

LABWARE®

ELN

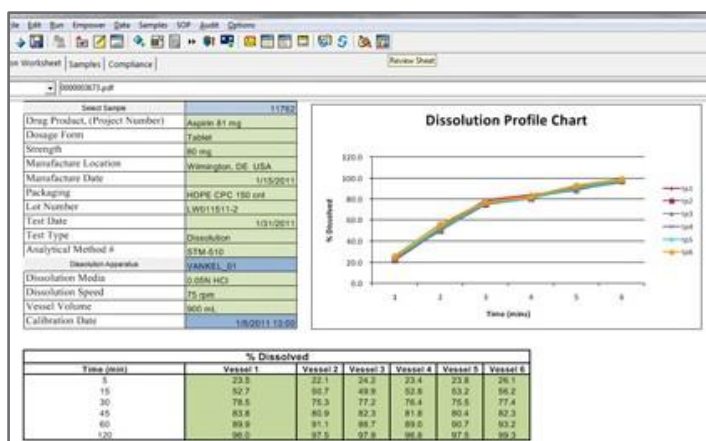


A feature rich Electronic Laboratory Notebook that is seamlessly integrated with the world's most popular Laboratory Information Management System



Project Overview

LabWare ELN is an experiment and/or procedure driven electronic laboratory notebook application designed to give your scientists the ultimate platform to capture and store both structured and unstructured data as they conduct experiments or execute laboratory procedures. The LabWare ELN user interface is entirely flexible and can be tailored by creating experiment templates that allow the scientist to easily enter information. Examples include: numerical information, textual comments including extensive journaling capability using our built-in word processing editor, easy attachment of one or more files or images, creation of charts, performance of calculations and the ability to work with instrument data. Whether you think of an ELN as an electronic replacement for your paper notebooks or as a compliance enforcement tool that helps your analysts run validated methods with- out making human errors, LabWare ELN can do it all! You determine the amount of freedom or compliance enforcement you want on a procedure by procedure basis. LabWare ELN is an integral component of LabWare's Enterprise Laboratory Platform and thus works seamlessly with our flagship product, LabWare LIMS, allowing any data contained within LIMS to be accessible by ELN and vice versa.



Integrating ELN products from different suppliers has significant practical challenges, technical limitations, and is expensive to develop and maintain over the long term. The benefit of LabWare ELN is the inherently elegant interface that exists between the two systems and the simplicity by which LIMS data and functionality can easily be shared and leveraged from within the ELN experiment or procedure.

Your scientists will feel right at home working with the intuitive and familiar user interface because LabWare ELN templates originate from Microsoft Office documents and spreadsheets that allow the freedom to design whatever experiment template or document template you desire in ELN using familiar Office editors or built-in spreadsheet and document editors. LabWare ELN automatically stores all structured and unstructured content in a powerful relational database which is fully searchable and reportable. Furthermore, data in ELN can have special relationships set up that allow the data to be associated with familiar laboratory objects such as studies, protocols, samples, tests, results and, of course, laboratory consumables and instruments.

LabWare ELN – Core Capabilities, at a glance

LabWare ELN provides a vast amount of out of the box capabilities that are useful to all laboratory types and most industries. These core capabilities enable laboratories to:

- Capture all data and metadata associated with either an R&D experiment or a QC procedure.
- Work with instrument data using LabWare's modular data acquisition tools.
- Eliminate paper notebooks, log books, and laboratory worksheets.

- Attach any type of file, image or document to the experiment with LabWare ELN tracking all revisions.
- Insert comments and yellow sticky notes to collaborate with peers or reviewers.
- Electronically review and approve experiments or procedures including their respective data.
- Easily search the relational database using any combination of search criteria from ELN (and LIMS).
- Use LabWare's built-in powerful report writer to summarize and report data in a variety of formats.
- For those customers working in a regulated industry, LabWare ELN can help to ensure regulatory compliance through its comprehensive audit trail, electronic records support, and configurable electronic signatures.
- Track calibration status of instruments and the compliance aspect of laboratory consumables such as reagents and standards and drill down on any related objects referenced in the ELN experiment or procedure.



Instrument Interfacing and Systems Integration

LabWare ELN provides built-in, out of the box capability to capture data from laboratory instruments. ELN can directly connect to instruments such as analytical balances, pH meters, and titration instruments using an RS-232 communications link over a network (LAN or WAN). For instruments that use a computerized data system, LabWare ELN provides the ability to parse and extract the data contained in reports produced by the data system and to enter that data directly into the ELN worksheet.

