

# Robust, Futureproof, IP Protection in Biotech

## 2021 CASE STUDY



USE ZONTAL TO  
RIGOROUSLY  
DEMONSTRATE  
A COMPLETE AND  
AUTHENTIC TRAIL,  
BACK TO THE POINT  
OF INVENTION,  
THAT WOULD STAND UP  
TO LEGAL SCRUTINY

## CUSTOMER PROFILE

Scientists and IP lawyers in a leading biotech firm that need to document experiments for future patent protection purposes and require archived documentation.

## WHO SHOULD READ

Lab heads, Patent Attorneys, IT Managers, IT Business Partners.

# IP PROTECTION

Your IP is one of your company's most valuable assets and the way you protect it should reflect that.

Read on to explore how ZONTAL has helped leading pharma and biotech companies achieve IP security.

# THE PROBLEM

Laboratory notebooks can be important evidence in cases of patent protection (see [Aptix v. Quickturn](#) - which resulted in the Aptix CEO going to jail for modifying a lab notebook). Such cases often occur 10 to 20 years after the experiments were performed. For notebook entries to be admitted as credible evidence at that point, the patent holder needs to guarantee that the notebook entries have not been modified after experiment sign-off.

In the past, paper notebooks written with ink were used by scientists. Today, electronic lab notebooks (ELN) are the common choice, however most ELNs do not provide an option to create digital signatures for their records. It is also common for large biotechs to have multiple different ELN systems in place. Without additional measures, ELN entries might not be able to provide necessary evidence in court.

## WHAT BIOTECH COMPANIES NEED

Experimental data, stored in various ELN, should be converted into digitally signed assets; any potential solution must enable users to digitally sign records from various and multiple ELN systems for legal protection. A digitally signed asset is the technical equivalent of a sealed and stamped letter containing all the original data, and provides robust IP protection in a potential lawsuit.

# THE ZONTAL SOLUTION

ELN systems are used to capture experimental data (notes workflows, entities, samples, requests) and associated documents (Word documents, Excel spreadsheets, and PowerPoint slides, etc). ZONTAL monitors the different systems and automatically creates a data package for each experiment. This consists of a long-term readable PDF and/or a rendition of all experimental data including: associated files, a digitally signed PDF, and copies of all raw data files stored in the ELN in their native format. This data package is bundled in a single information package and stored with descriptive metadata and a checksum to guarantee long-term data integrity (see figure below).

In addition to the export from data stored within the ELN solution, ZONTAL also enables linking of IP reports to experimental information captured from any other lab instrument. ZONTAL manages the masterdata, such as experiment ID, which can be used to create a logical connection with any other experiment using the same metadata. Employing ZONTAL as the data management solution fully integrates the digital laboratory and provides unprecedented insights to attorneys and scientists.



# ZONTAL

Electronic official file

The screenshot displays the ZONTAL Electronic Official File interface. On the left, logos for IDBS, PerkinElmer, and Benchling are shown. The central panel features a 'Provenance' table with the following data:

Field	Value
Entry Identifier (ELN)	etr_fVwqcSdT
Creator (ELN)	Dennis Della Corte
Created On (ELN)	2021-04-26T17:48:54.181578+00:00
Authors (ELN)	Dennis Della Corte
ApiUrl (ELN)	https://workshoptest.benchling.com/api/v2/entries/etr_fVwqcSdT
WebUrl (ELN)	https://workshoptest.benchling.com/workshop/f/11b_XKeXFinC-regeneron/etr_fVwqcSdT-sp-test-experiment/edit
Modified On (ELN)	2021-04-27T15:29:08.436934+00:00

Below the table is the ZONTAL Electronic Official File logo. To the right, a 'Legal search and retrieval' section lists several files:

- EXP21000026
- EXP21000026.json
- EXP21000026.pdf
- EXP21000026.pdf-a.pdf
- 000\_SP Test experiment 2021-04-26 (etr\_...
- LT data for zontal.xlsx
- PwrPoint for Zontal.pptx
- Test SOP for Zontal.docx

ZONTAL enables rapid legal search and retrieval of stored information packages. All data can be visualized on demand via standardized metadata. ZONTAL enables fully GxP compliant long-term archiving of all data stored within the system. As a result, legally important documents can be found, retrieved, visualized, and reused to support any future trials.



ZONTAL provides IP protection for data from various electronic lab notebooks.

# RESULTS

## BEFORE ZONTAL:

Upstream work resulted in frequent duplicate experiment documentation

Manual workflow created copies of all raw data which were difficult to manage

Source data needed manual transfer to ELN solution prior to electronic signing.

## AFTER ZONTAL:

Improved user experience through simplified workflows

The data is directly moved into ZONTAL and does not need to be copied

All source systems are automatically connected to a signature workflow

By implementing ZONTAL, leading biotech companies are able to save time and money, whilst protecting their reputation and maintaining regulatory compliance.

# WHAT'S NEXT

Generating digitally signed notebook entries is just the beginning of your digital transformation.

Our mission is to ensure full compliance in the digitally integrated laboratory. We provide end-to-end data genealogy and traceability throughout the Bio/Pharma R&D lifecycle. Delivered through explorative dashboards, visualizations and analytical tools, ZONTAL turns data into an asset that drives decision making and improves time to market.

We are ready to revolutionize your laboratory, send us an email to learn how!

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KEEP IN TOUCH:

