FOR TEAMS OUTSIDE THE LAB · 5-MINUTE OVERVIEW

# Bioanalytical ELN

A digital lab notebook built for the scientists who measure how much of a drug ends up in a blood or plasma sample — and the audit-ready record that inspectors, sponsors, and regulators rely on.

5 slides

No prior lab background needed

ICH M10 · e-signatures · audit trail

WHY THIS EXISTS

# Paper notebooks can't keep up with the rules

Before a new drug can reach patients, every sample tested along the way has to be traceable: who ran it, on what equipment, checked by whom, and when.

| A paper notebook | This ELN |
| --- | --- |
| • Can be edited with no trace of the change | • Every edit is kept, never silently overwritten |
| • Sits on one desk — easy to misplace, hard to search | • One shared, searchable record for the whole team |
| • Relies on someone remembering to get it signed | • Won't let a step count until it's reviewed and signed |

> The industry's shared checklist for "how do we know this measurement is trustworthy" is a guideline called **ICH M10**. Regulators can reject years of drug-trial data over gaps like the ones on the left — this software is built to close them automatically, not remind someone to.

WHAT IT ACTUALLY DOES

# One record, from first pipette to final report

### Full chain of custody

Every material, mixture, and test run is logged in order and linked to what came before it.

### Second-person sign-off

Nothing counts until a different, qualified colleague reviews and electronically signs it.

### Tamper-evident history

Every change is kept, not overwritten — you can always see what changed, when, and why.

### Role-based access

Investigators, Quality Assurance, Management, and Auditors each see exactly what their job needs.

### Secure sign-in

Password plus a code from your phone's authenticator app — or your company's existing single sign-on.

### Reports at a click

An audit-ready summary, generated automatically and ready to print or hand to an inspector.

HOW THE WORK FLOWS

# The path a single measurement takes

01

### Sponsor & Method

Who the work is for, and the tested procedure it follows.

02

### Materials

Standards and reagents are received and verified.

03

### Preparations

Solutions are mixed from those verified materials.

04

### CAL/QC

Calibration and quality-control checks prove the method is on target.

05

### Runs

Samples are analyzed on the instrument; results attach here.

06

### Validation

Proof the method itself performs reliably, once, up front.

07

### Review & sign

A second person checks and signs every step above.

Every stage lives in the same record — nothing is re-typed between steps, and nothing moves forward until it's been reviewed.

GETTING STARTED

# Five minutes to your first login

1 **Open your invite link and log in**

Your admin sends a link to the ELN. Sign in with the username and password they give you.

2 **Scan a QR code — once**

First login only: scan a QR code with an authenticator app (Google Authenticator, Authy, 1Password) to finish securing your account. After that, every login just asks for a fresh 6-digit code.

3 **Get added to a Project**

Ask your project lead to add you as a member — that's what puts real, relevant work in front of you instead of an empty screen.

4 **Use the Help Center when you're stuck**

Every screen has a `?` link to a short, plain-language how-to guide built into the app itself.

**Questions before then?**
Reach out to your project lead or the ELN administrator.

`You're ready when you can log in and see a Project`