

Implementing Paperless Electronic Laboratory Notebooks

Electronic Lab Notebooks (ELNs) deliver proven business benefits. Moving to a “fully paperless” ELN maximizes benefit, but can be an elusive journey. Key to a successful transition is the implementation of electronic signatures and electronic archiving.

ELN benefits

ELNs are replacing paper notebooks across the pharmaceutical industry. They are now the standard tool in both chemical and biological assays and deliver proven business benefits.

- Significant productivity gains.
- Significant cost savings.
- Re-use and sharing of ELN data.

The steps to a fully paperless ELN

Many companies deploy hybrid ELN solutions. This approach uses an ELN but retains paper for record generation and storage. Moving to a “fully paperless” ELN can provide additional benefits.

The critical steps to a “fully paperless” ELN are the implementation of:

- Electronic signatures to replace traditional wet signatures
- Electronic archiving to replace physical storage

The paperless challenge

A pharmaceutical company's Intellectual Property is tied up in laboratory notebooks, which are the sources of patent applications, and the defense of patent disputes. The legal issues and the role of an organization's legal department are often underestimated.

What must be done to ensure that a given document was created by a particular person, at a particular time, with the actual data contained within it, and that it has not been changed or tampered with?

Electronic signatures and archives must provide a legal equivalence to their paper counterparts. In short, ELN systems must ensure the following is maintained for each ELN record:

- Authenticity
- Integrity
- Identity
- Non-Repudiation

Furthermore, this must be demonstrated over the lifetime of the record, from creation through to final disposition.

Electronic signatures

There are many options available but key questions to ask are:

- What technology and strength of electronic signature should be used?
- What infrastructure needs to be in place for strong digital signatures?
- Should the ELN data be signed, or should a documentary rendition of the ELN be created and signed?

The legal status of electronic/digital signatures varies around the world, and also with the nature of the document and the technologies employed to guarantee their authenticity. For example, organizations must understand the difference in US and EU law for electronic and digital signatures.



Electronic archiving

The period necessary for patent defense is 15-20 years. Preserving electronic records over this period is a challenge recognized by technologists and archivists. Addressing this risk is the subject of much research and activity at national archives and memory institutions around the world.



Action must be taken now to put the appropriate ELN archiving framework in place. Again there are some key questions to address:

- Should we archive data or document renditions, or both?
- What formats and standards should be used?
- Should data be kept in the proprietary system that created it?
- What requirements are there on the archive to guarantee record authenticity and integrity?

The issue over what data to archive is a major concern for the Legal community:

- What will really be needed in 20 years time?
- Should raw data be archived?
- Should referential data be included?

Finally, introducing long term electronic archiving, whatever the records being archived, requires the involvement and cooperation of stakeholder groups well outside of the local business area: legal, regulatory, records management, corporate IT, local IT and divisional management. As such it is a corporate activity that needs to be addressed at the higher levels of the organization.

Planning and approach

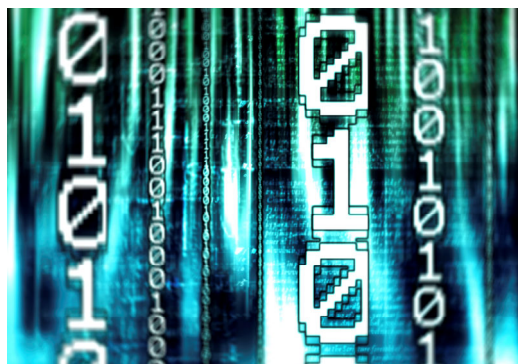
A complex set of drivers and constraints is involved in assessing and deciding how to get from paper to a paperless ELN in a way that minimizes the risk of presenting legally inadmissible records at times in the future.

The following activities should be considered as early as possible in the planning stages to minimize these risks:

- Get all stakeholders involved at the planning and design stage – including Legal, Records Management, and the scientists themselves
- Define clear roles and responsibilities to promote and move the project forward
- Clearly understand and document your ELN Business Rules and Processes in such a way that they will support the generation of long-term ready records
- Understand what systems your organization can already provide you – aim for corporate/global system consolidation, particularly maximizing electronic signature and storage infrastructure
- Use Strong Digital Signature technology with physical tokens and 3rd Party Certification
- Identify and agree with Legal what your ELN “Record” needs to be with detailed meta-data
- Define a self-contained structure for your archival record that can be portable over time as systems evolve
- Use open standards: for meta-data (METS, XIP, PREMIS); and for

documents and data: PDF/A, XML, TIFF etc

- Devise an evolutionary implementation strategy that allows you to put in place the paperless environment while delaying the detailed implementation of the “final archive”.



Why Tessella?

- We have a strong track record of successfully implementing paperless ELNs for a broad range of clients.
- 25 plus years of working with some of the biggest names in life sciences means we understand the industry issues.
- We are world leaders in long term archiving, and preservation. Our clients include the US, UK, Dutch national archives as well as organizations archiving and preserving the authenticity and integrity of scientific data and documents.



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