



Pharmaceutical R&D and Electronic Lab Notebooks - An Unbeatable Team

Two hundred years ago, when Sir Isaac Newton and his colleagues implemented a major paradigm shift from alchemy to *science* – rational thought, hypothesis, test, repeat - it was fine to record results on paper. Observation was everything, and the only types of scientific data they had could be represented with numbers, letters, and simple sketches. These scientists worked in isolation for years, until finally presenting their results to the Royal Academy. That model doesn't work as well today. Science is more collaborative, more dispersed, and more immediate. Collaborators are down the hall as well as across oceans, and we need to collaborate *instantly*, because we aren't the only ones fighting for that grant/patent/publication. Everything has to happen *now*– it needs to be validated and time-date stamped, and it must adhere to standards and regulations. Add to that the fact that we are generating more data, and more elaborate *types* of data; paper just doesn't cut it anymore. So what *are* the benefits of a well-designed, well-implemented electronic laboratory notebook (ELN)?

1. **Better, faster collaboration.** An ELN gives collaborators an instant view of all of the information they are permitted to access. This includes not only files and folders, but also notebooks of your peers and colleagues; you can see their work as they are doing it. But a good ELN is much more than that – it allows users to annotate entries on other individuals' notebooks, the digital equivalent of adding a sticky note. By leaving comments and feedback, or even files and protocols, on an *electronic* lab notebook, instantaneous collaboration is achieved. This eliminates the need to wait for others to finish using their notebooks or for a colleague to finish reviewing it – multiple users can simultaneously see the same notebook. This collaboration works whether you are in the same building or on opposite sides of the planet – a good ELN allows access to the information anytime, anywhere, and it performs crucial validation and signature steps.

2. **IP security and automatic compliance (time/date/user stamps, audit trails).** Securing your Intellectual Property (IP) is crucial. Even an academic lab faces competition from other researchers. In the race to patent, nothing is more important than time. That means getting there first, and being able to *prove* it. The 21CFR11 requirements mandate time, date, and user stamps (as well as audit trails) for all research done in an ELN. Data validation requires both researcher and manager to sign off on the data. How many pharmaceutical companies have lost a patent battle because of logistical pitfalls that mean signing can happen only *when all the individuals involved* are physically in the same room? Monthly signing parties are the standard at some organizations – which means that the life-blood IP is not secure until well after it was created. With an ELN, all data entered into the system are *automatically* time-, date-, and user-stamped – saving the researcher precious seconds, which over the course of days, months, and years significantly add up. More important, audit trails track all the changes to the record (including access tracking, which is important in verifying protocol

compliance or finding out who read a specific set of data, and when). An ELN does all of this automatically. A last, important consideration is that an ELN allows the digital signature workflow to occur asynchronously. In other words, a user can sign off on her work and move on to the next experiment while the ELN system functions as a “witness.” The peers and managers, in turn, can review the work electronically (from *anywhere*) and cosign when they are ready. There is no waiting until the end of the month; the signing can be completed whenever, wherever – most likely sooner than in the paper notebook world.

3. No more reinventing the wheel. There is more to securing intellectual property than simply making sure the basics of time/date/user stamp and resource audit trails have been properly captured. While this is sufficient to ensure legal compliance, the real advantage of securing IP is that it will be readily available to anyone in your organization. In the paper world, notebooks are single-instance – you can’t easily create backup copies, you can’t search a notebook by keyword, and your archived notebooks are essentially lost. Trying to find information in a paper notebook is often so cumbersome and difficult that it’s faster to redo the experiment. How many hours - days - weeks of rework is done simply because we don’t have easy and quick access to the original data? The problem is really worse, because a researcher may repeat an experiment if he doesn’t *know* that the organization already has the data. Pharmaceutical companies report that a large proportion of their experiments (as high as 66%) are inadvertent duplicates. They aren’t repeating the science to validate it, but rather because they simply don’t have good access to their own intellectual property. A well-designed ELN with good search capabilities can prevent both of these problems. It will still be up to the user to actually do the search in advance of a new study (to avoid duplication), but the time savings are potentially huge. Imagine spending a few seconds doing a query every time a new project is started – a small investment of time – only to discover that someone has already optimized a protocol for those specific conditions? Even if that only happens once a year it will *still* be time well-spent and a huge cost savings for the organization. An ELN can even help select and document that the proper materials and reagents were used and that these had not expired or been found to yield inconsistent results. Following detailed experimental protocols in an ELN helps scientists avoid (or at least note) any errors or deviations in methods. A single experiment that is wasted because the wrong method is applied, protocols or standards are not used properly, or because it is an inadvertent replicate can easily cost more than the total expense for the seat of ELN software that could prevent these mistakes.

