



*Having determined the strong business benefits that an Electronic Laboratory Notebook can deliver, implementation of the system presents its own challenges that must be overcome to ensure a successful deployment.*

# ELN implementation challenges

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**Electronic Laboratory Notebooks are becoming foundation platforms within many pharmaceutical companies because of the benefits that they offer to both the business and the scientists alike. Implementing an ELN within an established organisation presents challenges for the project team, both in terms of managing the impact on the scientists and the technical requirements for integration and data management. Implementation of a commercial ELN is not exempt from such challenges, and working with a third party supplier offers both advantages and additional challenges.**

Why is implementation of an Electronic Laboratory Notebook (ELN) such a challenge? It is simply another piece of software isn't it?

The challenge lies in the business change associated with the adoption of such a technological solution. This business change also increases the technical challenges for an ELN implementation project.

## The workflow challenge

An ELN should facilitate what the scientist is trying to achieve [1,2], otherwise the benefits of adoption are significantly reduced or negated. Thus, the ELN should mirror the workflow that the user is executing. This is the first of the implementation challenges.

The decision to implement an ELN built in-house or a commercial system has an impact on the degree to which workflow can be accommodated. Each has its own particular set of challenges.

The decision to build an ELN in-house may be taken on the grounds that the system can be closely tailored to the business requirements – surely the optimal solution as far as workflow is concerned. The development effort required to achieve such an in-house build is significant, however, and beyond the scope and capacity of IT departments of many pharmaceutical companies. Managing expectations for an in-house build is also difficult, with the inevitable scope creep as acceptance by the users becomes an ever-moving target. Outsourcing the development is an option [3,4], and a number of software consultancy firms offer this service

– in this instance the challenge is dealing with an external supplier (see below).

Purchasing a commercial system, normally after having evaluated a number of potential solutions against business requirements, will result in a “best-fit” solution, though it is more than likely a suboptimal one. Here the challenge is the realisation of benefits – providing the workflow-enhancing functionality from a vanilla product is likely to be difficult or perhaps even unachievable. User adoption of a system that fails to meet the needs of the user is a painful process, and the associated business change is likely to be lengthy and potentially damaging. That said, implementation of ‘out-of-the-box’ ELNs have been undertaken and, so long as expectations are managed and there is business buy-in, this can be a successful approach for rapid adoption of this technology.

The rapid evolution of the ELN market over the past three years [5,6] has seen vendors providing ‘specific’ ELNs targeting a defined user base, for example, chemistry; biology [7] and so on. This is often coupled with the ability of the systems to be flexibly customised and configured to mould themselves even closer to specialist user requirements. Potentially, these ELNs are able to adopt most closely the users’ workflow, and the challenge here is one of scope – How much do you customise/configure/integrate the ELN before deployment? Where is the balance between delivered value and expended development effort? Success with this approach is down to committed business involvement and good partnership with the vendor. As authors of the business change, the business representatives, at all levels, must agree on (and stick to) the scope. This allows the users’ expecta-

tions to be set at an early stage, and the vendor has the clarity required to plan and resource their development effort appropriately within the defined timescales.

A common theme in all the above implementation scenarios is the emphasis on well-defined user requirements. Obvious as it may sound, the success of implementing an ELN is the system's conformity to the predefined requirements. Time spent on business process modelling and workflow analysis as part of requirements definition will pay dividends in the end and avoid 'new' requirements surfacing late in the day.

### The electronic data challenge

The switch from paper to electronic as the medium for recording experiments leads to other complexities that need to be managed as part of ELN implementation, namely the protection of the electronic record and the availability of the electronic system. The electronic record may be required to support a patent interference five to ten years after it was created, or in a court case more than 30 years later. The electronic record must, therefore, be created and safeguarded such that its trustworthiness cannot be called into question. This requires careful consideration of both the record keeping system (the technology) and the record management process (the procedures).

Much debate has taken place on the security of intellectual property when held solely in electronic format [8,9]. More recently the outcome appears to be that the advantages outweigh the risk, and ELNs providing electronic signatures are beginning to be widely adopted.

Implementing a fully electronic ELN requires the full support of the IP and Archiving Departments. These groups need to be satisfied that the electronic record can be guaranteed authentic, unalterable and recoverable in human readable form. Electronic signatures provide a mechanism for record authenticity, in terms of author/witness corroboration, along with the dates of these events. An audit trail provides the evidence that the record has not been changed in any way. The most popular formats for the electronic record are PDF or XML, which provides the best recovery options. All these aspects should be confirmed as part of the e-signature functionality, whether provided by the ELN itself or by some additional system. This must be underpinned by documented procedures that describe how the electronic record is created and managed as part of the standard business process.

In addition, the ELN infrastructure must be secure from tampering and adequately backed up. In Discovery research, where regulated environments are not required, a validated platform is still necessary. When a company's IP is at stake, the provision of multiple servers and a disaster recovery plan are necessary to ensure, as near as possible, zero data loss.

From the point of view of the business user, system availability is crucial. Whereas a paper notebook was always available to its owner, the same cannot always be said of IT systems. Even with the provision of a load-balanced multi-server infrastructure, there is always the possibility of network outage. Contingency in the form of a business continuity plan is therefore required. The ability of the ELN to continue to capture data on the client PC while "offline" is an advantage, removing the need to revert to paper if the network or server is unavailable.

