



# **DIGITAL LAB DOCUMENTATION**

**IMPROVE COLLABORATION,  
PRODUCTIVITY, & REDUCE COSTS**

White Paper for Life Sciences



## LIFE SCIENCES INDUSTRY CHALLENGES TODAY

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Life Sciences organizations need to bring new high-quality therapeutics to market fast to respond to patient needs specific to different diseases and geographies. But development time and costs for new therapeutics are gigantic with an average accrual of \$2.6B and 12 years from ideation to market. Reasons for the struggle include (1) the long “time to fail” in new target identification, (2) increasing global and regional regulations and scrutiny, and (3) the major efforts required to ensure that therapeutics are safe, efficacious and compliant with specifications. Personalized Medicine and Patient Centricity add complexity to Development and Manufacturing. