

Electronic lab notebooks – a crossroads is passed



'...the adoption of electronic media for laboratory notebooks is not a revolutionary change, but an evolutionary process...'



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Scientists have traditionally used paper notebooks to keep track of their experimental ideas, observations and research results. Maintenance of accurate records of the experiments performed is an important aspect of all laboratory work. Among scientific documentation, the laboratory notebook is the most prominent, being the official record of laboratory measurements and observations. For the researcher, a properly maintained notebook can be a source of useful information for many years. For a scientific organization, lab notebooks are a potential goldmine of knowledge and experience. Enabling electronic access to lab notebook data might greatly improve knowledge management capabilities, eliminate the waste of information that is inherent in the paper system and improve efficiency by helping to reduce work duplication.

After the rapid adoption of digital technologies during the last decade it might appear a curiosity that paper lab notebooks still persist. The main reasons for this are that laboratory notebooks can contain important legal information related to priority of patent claims, as well as verification of compliance with regulations such as GxP. A precondition for shifting towards electronic laboratory notebooks (ELNs) is that the new medium must be acceptable in all legal proceedings. This has so far not been proven in practice, causing many initial ELN initiatives to stall.

In reality, the adoption of electronic media for laboratory notebooks is not a revolutionary change, but an evolutionary process that has been going on for some time. Think for a moment about just how 'paper' your lab notebook of today really is. Looking around your lab, what do you see? For over a decade now, almost all modern lab instruments have been producing digital output. Even traditionally low-tech devices such as balances have been connected to computers. And can you even think of producing a chart without using spreadsheet software?

As a result, you have been literally cutting and pasting these computer printouts. An unscientific poll in our organization showed that, depending on the area of research, pasted printouts constituted 25% to 80% of all lab notebook content. The latter notebooks easily swell to triple their original size. It is a nightmare for archivists, not to mention a frustration to the intellectual property staff.

Manually copying documentation into a paper notebook is counterproductive and takes up the valuable time of the highly qualified workforce. Worse still, in the growing area of *in silico* studies, or in studies where massive amounts of digital raw data is generated, the mere idea of putting everything down in a bound paper notebook seems absurd. In addition, bound lab notebooks, sequential in nature, are ill suited for documenting events occurring automatically and simultaneously, such as parallel synthesis. The result of all this is a steadily decreasing quality of documentation that needs to be addressed immediately.

'Electronic' is not 'paperless'

Many interested parties had been predicting that the legal adoption of electronic records in terms of evidence value was imminent and opted to wait for the legal precedent to happen. Our personal opinion, and the experience of recent years, tells us that this might not be the case.

In the early years of computers, electronic records were inferior to paper, being less reliable, easier to tamper with and more prone to inadvertent damage or destruction. Although the computer industry claims now that it has all the components required to build reliable electronic documents and signatures, the fact remains that by their nature, electronic records remain much less tangible than paper

and are likely to continue to prompt extra scrutiny in court. From the legal perspective, these technologies are also very much new and unproven. Only five years ago, the FDA was the first legislative body to acknowledge the use of electronic records and signatures for regulatory documents, but the related 21 CFR Part 11 has not been free of significant conceptual oversights.

All this has been bad news for the advocates of the ELN, simply because the ELN has been thought of as synonymous with 'paperless'. We do not think this is the case – and not just because of legal reasons. Often overlooked in the ELN debate, there is one more area in which paper records excel over electronic records – archiving. Considering that patent evidence is maintained for somewhere around 30 years, in terms of durability and reliability, paper records are still far superior to their electronic counterparts.

It would seem that the initial assumptions of an entirely paperless ELN system were not realistic. Paper has to be involved at some stages of the process. Based on the current state-of-the-art, such a system would mean electronic data entry and storage, augmented with signing and archiving in paper. Although it might sound like a compromise, it is not – it is just a logical consequence of recognizing the different strengths of paper and electronic media and using them to their best advantage.

Designing a solution

We have listed a set of key requirements for a successful hybrid ELN system:

- (1) End-user acceptance; the ELN must offer ease of use comparable with or better than its paper counterpart.
- (2) Fully featured; an electronic system must be constructed in such a way that paper notebooks can be altogether eliminated.
- (3) Availability; like a paper notebook, the ELN must allow for instant note taking as observations are made. Access to a personal ELN must be provided to each scientist at all the usual workplaces.
- (4) Legal; the system must provide legal evidence for patent protection of the same or higher quality than the currently used paper notebooks.
- (5) Flexibility; data differ significantly between scientific disciplines. An electronic system must be able to accommodate all kinds of scientific data.
- (6) Access; all lab notebook records should be categorized and fully searchable.
- (7) Longevity; the system shall support archiving of all lab records for a period of at least 30 years – beyond the projected lifetime of computers running the ELN system.

Formulation of these requirements leads us to the insight that a successful ELN solution must not only comprise a piece of software, but also the organization of the work environment and procedures, supported with the necessary hardware and material.

From the legal perspective, a hybrid system still produces a signed original document on paper, so the evidence value of the records in potential court dispute is retained. As for the burden of manual signing and countersigning records, proper procedures can make it about as easy (or awkward, depending on your preference) as your lab notebook of today. For example, imagine that once every few days you decide to print a few pages containing the newest additions to your ELN. You then pick the printed pages from the nearby printer, sign them, and go over to a colleague to get them verified and countersigned. Once ready, you put the signed sheets into a special envelope addressed 'ELN Archive', and put everything in the outgoing mail basket. Difficult? Hardly. And you still have the electronic record available at your computer to read, search or produce secondary copies for your own use.

We are convinced that such a hybrid system will provide an effective ELN solution. It is fully feasible today, providing that a few points are given further attention. For example, although for legal purposes the system relies on paper, it is still different from handwritten bound notebooks. In addition, the old lab notebooks contain bound, pre-numbered pages, whereas computer printouts come on loose sheets of paper. The risk of tampering with individual pages therefore needs to be addressed. It can be done with a numbering system identifying each experiment and sheet to ensure that no alterations or deletions of paper records have been made.

The temptation of making the ELN generate the records automatically should be avoided. However attractive it might sound, it should be remembered that the primary goal of a laboratory notebook is to take notes on observations. Humans, not machines, should write these notes. Notes can contain things and ideas that are spontaneous, out of the ordinary and that do not fit in predefined templates. Therefore, before doing anything else, the ELN system must be an effective notepad, promoting note taking rather than merely collecting data from automatic sources.

Make ELN the good news in your organization

On a final note, it should be remembered that electronic or not, badly maintained records are always harder to defend in court than orderly records. If a computer system helps to keep orderly records, it might help to demonstrate in

court the care and accuracy with which lab notes were created. Our experience shows that ELN often lead to better and more complete notes, and most definitely more readable ones! The ELN system might also provide supporting legal evidence in the form of timestamps, chronology of events, audit trail data and so on.

So our conclusion is – there is no need to wait. If ELNs are compatible with your knowledge management strategy, they are well worth using. The technology is there, legal issues are manageable, as is the work process associated with the hybrid system. By following the guidelines described here, by taking the holistic approach and by taking into

account the computer software, policies, work processes and quality in your organization, you have a great chance for success!

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