It’s Not About the Paper

Second in a series on the Electronic Laboratory Notebook (ELN) market

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Remember the days when everyone believed that computers were going to create "paperless offices?" The belief was that by implementing systems in areas such as accounting and administration, the need for paper would be eliminated. Despite billions of dollars in investment, our use of paper has dramatically increased! However, personal productivity has risen significantly during the last 30 years, and our ability to create and share information is unprecedented in human history.

Given this background, it is a surprise that you still hear calls for implementing "paperless laboratories." In research, most organizations print intellectual property research on paper anyway, as many company lawyers are unsure if they can defend patents based only on electronic records.

It is not about the paper. Electronic Laboratory Notebooks (ELNs) are about creating a more efficient organization and a secure institutional memory. If all you do is get rid of the paper and have the same bottlenecks in your research efforts, what did you really gain?

Paper notebooks have been around since Leonardo da Vinci sketched his first flying machines and the need for them has not changed much since his day. A notebook provides a complete record of why and how experiments were designed, the recording of experimental results, and observations on their success or failure. It is a repository to relate data from a number of different sources and to create contextual relevance. Additionally, notebooks support patents filed in the U.S. by creating proof of first inventorship and the first reduction to practice.

However, paper notebooks are imperfect tools for sharing information. As pharmaceutical, chemical, personal care, and food companies have become more global, so have their R&D efforts. Mergers and acquisitions, joint ventures, and partnerships have forced R&D teams to work together across sites and across countries like never before. How can a bound paper notebook, which is often difficult to read, be shared amongst those researchers?

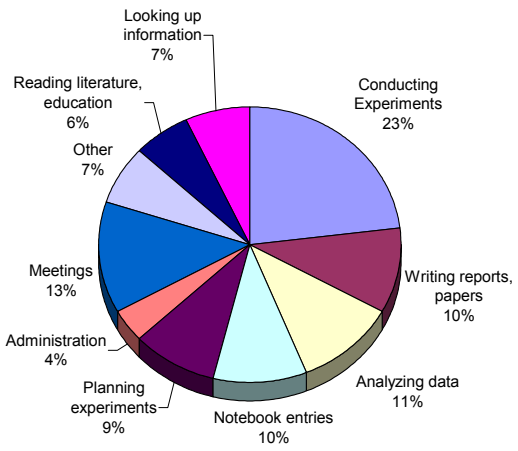
Organizations that have successfully implemented an ELN for their R&D organizations report common benefits. These

systems have gained them efficiencies in their research, improved the quality of their data, created a searchable repository of knowledge, and have enhanced their ability to protect intellectual property.

Improving efficiency

A researcher's time is spent in a wide variety of activities, from conducting experiments to attending meetings. Many of their required administrative activities dilute the time they have to fulfill their scientific responsibilities.

At a recent IntelliChem user's meeting, several speakers reported that between 20 and 40 percent of their scientists' time is spent completing notebooks, searching for information, and developing reports. With a shortage of skilled chemists, and economic pressures precluding new hires, these companies realized that they must achieve higher throughput — as measured by the number of experiments performed per week per scientist — from existing resources. They determined that they needed a tool to eliminate manual paper entries, eliminate the "reinventing the wheel" (i.e. redoing experiments which were done before), enable faster access to information, share knowledge between workers, and provide tools which streamline processes.



A Typical Research Chemist Time Allocation (Source: Atrium Research)

By implementing a specific ELN — an ELN that is functionally rich in one or more application areas such as synthetic chemistry — they have been able to achieve their objective of increased efficiency. For instance, through the use of features like design of experiments and structural searching, what used to take hours now takes minutes. Less time is spent on manual data entry and the development of reports. One Top 10 pharmaceutical company reported they achieved a 20 percent improvement in throughput in their process development department. By having a tool that is specific to the way they work, the users have readily adopted the technology as it has eliminated "drudge" work and allowed them to dedicate more time to science.

Improving data quality

Another benefit expressed by users is that the ELN improves the quality of their information.