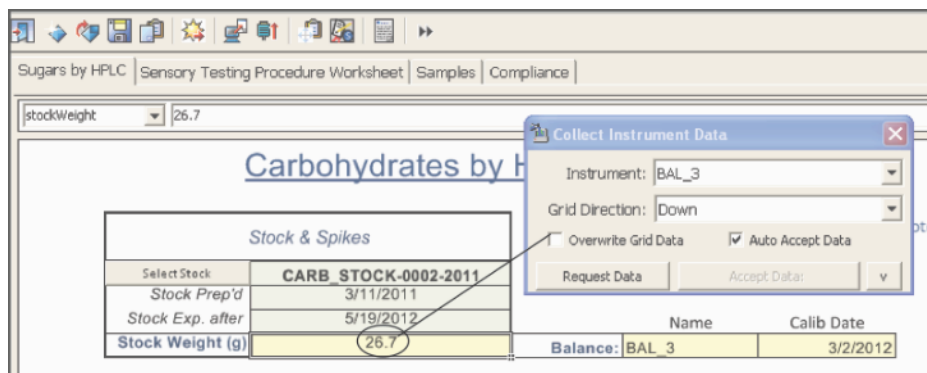


COMPATIBLE

LabWare also offers a seamless bidirectional interface to the Waters Empower® chromatography data system that provides a functionally rich environment for interacting with chromatography data directly within an ELN experiment or procedure. Users can build sample sequences by combining samples and standards associated with the ELN experiment and saving them directly in Empower. Once the chromatography data has been acquired and processed within the Empower software, the ELN-Empower interface allows that data to be easily brought back into the experiment or procedure where it can be visualized or trended against historical data. One of the powerful features of the ELN-Empower interface is its ability to navigate from results in ELN to the associated chromatograms in Empower with a simple click of the mouse button. The integrated chromatograms along with all related processing information are displayed in the Empower Review application for further inspection.

Laboratory Execution System (LES) Capabilities

If you are working in a QA/QC environment, you may require your ELN to operate in a controlled,



“method execution” mode, in order to guide users stepwise through validated analytical methods. LabWare ELN is fully capable of working in this mode of operation delivering enhanced laboratory productivity and procedural compliance.

LabWare ELN allows analytical method documents to be attached to ELN method templates. These method instructions are displayed to end users anytime they perform the method in ELN, either through our “pop-up” SOP window or using split screen view (as depicted below). A flexible and graphical workflow tool allows stepwise highlighting of method text as the procedure is executed in ELN. Furthermore, the workflow tool can sequentially show and hide sections of the ELN method template to precisely control which results and relevant metadata are entered for each step of the method. For example, a method might require instrument set up, followed by reagent preparation, followed by calibration, etc.

GENERIC: EXP-GENERIC-2012-0006 - [

Recent File Edit Run Data Samples SOP Audit Design

Summary Generic Procedure Example Samples Compliance

Originator: S.Mitchell Reviewed by: G.Brooks Approved by: H.Wilson

4.3 Calibrate the UV Spectrophotometer

4.3.1 Switch on the UV Spectrophotometer, and wait for 30 seconds before proceeding.

4.3.2 Set the UV to 690 nm and record this setting is being used.

4.3.3 Remove the five, 10-100 mg/ml UV standards from the Refrigerator 501 and measure in sequence, recording the absorbance.

4.3.4 Confirm the calibration curve is linear.

B19

Switch on UV Switch On Instrument ready

Wavelength nm 690

Std. Concentration mg/ml	Absorbance
10	0.8
25	0.93
50	1.1
75	1.2
100	1.3

Regression coef R² = 0.97331
Correlation coef R = 0.98657
m (slope) = 0.00546

Y = 0.0055x + 0.7622

Equipment / Reagents, Calibrate / Measurements

LabWare ELN in Method Execution mode using the optional split-screen display

LabWare ELN can guide the operator through each step, displaying the relevant section of the method, prompting for instruments/equipment and reagent lots suitable for the method and at the same time conveniently check expiry dates, stock levels etc. by interacting with LabWare LIMS. LabWare ELN can even enforce countdown-timer controlled wait times to allow equipment such as water baths to warm up, etc. before allowing progression to the next step of the method. This is what LabWare refers to as Compliance by Design (CbD) and it can dramatically reduce human error, increase laboratory efficiency, and minimize tedious investigations and CAPAs!

