



Protect your Intellectual Property rights with ConturELN

Protecting your IP rights is about having the correct procedures with best tools to help you.

By the use of ConturELN you can be sure that your experiments are recorded, signed and stored in a secure and credible way.

Background – Important factors to protect your patent

Laboratory documentation is part of the evidence in patent proceedings. The implementation of a credible laboratory record-keeping system is essential.

Laboratory documents are also needed to establish inventorship and the date of an invention (both conception and reduction to practice). This is especially important for “first to invent” jurisdictions, most importantly the US. To be credible, this evidence needs to be corroborated by a non-inventor.

Electronic Laboratory Notebooks are required therefore to provide credible evidence both of the work performed and who carried out that work.

In the last years electronic evidence have been used successfully in patent interference cases (example: Jolley vs. BPAI, Ref: 64 USPQ2d 1901, Fed. Cir. 2002). Based on this acceptance of electronic records in these cases, many science-based companies have chosen to replace their paper notebooks with an ELN system.

The attitude towards electronic records and electronic signatures has shifted and one might question the security aspects of maintaining paper laboratory notebooks. Paper notebooks, when compared to a well-built ELN system, often have a lower compliance with good record keeping policies. For example, it is harder to ensure that records are signed, witnessed, dated etc. Notable is that there are also patent interference cases where paper laboratory notebooks did not qualify as credible business records (example: Chen (BMS) v. Bouchard (RPR), Ref: Interference No. 103,675).

The ConturELN Solution

ConturELN was designed from the start with IP protection at the forefront.

ConturELN has some key features which ensure that credible evidence is provided for both when the work was performed and who carried out that work:

Experiments in ConturELN have a clear structure that mimics a paper page.

The archived experiments (PDF files and/or on paper) have the same structure.

Locked records cannot be changed or deleted.

Additions/corrections are made using a new record.

It is clear who created the documents and when.

There is only one author per experiment.

Contributions from other users are clearly marked.

There is no information hidden from the viewer.

In addition, Contur produces, maintains and supports its software in compliance with high quality standards, meeting the exacting requirements of the biotechnology, pharmaceutical and chemical industries. Contur has always endeavored to produce high quality software according to GxP standards and enabling 21 CFR part 11 compliance.

Evidence from our customers has shown that using ConturELN gives an improved documentation quality. There is an improved adherence to standard procedures and experiments are signed and witnessed much more quickly.

Signing, dating and archiving

In addition, ConturELN provides tools for the signing, time stamping and archiving of experiments.

All experiment submissions must be signed by the author. ConturELN supports both fully electronic signatures and signing of experiments printed on security paper.

ConturELN uses digital signatures. When the author and the witness sign an experiment, a digital signature file is created. These files are stored outside of the ELN and can be used to both check that the archived file has not been altered and also who signed the document and when. This is necessary in order to meet regulatory demands and to provide authenticity and date of invention. A ConturELN digital signature is valid without the need of any proprietary tools like Adobe Acrobat Reader, Microsoft Windows or ConturELN itself.

A third party time stamp can also be added to the electronic signatures.

Experiments are archived electronically in the ISO19005-1:2005 (PDF/A) standard. All documents are in a standard human readable format.

Terminology:

GxP	A generalization of quality guidelines, predominantly used in the pharmaceutical industry.
21 CFR part 11	Deals with the FDA guidelines on electronic records and electronic signatures in the US. It defines the criteria under which electronic records and electronic signatures are considered to be trustworthy, reliable and equivalent to paper records.
FDA	The Food and Drug Administration, an agency of the United States Department of Health and Human Services that is responsible for the safety regulation of most types of foods, drugs, vaccines, biological medical products, cosmetics etc.
IP	Intellectual property, a legal concept that includes copyrights, trademarks, patents, and related rights.
SOP	Standard Operation Procedure. A term used to describe a best practice approach to executing tasks related to hardware and software maintenance, as well as incident and change management.
PKI	Public Key infrastructure. The dominant standard for handling public keys. A public key is inserted in the signing file to validate the authenticity of the document.
Electronic/digital signatures	Digital signatures are often mentioned as e-signatures but there is a slight difference between them. E-signatures use a simple local sign-in and password procedure that does not offer a high degree of security. Digital signatures have the highest security level using certificates.
Checksum	A checksum is a simple way to protect the integrity of data. It works by adding up the basic components of a file, typically the bits, and storing the resulting value. Anyone can later perform the same operation on the data, compare the result to the authentic checksum, and (assuming that the sums match) conclude that the file has not been changed.