needed for working on the applications but will be in competition with the normal work • Staff must be dedicated to the project (include changing position descriptions) • Some staff may need to be retrained with skills for implementing computer applications
Involve External Departments and Organizations	• Who is used in generating samples for the laboratory? • Who uses the information generated by the laboratory? • All need to be involved in designing the strategy and also when specific applications are being designed and implemented
Multidisciplinary Project Teams	• Involvement of Information Technology, Quality Assurance and vendors in the projects that make up the overall strategy is key
User Support	• Systems will not operate on their own and will need laboratory staff to use them • A communication program is essential to persuade people to change their ways of working • Solicit and use offers of help • Request input into the systems design • Demonstrate prototype systems for user feedback
Maintaining Current Work Commitments	• Laboratory must maintain commitments to the organization while implementing applications • Consider use of temporary staff, contract laboratories, etc.

Designing paperless operations

Here is an example of moving from paper-based operations to electronic ways of working involving a CDS interfaced to a LIMS.

Electronic Signatures in a CDS

High-level Process and its Improvement: Figure 3 shows the current high-level process. Here, calculations of the system suitability test (SST) results and the calculation of the chromatographic results are performed in the LIMS after manual transfer of the peak area data from the CDS. Note this work is done post analytical run, if there are any issues with the results, then there is the need to go back to the CDS and chromatograph, investigate and, when resolved, rerun the samples. This is slow and inefficient.

In the redesigned process, Figure 5, the CDS system has been set up to automatically calculate the SST results immediately after the individual SST injection has finished. The results from

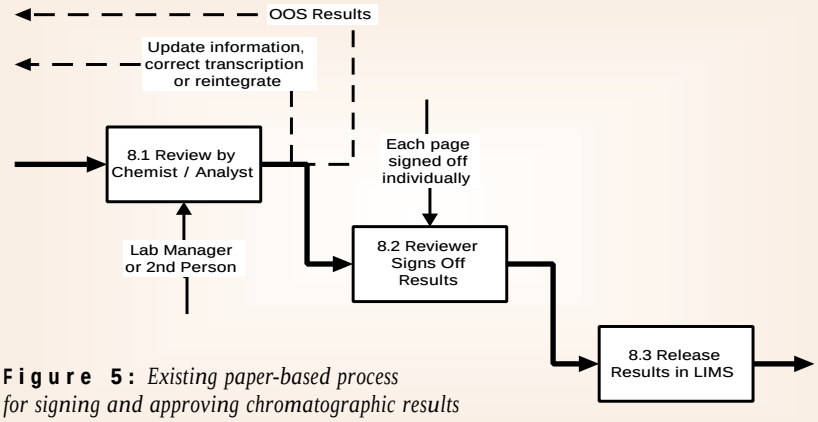

Figure 5: *Existing paper-based process for signing and approving chromatographic results*

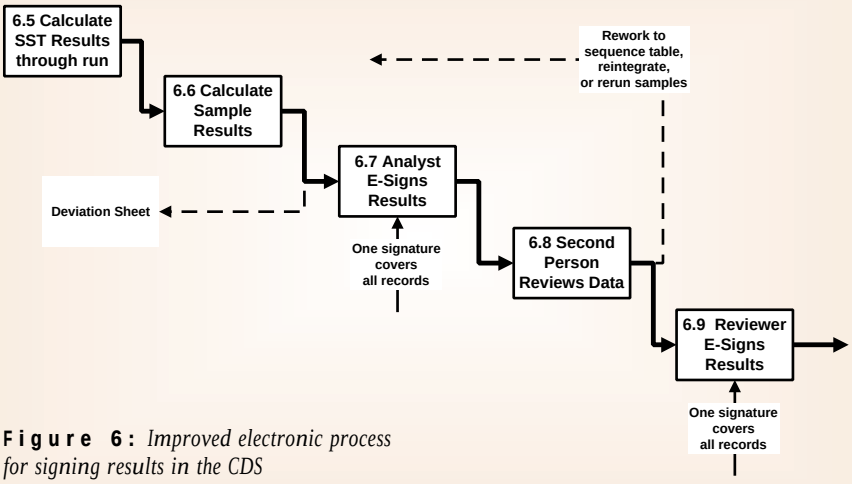

Figure 6: *Improved electronic process for signing results in the CDS*

all SST injections are averaged immediately after the last injection has finished, checking if the chromatograph meets the criteria for system suitability. The system will continue if the result meets predefined criteria. However, if the SST fails, the samples are not committed for analysis. This means that the sample is not wasted if the chromatographic system is not fit for purpose and the issue preventing analysis can be resolved more expeditiously.

Electronic Review and Approval of Electronic Records: When looking at the review and approval of results in the existing process, the chromatographer and the supervisor sign off on results manually: each page is signed and dated by both individuals. This is a very slow, laborious and tedious process as shown in Figure 5.

The redesigned process, Figure 6, uses electronic signatures and the ability of the data system to highlight potential issues for the analyst and the supervisor to investigate. If there has been manual integration of a sample, the database view-filters highlight the fact in the review screens and this enables a user to focus on a specific event or events. Setting the view filters to highlight manual integration means that the placement of baselines in those chromatograms can be assessed and reviewed more easily than on paper.

Signing results electronically is streamlined over the existing process; instead of signing every paper page, a report is generated electronically and signed by the analyst who did the work and then by the supervisor who reviewed the work. As per the GMP requirements under §211.194, only two signatures are required for these results. Following electronic approval, the results are transferred to the LIMS electronically.

The interaction with the CDS and LIMS have been transformed from a paper-based to an electronic process with tangible time and cost savings. Signed results are transferred electronically from the CDS to the LIMS, automatically saving manual input and transcription error checking. CDS calculation of the SST results means that a go/no-go decision for analysis of a batch against pre-defined criteria can be made automatically, immediately and by the CDS. This is a great improvement over waiting until the run is over, then manually imputing the results into the LIMS and deciding if the SST results are in or outside of the criteria.

The promise of the paperless laboratory is there to be exploited for those who plan and implement carefully.

Critical success factors

The main issue regarding a paperless laboratory is the human one: can we work electronically? In principle, the answer is yes. However, it needs to be managed carefully. Change management is the critical component that will take us from the paper domain to an electronic one.

The issues are summarized as follows:

- We are used to working with paper, it has been used for virtually 2,000 years.
- We are moving to an intangible magnetic and optical medium that's existed for 30 years at best.
- The way to sell this to users is to design the system to eliminate boring and repetitive jobs, such as transcription error checking, and allow analysts to focus on scientific activities.
- Electronic workflows for laboratory systems are in their infancy (notification of work pending, and so on) and need to be enhanced to entice users.
- The role of senior management and management in this process is key. Without their support and encouragement over the long-term, it is not worth considering the project.

Table 1 lists critical success factors (CSFs) for the implementation of a paperless laboratory.

Robert D. McDowall is Principal of McDowall Consulting. He may be contacted at sceditor@scimag.com.