

Examining the World of ELN

Lessons learned from the 10th annual electronic laboratory notebook conference in Barcelona



Michael H. Elliott

The largest event examining the world of ELN is the annual IQPC ELNs and Advanced Laboratory Solutions conference held September 26-28 in Barcelona, Spain. This three-day event illustrated the evolution of the ELN market, as a majority of attendees have a system in production. This is a significant shift, considering that in 2002 conferees struggled to even define what an ELN should do; the talks were more about concepts than reality.

There were over 30 presentations and workshops, as well as roundtable discussions and a supplier exhibition. As was the case in past years, the vast majority of speakers were from the pharmaceutical / biotechnology community, representing an array of different domains and geographic territories. Notably absent was the heavy concentration of synthetic chemistry representatives that dominated the event in the past. The majority of participants this year seemed to be more involved in biology applications. However, like the science itself, the application of ELN varied widely from those supporting a biologics workflow to pharmacology. There was also a good mix of users from regulated and non-regulated areas.

THE LEGAL VIEW

The most-talked-about presentation from the first day was a workshop given by patent attorney Colin Sandercock of Perkins Coie LLP. Sandercock is a recognized expert in the use

of electronic records in patent cases and has presented at this and several other ELN conferences over the years. His lecture was quite different this year, with the U.S. moving to a first-to-file versus a first-to-invent patent application process.

A common perception is that first-to-invent will diminish the role ELN plays in an intellectual property (IP) management strategy. Sandercock disputed the premise that lab records will not need to be maintained with the same care as they were before due to



the nuances contained in the “Leahy Smith America Invents Act.”

“The act only partly eliminates first-to-invent rights for any applications having an earliest-claimed priority for a claimed invention that is on or after March 16, 2013 (the US transition date to first-to-file),” said Sandercock. “Interferences may continue in force for many years and involve inventions well after the transition date.” He went on to discuss how all electronic records are still discoverable and will need to pass scrutiny. “Everything in your ‘custody and control’ must be timely located and produced, including all raw data and unsuccessful experiments, and including all electronic records and metadata.”

The increasing trend toward cloud computing was another area Sandercock touched upon. He pointed out that “as with any IT outsourcing, ELN clouds have the potential to save time and money — but they present potential legal issues.” He explained that having a system in the cloud does not eliminate the need for record preservation or timely production, and that an agreement must be reached with the provider to ensure production. “Using a cloud provider will not excuse the failure to satisfy preservation and production duties.”

THE QUALITY PERSPECTIVE

Informatics conferences tend to be heavily weighted to research and development. This year, the use of ELN in a global quality control deployment was represented well by Ian Cooper, Strategy & Portfolio Manager at AstraZeneca. Through an examination of changing business drivers and the current IT landscape, AstraZeneca developed a strategic roadmap of their future state of quality operations.

Though to a lesser degree than how it had been used in the past, they determined that a laboratory information management system (LIMS) was still necessary, containing the technology to an area of core competency, or what Cooper referred to as the “thin-LIMS concept.” After process analysis, ELN was targeted as a key system that could deliver 20 to 30 percent improvement in analytical method execution and 50 percent reduction in review and approval cycles. Additionally, the chromatography data system (CDS) environment was consolidated into a single service, offering substantial savings over the previous decentralized approach.

Using lean processes to build their IT architecture, a single vendor each for LIMS, ELN and CDS was selected and deployed into three integrated hubs serving

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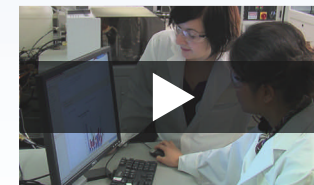
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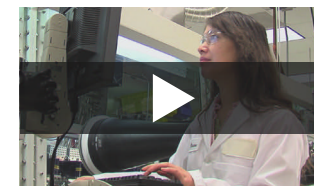
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North America, Europe and Asia. This replaced a cornucopia of site-specific systems scattered across the AstraZeneca global manufacturing operations. The decision for a leading provider of a procedure execution system was based on “the right ELN” for the quality organization versus leveraging existing systems already in use in their research organization. “A generic ELN customized to meet needs of discovery, development and operations was considered too expensive and difficult to implement,” said Cooper.

Cooper also declared that, after putting the system into production, ELN did meet the targeted projections of efficiency gains through removal of manual transcriptions, process automation and simplified review. Risks were reduced with “right first time/zero laboratory error and traceability from sample and method through reagent and standard preparation to equipment data files.” AstraZeneca also collaborated with their supplier to extend the ELN to include support for environmental monitoring — an application traditionally thought of as being in the purview of LIMS.

THE GREY AREA BETWEEN ELN AND LIMS

Cooper’s presentation was just one of several to discuss the overlap between ELN and LIMS. IT Account Manager Markus Duerring of Novartis claimed that an examination of the history of lab technologies begs the question “Is an ELN the next LIMS?” In his presentation “Delineating the Grey Area between ELNs and LIMS,” Duerring said that “Large ELN vendors pack more functionality into their products and penetrate the LIMS domain” and that “ELNs

today are much more than a simple replacement of paper lab notebooks.” He went on to say that “solution providers try to support the whole range of lab automation. This may work for small companies, but can be challenging for complex environments.” Large companies tend not to replace existing systems; therefore integration means narrowing the functional scope of LIMS and ELN. “There are reasons that LIMS and/or ELNs separately co-exist in the paper-

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Markus Duerring, Novartis

less lab,” he said. “The rules to separate both system types are environment dependent.”