As a result, this enhances their ability to make informed decisions. Decisions are based more on facts and less on subjective criteria. Paper notebooks also are notoriously difficult to read. Often, the only one that can decipher pages is the person who wrote them! The elimination of handwriting allows experiments to be read today as well as in the future.

Most ELNs on the market have template functionality. These templates, which can be developed for entire notebooks or individual experiments, define a workflow and structure for the entry of information. This assures consistency of data capture from scientist to scientist and can be used to enforce the steps of an experiment or a procedure. The data elements of the template can be checked against a database as well as for proper rounding and format. For example, a compound number can be verified against a registration database to ensure that it is a valid entry. Templates also can define calculations or have embedded Microsoft Excel worksheets to automatically calculate results, further reducing the risk of mistakes.

To eliminate data transcription errors, a few companies have implemented automated data capture capability into their ELN. VelQuest, which provides an ELN for compliance and process execution, has direct interfaces to a number of instruments, such as balances, chromatography automation systems, and pH meters. When an analyst is at the appropriate step in a method, data is automatically transferred to the notebook. Results also can be automatically checked against specifications, alerting the user of a potential need for a retest.

Creating an institutional memory

In the age of the paper notebook, experiment designs and results are locked away in an archive rarely to be seen again. Experiments are repeated over and over as the knowledge of their coworkers is lost to a filing cabinet.

An ELN enables an organization to create a knowledge repository of both tacit and explicit knowledge. The searching capabilities of an ELN provide researchers the ability to mine this knowledge repository to learn from others and to make faster decisions. Data can be mined for patterns, reanalyzed using new techniques, or repurposed for another therapeutic area.

Procter & Gamble, which is currently evaluating ELN technology for 3,700 R&D personnel in their Beauty, Feminine and Health Care division, sees the benefit of building an institutional memory. "The costs of repeating experiments are high," said Keith Caserta, the division's information technology director. "The primary benefit we see of an ELN is the ability to allow us to access historical data. Experiments that are successful end up in R&D reports, but experiments that fail do not. If you don't know what experiments failed before, you are doomed to repeat them."

Infinity Pharmaceuticals, a biotechnology company out of Cambridge, MA, has been a pioneer in developing a fully electronic drug discovery environment. Over 20 applications are integrated using XML Web services with CambridgeSoft's E-Notebook as the primary interface for the scientist. Andy Palmer, the CIO of Infinity says "the purpose of Infinity is to discover novel new medicines. To do this, we need to optimize the allocation of resources. We feel that an important way to accomplish this is to share the incredible amount of information and knowledge that is generated by the organization." For example, Infinity's researchers store TLC plate images along with textual information on experiments. If another scientist is having trouble with a reaction, they search the ELN and find out what did and did not work previously. They are able to see other researchers' plate images and data which helps them to optimize their own reactions.

Protecting intellectual property

Despite the reluctance of many corporate lawyers to allow a complete electronic environment for patents, most organizations feel that an ELN offers enhanced intellectual property (IP) protection. By managing the entire project data associated with a new material in a secure and archivable system, an ELN provides a safer environment against data loss. With a paper notebook, months of work can be destroyed by a simple coffee spill! There also is no risk that the ELN can walk out the door in someone's briefcase.

Most ELNs have very good security features that will restrict data access and provide full data traceability through an audit trail. This will limit access to a company's IP and can record who has actually viewed, modified or entered information. Restricted users may be able to see information, but they cannot alter it or delete it. There is no way to cut out a page!

Long-term data preservation can be accomplished more completely than with paper notebooks. The traditional notebook has to be scanned, page-by-page, which is a tedious process prone to errors. The ELN creates long-term archives and backups of data, which can produce paper records at any moment. The enhanced data quality of the ELN creates more accurate records for patent filings. Encryption, hash algorithms, PKI, time stamps, and other means of authentication are superior to the subjective handwritten dates and signatures of a paper notebook.

In summary, an ELN does not create a paperless environment. It does help to create a cultural shift to a more efficient and collaborative atmosphere while improving the data quality and intellectual property protection of the organization that adopts it.

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