Simple and Efficient Method Setup

Setting up methods in LabWare ELN is very easy and straightforward. Method templates can be assembled from one or more “workbooks” using the built-in editors and wizards. While LabWare ELN does not have any dependencies on the Microsoft Office applications, we've made it very simple to begin with either a pre-built Excel spreadsheet or a Word document as the starting point for your ELN method template. This modular approach also allows re-use of “component” workbooks for commonly used tasks such as conclusions and summary information, preparing new batches of reagent, acquiring data from instruments, or preparing a series of standard dilutions, etc. This can significantly accelerate method set up time and allows your scientists and/or QC analysts to use something they may already be familiar with in the laboratory. Built-in wizards and dialogs in the ELN method designer give you the ability to easily set up mappings and relationships between existing LIMS and ELN database fields and their corresponding objects (Manufactured Batches, Samples, Tests, Results, Reagents, Instruments, etc.).

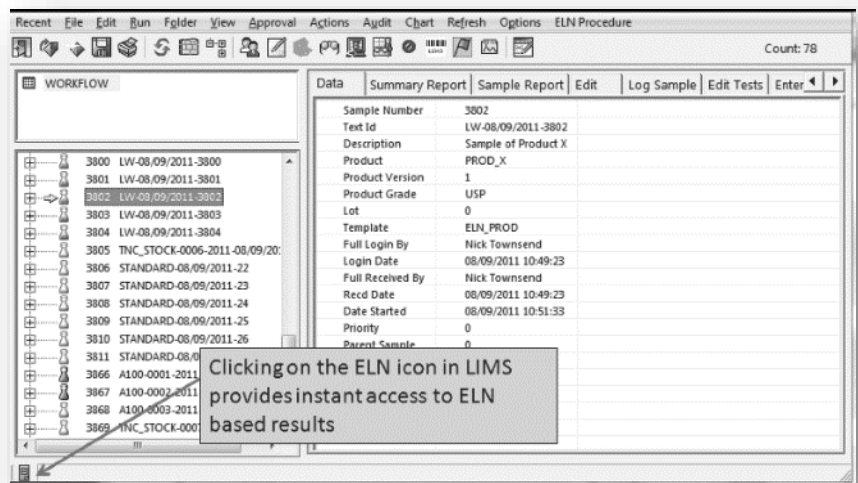
Powerful Data and Review Tools

LabWare ELN provides a fully configurable data review workflow that can easily accommodate customer specific preferences and business rules. Powerful review and data visualization tools are provided within the ELN such as a colorful “at a glance” Compliance Summary screen that’s useful to quickly spot any non-conformances within a method procedure such as out of specification results, out of calibration instruments, and the use of any expired standards or reagents. Whether you are working within the LIMS or the ELN, a person reviewing data can conveniently drill down into the respective ELN procedure and all of its relevant data while maintaining the full context of who, what, when, and how the information was collected within the system. LabWare ELN is supported by a full audit trail and a powerful data visualization tool we call Data Highlighter, that allows reviewers to pinpoint what elements of the procedure were entered together and by whom. Data Highlighter enables a user to visualize data that meets common criteria such as: data entered by, data reviewed or witnessed by, data originating from a particular instrument, data involved in calculations, and many other common scenarios. The Data Highlighter tool also allows the user the opportunity to mark the highlighted data as complete, reviewed or witnessed.

Benefits of an Integrated Enterprise Platform

LabWare ELN fully leverages the seamless, bidirectional integration with the LabWare LIMS platform in a manner which is much more sophisticated than can be achieved by interfacing LIMS and ELN products from different vendors. For example, multi-level product specifications held in LIMS can be checked in real-time by LabWare ELN and trend analysis of historical product data in LIMS can be displayed. LIMS alerts and investigations can be initiated from ELN methods and, most importantly, updates to data in LIMS and ELN are automatically synchronized using LabWare’s Active Sync™ technology. Active Sync ensures there is never a situation where the data in LIMS is different from the data that’s stored in ELN and vice versa.

There are also significant IT benefits and cost savings when using a fully integrated LIMS and ELN platform. Very few customers have achieved satisfactory integration between third party ELN software and their LIMS because of the inherent expense involved in developing a customized interface and then having to fund the cost to maintain and enhance the interface over multiple years. An integrated LIMS and ELN platform eliminates the cost and expense of integration projects, while at the same time allowing the organization to standardize on common enterprise hardware and software platforms. This reduces application support and hardware maintenance costs, and allows the support staff to leverage common skills that can be applied across both applications.



ELN Training and Implementation Assistance

LabWare offers both basic and more advanced ELN customer training classes to get you up and running quickly through LabWare's Global Services organization. Training classes can be provided on-site just for your company or provided as a public class at one of LabWare's regional training centers. The ELN training consists of both lecture and hands-on exercises with expert guidance from our certified trainers. LabWare provides a full complement of professional services to help you get your new system installed and implemented in the most efficient way possible. We offer project planning and project management assistance, expert configuration services, and can assist you with any testing and validation activities you may require.





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