Julie Spry of Pfizer spoke to the ELN project in the company’s BioTherapeutics Pharmaceutical Sciences group. This followed implementations of LIMS, CDS and data archival supporting bioprocess, pharmaceutical and analytical R&D at their Chesterfield, MO, research location. The project objectives included

- capturing structured and unstructured data
- journaling
- managing work requests
- reducing transcription
- stability
- facilitating collaboration
- query and reporting across experiments

Many electronic laboratory notebook products were evaluated, including stand-alone systems used elsewhere in the company.

Due to the need for tight integration with the work request, stability, and sample and test processes maintained by LIMS, their team made the decision to deploy an ELN developed by their LIMS vendor based on a common core between the two technologies.

Though the system has a “less fancy interface for unstructured data” when compared to ELN vendor-produced systems, Spry indicated the advantages of existing expertise, integration, contract research organization (CRO) portal and pre-existing validated functionality (e.g., stability, environmental monitoring) offered them a better overall solution. “The overall sum of the solution is what counts,” said Spry.

A slightly different architecture at Pfizer was expressed by Jim King, Director, R&D Business Technology in the company’s Diversified Businesses group. The same LIMS and CDS are installed as in Spry’s laboratories, but a system from one of the major ELN suppliers was integrated into the design. King discussed his lessons learned from implementing this suite of solutions across a diverse range of laboratory types. He stressed that success comes from a close partnership with the business, process knowledge, knowing key business drivers, and scope management.

“Technology is the easy part,” said King. There is a need to “change the cultural view of informatics as individual components and promote the perception of an intra-organization informatics ecosystem.” A key takeaway message was for implementers not to

“manage to the edge case.” Users always will push the requirements to try and address every scenario, and a project should be scope-managed to the broadest needs that provide the maximum return.

USER INVOLVEMENT IS ESSENTIAL

Although the talks were dominated by life science companies, Morten Meldgaard, Project Director at Christian Hansen, spoke to the needs of the food and beverage industry. Christian Hansen is a global supplier of bioscience-based ingredients to the food, agricultural and other industries, with research sites across the globe. The goals of their ELN project were to build a global repository of “innovation data,” with capabilities of search and collaboration across all those sites. The project was tagged as “Innovation Data Management” to emphasize that its purpose was beyond simply replacing the paper notebook.

However, Meldgaard did warn potential electric laboratory notebook project managers to “not make the project too big.” He said a key learning was that “requirements of an ELN cannot be described from the beginning. It is an iterative process.” He also suggests that “A pilot period is valuable to establish a robust system. ELN provides new opportunities. So, using the system is necessary to work out details on how to optimally work with the system. Future users and IT must be involved as early as possible.”

The notion of heavy user involvement was reinforced by Marc Smith, Knowledge Management System Project Team Leader at Lonza Mammalian Development Services. “It’s not just about the technology,” said Smith. “You need to make sure that the user — the ultimate consumer of the ELN — doesn’t get lost in the process.” He recommends a

cross-functional team approach in the early phase of the project that represents every scientific department, IT, business leaders, legal, purchasing and quality. There also need to be “silos within the team to ensure that all users’ needs are represented.” Additionally, there should be “respected, techno-savvy enthusiasts who are able to envisage ‘the art of the possible.’” To support the mobility needs of the scientists, Lonza selected as a client computer a “mobile clinical assistant” which is a ruggedized tablet PC designed to meet clinical environments.

Environments that have both regulated and non-regulated workflows often struggle with the question of whether or not they must have two software instances. It was refreshing to hear Lonza supporting both GMP and non-GMP tasks on the same platform, which is an ELN from a major supplier. This required validation of the core systems and a segregation of “controlled records” from “research records” on the same instance. Records isolation was accomplished using the configuration capabilities provided by the ELN supplier.

A BROADER ECOSYSTEM

There were many side discussions regarding the growing need to integrate collaborator data and the best ways to accomplish this. Thankfully, Manli Zheng, Senior Group Leader from Abbott Laboratories discussed her experiences deploying ELN to Asia-based collaborators and contractors. Originally, Abbott leveraged contractors for staff augmentation where information logistics was limited in scope. But, the company has moved to a risk-sharing collaborative model where the need for data exchange is more crucial to project success. Systems are needed for project monitoring, data capture, transfer and analytics. This

raised a number of legal, security, procedural and personnel issues beyond just the technology hurdles.

Manli’s team has deployed several hundred clients of two vendor ELN solutions (one for chemistry, one for biology) to several offshore contractors. Clients, which in some instances are executed through Citrix, communicate back to application servers installed at their data center near Chicago. Both systems use the same signature workflow process based on Adobe Livecycle and Citibank’s SAFE Biopharma-compliant digital signature service. Key challenges faced by the IT team were keeping up with the ever changing business needs, managing speed versus complexity, and a careful balance between sharing and security. “You must understand the local culture,” said Manli. “Do not make assumptions about how people work, especially in Asia.” Modes of operating in western countries cannot be taken for granted. She summed up her experience advising project managers to be “cautiously optimistic.”

The 10th annual IQPC ELN conference was a successful gathering of ELN experts, suppliers and those new to the space. It was a tipping point for the forum; for the first time, the majority of attendees had a system in production. This was a valuable networking experience, as exemplified by the lively debates in the roundtable discussions. In the future, we hope the organizers will place a greater emphasis on sessions for improvements to products, infrastructure, integration, collaborator integration, standards and networking to recognize this shift to a forum primarily for users. [SC](#)

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