4. Rapid approval and validation. Building on the above, it should seem obvious how the ability to sign off on an experiment rapidly and asynchronously could be applied to protocols, SOPs, and IRBs. An ELN can manage and track the design and approval of such documents as well as automate compliance, and the audit trail easily enables managers to see who has (or has not) read and signed off on any of these documents. Better and faster decision-making in R&D leads to information being gathered more quickly for regulatory submissions (patent, FDA). Using an ELN, R&D management is able to make better decisions based on a complete and accurate body of enterprise knowledge - choose the right drug candidate and the selected patient population to treat

(avoids approval failure, market recall). As a result of increased development productivity, additional revenue can be achieved by bringing a new drug to market faster than the competition or getting a drug approved for a targeted market rather than a drug that fails to achieve FDA approval.

5. Reduced cost of recordkeeping and archiving. Many researchers may not realize that their paper notebooks can cost a significant amount of money – much more than the simple composition book that it appears to be. Even a simple notebook costs *something* – the more sophisticated paper notebooks used in the pharmaceutical industries involve tracking and management, and can cost *significantly* more. Now add in the cost of the archivist and librarians involved in this management, as well as the cost of *archiving* the paper, which may involve anything from duplication and preservation locally to off-site secure archiving for several years, if not decades. These costs rapidly become non-trivial, and by contrast an ELN can end up *saving* the pharmaceutical organization money simply by reducing the archival costs (and by offering better search and retrieval, as outlined above). Paper notebooks may cost more just for daily progress report meetings where each scientist creates duplicate copies of vital experiments and hands them out to every attendee, only to have these duplicates discarded at meeting's end. How much easier it is to connect a laptop to an overhead projector, display the results, and send direct in-system links via the ELN to the data so that each scientist can peruse the data directly – with no additional cost, or waste of time.

6. Knowledge Retention. As researchers come and go in organizations (or even across departments within their company) the knowledge and insights they have gained run the risk of being locked up in the heads and paper notebooks of the scientists, inaccessible in the future. The work one scientist does painstakingly to purify a protein or prepare a sample can be lost forever only to be duplicated in the future, wasting time and money. Enter the well-designed ELN. It deals with all data, all formats, and all sizes. Data can be captured, retained, and reused easily. ELNs offer nightly incremental backups of *everything* – lab data, journal articles, and notebooks. And, if the ELN is truly well designed, it enables 'lessons learned' that can be applied across studies to streamline the development of new research methods. This means that the work one scientist does to purify a protein or prepare a sample can be readily found and utilized to facilitate work on an analogous project. Finally, a good ELN gives you exported, portable archives of all the actual data files - text files, spreadsheets, instrument data, *everything!* The above is hardly an exclusive list, but we hope you've found some compelling arguments for why an ELN is not just useful, but *essential*, to any organization that wants to stay competitive in the modern world of science. The question shouldn't be "Do we need an ELN?" rather the questions should be "Which ELN is right for us?"

About us: *SigmaCERF combines electronic lab notebook (ELN) and scientific content management to collect, secure, share, and leverage data and lab records in collaborative projects. For additional information contact us at info-usa@systat.com or 408-715-7083.*