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Implementing a Successful Cultural Change

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Array's Decision on ELN: Motives and Origins

In 1999, our biopharmaceutical company, Array BioPharma made a corporate decision that chemistry-based data should be captured electronically. Biology-based data was already captured in commercially available database programs, but valuable chemistry knowledge was still confined to the individual chemist and their recollection.

Over time this information was lost either due to attrition or just plain forgetting. To overcome this, Array planned to incorporate an ELN specifically for chemists: one that would replace the standard paper notebook and, most importantly, be electronically searchable across the organisation.

At the time there were essentially no products available on the market. That left two possibilities: design, create, and implement an ELN from scratch using our own internal resources or collaborate with a vendor. The former option ensures that the product will be custom- designed to meet our needs, but wastes time and money on creating a product that is outside a pharmaceutical company's core business.

Therefore, Array decided to collaborate with CambridgeSoft to develop a chemistry- based ELN. Array provided input into the early design of the product and CambridgeSoft received an enterprise ELN they can market that was directly related to their core business. Today, there are many more vendor options available for an organization to consider when selecting an ELN.

Coordination with Legal Teams, the Need for a Phased Approach

With about six years of ELN use under our belts, a number of lessons have been learned. First, it is important for the legal department to be intimately involved in the ELN selection process and in establishing, for example, the SOPs (standard operating procedures) that will be used. Procedures that might be obvious or insignificant to an IT department could be of grave concern to a lawyer who will be responsible for defending any system in a court of law.

Initially, we used a hybrid approach where each experiment was printed, signed and bound. Thus, the company's archival copy was the paper bound copy, similar to any paper-based notebook, and the electronic system was just for internal use. Eventually Array converted to a completely electronic version with digital signatures and archived PDF files by purchasing the PatentSafe software from Amphora.

The process we used to define system requirements, identify a vendor, and implement the software was done hand-in-hand with our legal department and is an interesting topic for discussion that's outside the scope of this article. Unfortunately, there are no standard processes, so each organisation will need to define their own method that satisfies their unique legal requirements.

User Acceptence and Complience

Initial implementation of an ELN focuses predominantly on compliance and getting buy-in from the user community.

Generally, there are early adopters who are willing to put up with the inevitable problems that occur with any new software, along with the reluctant diehards who will eventually convert only after much discontent. There are a number of reasons that a particular individual will use to delay adoption, and here are a few of the more popular reasons:

î Electronic systems, including the ELN, are generally more structured than a user wants it to be. There is always something that needs to be done that the ELN is just not capable of handling.

î There is an operational learning curve associated with shifting to an ELN and a user may not have time to focus on learning a new system.

î Data entry is not always faster, especially if the user doesn't possess adequate typing skills.

î Any computer system can go down and that can cause a major problem for the user.

î Initially, there is nothing to search in the database, the major advantage for using an ELN. It could take years to establish a well populated database, dependent on the size of the user community.

î The 'Big Brother' syndrome – Anyone can see their notebook and this does have a tendency to put some users off a bit.

The in-House Sales Pitch

There are many ways to ensure ELN compliance among users. Most obviously, an ELN must be intuitive to use, allow some degree of flexibility for individuals, and maintain solid performance. Nothing will hamper an ELN project more than a slow, clumsy system that takes too long to learn or use. Although there is an obvious strategic rationale for the ELN, it is more productive to tout the tactical and other advantages to using an ELN.

This is where integration of an ELN with other data systems really pays off. For example, in the chemistry world, analytical data including NMR (nuclear magnetic resonance), IR (infra-red), HPLC (high-performance liquid chromatography) and MS (mass spectrometry) can be easily integrated with the experimental data, making for a more complete record of the experiment. This can be done manually or more elegantly via direct integration of analytical machinery with the ELN.

At Array, this was seen as a major advantage and was the key feature that drove prompt compliance among the chemistry staff. We also integrated our stockroom inventory system with the ELN so that it matched the chemist's workflow. To begin an experiment, a chemist first obtains the needed experimental reagents and then uses a barcode scanner to enter them into the ELN with all the appropriate data necessary, making the setup simple and efficient. We also found that integrating

workflow software and LIMS (laboratory information management) software with the ELN was a good way to improve prompt compliance.

For example, we took our analytical data analysis software, where scientists can review, analyse and interpret their data directly from the equipment, and added a backend that summarises the information for direct input into the ELN. We have found this approach very useful for gaining quick acceptance of an ELN by scientists in other scientific departments like analytical, biology, pharmacology and drug metabolism.

Training with Peers

Another very important way to ensure prompt compliance of the ELN stems from the training program. Array has found that training by fellow scientists is far better than using the vendor training programs that are generally available; fellow scientists understand the relevant issues and they are in the lab to answer questions as they arise in the normal course of using the software. Rather than train on the software in a classroom setting, scientists train using the ELN within their environment, focusing on the tools and steps necessary to accomplish their work.

Lessons: A Look Back

Over the past six years, Array has been using an ELN with solid success. All departments have now been moved from a paper-based notebook to an ELN. By using individualised templates, we have found that one software product is sufficient for the whole research organisation, contrary to what others have proclaimed. In addition, we have found that once scientists have made the transition, they do not wish to return to paper, especially when all the integrations mentioned above are incorporated. However, the ELN is not a panacea, and some of the generalisations attributed to an ELN may not necessarily hold true, for example:

î Using an ELN makes you a better note-keeper. This is not true; if you're bad on paper, you're bad on a computer. The real advantage though is supervisors can monitor notebooks from their own desk.

î ELNs make you better organised. This is true, especially when data integration is considered. Having experimental data and its supporting data in the same page of an ELN is very useful.

î ELNs make you more productive. This one varies with discipline. For example in biology and medicinal chemistry, where note-keeping is not the limiting factor, the gain is minimal. However, in analytical chemistry and high speed analoguing, note keeping is an issue and major productivity enhancements can be achieved. There can also be major time savings when writing patents based on the work stored in the ELN. The one area that yields the greatest time savings is the most difficult to quantify: how much time is saved when a search result provides useful information. Whether it's time saved doing the correct experiment or, even better, if time and money are saved – and frustrations avoided - by not doing the wrong experiment.

In conclusion, Array has found the transition from a paper-based notebook to an ELN to be a very valuable and worthwhile endeavour. We have taken a very conservative approach to what an ELN represents by only focusing on documenting our intellectual property. There are some that believe the ELN should be the portal to all information, outside and inside the company. Although technologically a reasonable idea, we have not shared in that belief.

Over the years, we have gone from a chemistry-based hybrid system to a complete company-wide research ELN with fully electronic signatures, file storage and backup.

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