

Tech Talk

Implementing an Electronic Laboratory Notebook (ELN) System - A Case Study

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A paper lab notebook is the primary method of recording research. Researchers have used lab notebooks for hundreds of years to document their hypotheses, experiments and their interpretation of the results. The notebook serves as an organizational tool and can also be used to protect any intellectual property that comes from the research. One of the most widely known lab notebooks was that of Leonardo Da Vinci. Da Vinci, a thought leader of his time, employed methods that made his notebook unreadable to the casual viewer by using a reverse writing technique. His rationale for doing this is unknown but, coincidentally, these same issues of security and safety remain present today with paper lab notebooks.

Over the last decade software vendors have been developing solutions specifically focused on the automation and replacement of paper laboratory notebooks. As technology has advanced, the capabilities of these systems have developed to the point that they are now a viable alternative to using paper. Some of the benefits realized from implementing an electronic system include, but are not limited to, the following: backup, security, compliant electronic signature, collaboration and indexing. These benefits save time for the researcher and allow more time for doing science and less time annotating results.

Replacing paper notebooks can at first seem like a daunting task. While the rules for authoring a notebook are well understood, every scientist tends to work differently. It is easy to draw parallels to front office procedures where word processors and spreadsheets long ago replaced typewriters and ledgers. But science has its own set of rules, with professional and legal requirements that are quite different.

Scientists are trained to maintain notes in a fashion that allows for review and discovery. Deletion of data is not allowed but corrections are permitted and transparency is a must. Both the existence as well as the absence of data can be crucial, not only at the end of the experiment – but even years later. The notebooks themselves are considered legal documents that can be used as evidence in a court of law – even if the scientist is not available to testify.

To a business or research organization, the content of their lab notebooks is the “crown jewels” – the organization’s intellectual property. The notebook is where ideas are captured which one day may be patented. In the United States, patents are awarded based upon “date of invention.” Accordingly, making sure that each entry in the lab notebook is signed and dated is critical. Additionally, many organizations need an Electronic Lab Notebook (ELN) that supports collaboration, data mining and automated communications. Each of these requires a level of standardization for data entry, database schemas and terminology that goes well beyond paper-based systems.

To ensure success with the implementation of an ELN, many companies follow a structured evaluation and selection process. In its simplest form this process often consists of:

- 1) Documenting the user and corporate needs in a User Requirements Document (URD).
- 2) Surveying and evaluating ELN solutions available from vendors.
- 3) Evaluating the selected ELN solution with a pilot implementation.
- 4) Rolling out the ELN solution to the whole organization with a phased implementation plan.

Two organizations that recently evaluated and implemented ELN solutions are described below. While very different, these two organizations shared many of the same objectives that other labs identify for their ELN projects. Their successful implementations can serve as models for other labs looking to replace paper lab notebooks with an ELN system.

The US Veterans Administration - Cooperative Studies Program (CSP)

The Cooperative Studies Program Clinical Research Pharmacy Coordinating Center is run by the US Veterans Administration. The CSP conducts clinical trials and epidemiological research on diseases affecting US veterans. In 2007, the Quality Control Laboratory of the CSP, under the direction of Mr. Gary Eden, QC Lab Chemist, evaluated commercial ELNs.

The requirements for the ELN included ease of use, the need to create custom templates to support queries and data mining, and integration with the US government security infrastructure for wireless networking. The ELN needed to be a thin client application (browser-based) that aligned with the IT-supported platforms in place in the VA. It also needed to be validated to meet cGMP requirements of the US Food and Drug Administration.

The selected ELN was implemented and validated within two months time. Within four months of purchase the QC Laboratory was fully operational in a “paper-less” mode. According to Gary Eden, the ELN implementation was very successful. He stated it “enabled our lab to be more cGMP compliant - having all our data and write-ups in one place and organized makes it easier for us to find information when we need it.” When asked about the challenges posed by switching from paper, he added it was a “quick learning curve and easy to use in practice.”

Regulus Therapeutics

Biotechnology is at the forefront of fighting many diseases today. And Regulus Therapeutics is right there on the front lines. Its mission is to discover, develop and commercialize micro-RNA based therapeutics.

In 2009, Regulus set out to replace all of its paper notebooks with an ELN. Like many companies in life science, their researchers use a variety of computers, including both Macs and Windows PCs. Although many requirements were defined and evaluated, a dual platform was a high priority for Regulus. The selected ELN would need to run in a browser and support the Windows and Mac Operating Systems, allowing the users to share notebooks and files seamlessly.

As Aimee Jackson, Director of Drug Discovery, recently wrote, “Regulus Therapeutics embraces leading edge technologies to improve efficiency and advance scientific discoveries. With the implementation of the ELN technology, we have realized enhanced communication through rapid, effective, and secure archiving and sharing of data and information. This enables us to spend more time doing research and less time tracking and retrieving information.”

For both of these companies, the selected ELN proved to be a great productivity tool. Paper can be a large drag on the productivity of laboratories. ELNs provide almost instant access to all of the laboratory-generated data when it is needed and where it is needed. Searching and retrieving notes and files is much faster than with paper-based systems.

Communications can also be greatly improved by an ELN system. No scientist works in an isolated environment. Laboratory work needs to be witnessed, approved and communicated to others. In both of these case studies, the ELN user discovered many benefits from the built-in communications functions of the ELN software.

Selecting the right ELN is not hard and it doesn't have to be complicated. The key to success is clearly defining your organization's and your users' requirements. Choosing a system that best meets those requirements can be done by surveying the market place and thoroughly evaluating the choices.

To summarize, ELNs offer many benefits. They save time and money as researchers can spend more time doing science and less time annotating results. Additionally, organizations benefit from the convenience of the communication and collaboration tools and have the peace of mind that comes with knowing their intellectual property is safe. Finally, ELNs are a bargain when compared to paper. The investment need not be large and the return on investment is quick and substantial. And most telling of all: if you were to ask an ELN user if they would switch back to paper, most would quickly say, “Not without a fight!” ■

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