### The integration challenge

No ELN is an island – additional benefits come from integration with other systems and the exchange of data. The question is: how far is integration practical and justified?

Examination of the workflow should provide an indication of where benefits can be realised through integration – for example, in a chemistry ELN, linking to reagent inventory and registration provides key components at either end of where the notebook itself fits in the workflow.

When integrating with the ELN the challenge is to deliver loosely coupled systems. The creation of a tightly integrated monolithic system is undesirable, from the perspective of both support and future adaptability. Service Oriented Architecture (SOA) can be used effectively to achieve this goal. An Enterprise Service Bus (ESB) can be used to provide a communications interface between the ELN and other in-house systems. The ESB allows a modular integration strategy, with the web services that it hosts providing an effective way of transferring data to and from which-ever systems are plugged into it at the time.

Integration requires suitable interfaces to be available within the ELN, as well as the in-house systems. The ELN must have a Software Development Kit (SDK) to enable the development of such interfaces. When implementing a commercial ELN, the vendor will usually provide professional services to assist with, or undertake, this development work. This presents a challenge in terms of the learning curve required to understand what in many cases are complex customer-written systems. High quality system documentation greatly facilitates this process, but it is not always available.

Development of interfaces by a third party also presents them with a challenge in terms of direct access to the in-house system not always being possible during development. The testing of the interface requires a build-and-deploy cycle in the customer's environment and can significantly add to the development time. Providing the vendor with external access can pay dividends but may be difficult to achieve for security reasons.

### The deployment challenge

Deploying the ELN is the key challenge. The difficulty of this task depends on the number and distribution of the user base and whether a phased rollout is chosen over a 'big bang' approach. This is true of any software implementation, so why is an ELN any different?

The associated business change of replacing a paper notebook system with an electronic one is something that should not be underestimated. The paper notebook has survived for centuries, and despite the benefits of an ELN being well known, the process of change is a difficult one. It is, therefore, essential that support for ELN adoption is visible at the highest level within the organisation and is recognised from the outset as a Business Change Project – not an IT-enforced change.

An impact assessment should be undertaken to determine the areas that need to be addressed before implementation can commence, or which will require managing explicitly at the point of deployment. Early identification of any obstacles to deployment forms part of a risk-managed approach to ELN implementation.

One area that needs to be addressed is access to the ELN from the laboratory. In recent years the move has been to separate the office

and laboratory environments; the write-up area moving to the office. With an ELN, the point of data capture is the laboratory, and PC access is required close to the scientists' work area. One solution is a remote keyboard/VDU/mouse linked to the PC in the office. This provides a one-PC per scientist option with the PC itself in the safer office environment.

As with any software, effective training must be delivered to ensure rapid-uptake and compliance with procedures for use. The latter particularly so for a system that is going to hold a company's IP. Training should include not only the operation of the ELN itself but also any local workflow changes associated with the deployment. In order to facilitate uptake, a group of expert users can be put in place within the user community to help their colleagues overcome any initial problems with the system.

### The vendor challenge

Implementing a customised version of a commercial ELN is the popular choice for pharmaceutical companies. To accomplish this successfully requires working closely with the ELN vendor. Establishing a partnership approach, where both parties have strong commitment to the success of the implementation, provides a good foundation for the task in hand.

Communication plays a major role in developing and sustaining a good working relationship. This is more of a challenge than it might sound. The two project teams must meet regularly, but following initial kick-off meetings, this is likely to be by teleconference. Although a viable medium in modern business communication, it does suffer from being impersonal and lacks the visual component that often adds context and expression to what is being said. Communication must be open and honest – expectations must be clearly stated and managed; deliverables and timelines agreed that are acceptable to both parties; risks and issues identified, raised and mitigated against. Unrealistic demands, fail-

ure to deliver on commitments and covering up potential issues do not leave a project in a very healthy state.

Documentation exchange is a necessary part of any collaborative working, and providing an electronic repository accessible to both parties can greatly facilitate this. If the vendor is providing professional services to assist in customising and configuring the ELN, then the quality of documentation must be high so that no ambiguities exist. Since the customer has little direct control over the development being undertaken on their behalf, it is important to provide regular progress updates – this is most effectively accomplished by demonstrating the software as it evolves. Such an approach instils confidence and provides early opportunities to rectify any misunderstandings of what was required.

The testing of the software is vital as part of its development cycles. The challenge arises in communicating and tracking defects. The two parties are unlikely to have the same mechanisms in place for this. Visibility of the status of reported defects is clearly advantageous from the customer's point of view, and the provision of a view into the defect management system employed by the vendor would facilitate this. A direct view avoids the use of a third medium (e.g. a spreadsheet) to exchange defect information; something that should be avoided at all cost, being not only labour intensive but prone to error also.

### Conclusion

No two ELN implementations are the same, and each will have its own challenges. The above aspects represent some of the common challenges facing an ELN implementation project. By recognising the importance of the business change and making this a key part of the implementation, the chance of success is raised markedly.

An ELN must also be a system that continues to evolve as its users' workflow change. An initial ELN implementation will be just that – the first.

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