

OpenText in the Life Sciences: Electronic Laboratory Notebook

Ensure effective information capture, reuse, collaboration,
and knowledge management

The primary role of a scientific notebook is and has been to protect the ownership of the invention. But the primary role of the researcher has been to invent. So enter the electronic world, and a host of possibilities are created. Instead of staff meetings and peer reviews, those involved in R&D now have a mechanism to easily share that information and foster more of a team approach to research. While meetings and reviews aren't entirely eliminated, they become more focused and efficient. An enterprise Electronic Laboratory Notebook (ELN) facilitates collaboration by supporting workflow coordination across geographic and business boundaries. The ELN is adaptable to meeting the needs of multiple disciplines in a collaborative R&D environment, and is a strategy for improved success, increased Return on Investment (ROI), enhanced productivity, and protection of intellectual capital.

Increased Operational Effectiveness

Paper notebooks today are comprised chiefly of disparate pieces of paper and types of data pasted onto paper notebook pages, along with some handwritten components, signed, witnessed, and dated. Once the notebook has been completed, they are generally "backed-up" through microfiling or scanning into an electronic format. They are then stored

in a corporate vault, which is not very effective for increasing and sharing the knowledge within an organization. By moving to an ELN, and implementing the use of social media tools, the collective tacit knowledge within an R&D organization can be transformed into explicit knowledge, thus forming the basis for an overall corporate knowledge management strategy. Electronic notebook systems have delivered significant productivity gains of 10-30% and more, and since the researcher can use electronic

BEING BUILT ON A TRUSTED MODERN PLATFORM IN CONTENT SERVER MEANS

- ✦ Scalability is never a problem
- ✦ Security, even on a global scale, is the best in the industry
- ✦ Industry leading search capabilities
- ✦ Records management and archiving are all standard with OpenText ELN
- ✦ Ability to integrate to enterprise systems like SAP and Oracle, as well as LIMS

tools (Word, Excel...etc.) familiar to them within the ELN, they can be more effective in terms of performance.

Mitigate Risks Associated With Regulatory Compliance

Paper notebooks are subject to increased scrutiny by an audit commission, since they lack traceability, generally do not follow common entry methodologies, are often difficult to read because of legibility issues, and lack any mechanism for validation. Furthermore, because they are restricted to paper, the continuation of experiments across multiple pages or even notebooks can lead to confusion regarding experimental comprehensiveness. Being paper, they are also subject to increased risk simply because of the environment common to laboratories, as well as accidental loss or destruction. With an ELN, regulatory compliance risk is lowered:

- Security enforcement allows access to only authorized users with integration to corporate directories.
- Comprehensive audit trails provide a traceability matrix to what has changed and who made the change.
- Versioning assures a historical record of experimental data.
- Quality of data is improved through mandatory fields, the use of forms, templates, controlled vocabularies, and checks.
- Workflows improve the process through enforcement of stepwise progression.
- Electronic signatures and witnessing assure proper data authentication in a timely manner.
- Reporting features can produce on-the-fly integrity reports for auditors.

Corporate Data Quality Improvements

It is a simple fact that better decision making can be attained as a direct result of the quality and integrity of the data being consumed. Consistency in experimental record layout for the capture of data, along with elimination of handwriting inconsistencies, will lead to a higher level of data quality. An ELN will improve data quality through:

- The use of templates for experimental data capture, which provide a consistent mechanism across projects or departments, thus enforcing consistency between researchers' data input.

- Workflows based on sound laboratory practices provide a means by which a stepwise progression of experimental data capture can be enforced, thus eliminating or reducing the likelihood that key data components comprising the overall experiment could be missing.
- Controlled vocabulary, drop-down lists, and required fields lead to completeness and consistency.
- Because the researcher will be using authoring tools (e.g. Word, Excel...etc.) familiar to them, issues with handwriting legibility are eliminated.
- Integration to legacy systems or instrumentation assures that the right data and all the data necessary to document an experiment is captured.
- Once complete, the "experiment" can be published in a consistent format, showing all versions and audit logs, providing a complete historical record.
- As the historical R&D data repository grows, it becomes a collaborative framework for sharing ideas, concepts, and experiences, reducing the likelihood of unintentionally reproducing experiments, and increasing the likelihood of repurposing past knowledge as a point of departure for new experimental work.

Intellectual Capital Protection is Superior

ELNs offer superior intellectual capital protection through mitigation of data loss because of the electronic nature inherent to an ELN. IT departments backup the ELN into data archives, usually with redundant copies secured off-campus. Because experimental data is controlled and held electronically:

- Electronic records are not subject to either environmental or human hazards, such as acid spills or worse yet, a fire in the laboratory.
- The ELN is permission-based, assuring only those with proper authority have access to the information.
- Because of inevitable employee attrition, the organization can be assured that the investment in work product remains with the organization when employees leave. If a copy of the ELN were to be made by a departing employee, the audit trail capability previously discussed could flag the organization warning of a possible breach of data security.

Electronic Laboratory Notebooks can mitigate risks during the regulatory approval and audit processes.

- The ELN provides consistency between notebook entries and notebooks themselves, assuring the cleanliness and integrity of the experimental data.
- Electronic signatures, time/date stamping, and comprehensive audit trails insure the indisputable authenticity of the work product and adherence to 21 CFR Part 11 & GxP by answering the questions of: a) who created the record; b) when was the record created; c) what has been changed (between versions); d) why it was changed (through annotation); and, e) whether the work product can be reproduced.
- Electronic records are now explicitly classified as having the same weight as paper records in both Patent Application and Interference cases, pursuant to 37 CFR 1.671.

With drug discovery and development costs spiraling beyond \$1.4 billion, maintaining intellectual property and speed to market is especially critical.

The American Invents Act

The American Invents Act, effective January 2013, changes the paradigm from first-to-invent to first-to-file in the United States, the policy already in use in much of the rest of the world. The importance of the ELN under the new guidelines will not diminish, since it is important to prove that a document serving as evidence actually existed in a particular form at a particular time. Even under the changes to U.S. patent law, there will still be disputes as to whether one claiming to be an inventor derived the claimed invention from another. Such cases will be settled by an inventor's right to contest before the organization currently known as the Board of Patent Appeals and Interferences. Evidence documenting who was the actual inventor and who might have derived that information from the actual inventor will remain important. The need to be diligent about the management and integrity of records will be the same. Furthermore, it will be incumbent upon organizations to automate their processes in order to streamline the period from ideation to filing. The America Invents Act will inevitably change the landscape of the ELN from another tool for Intellectual Property documentation to an enterprise strategy for expediency and productivity to gain a first to file advantage.

Summary

Organizations involved in R&D are under pressure. Particularly in Life Sciences, where the cost of taking a new drug to market is spiraling beyond \$1.4B. Life science organizations must expedite development of new products to overcome loss of revenue due to loss of patent exclusivity, and to fend off significant generic incursion impacting revenue. An overwhelming goal in all R&D related industry is cost reduction and time to market. Globalization is affecting both speed and the ability to collaborate in the R&D/discovery process. R&D organizations need to decrease costs, increase productivity, and at the same time protect intellectual capital.

ELNs offer superior intellectual capital protection through mitigation of data loss since they are electronic and will conform to the policies of the R&D organization. The added benefits of increased productivity, insight to historical information, a truly collaborative environment, and visibility into R&D projects can be realized. In short, as R&D continues to face cost-reduction measures in an ever increasing competitive environment, the adoption of technologies aimed to improve the R&D process will become imperative to survival and revenue streams demanded by investors. ■

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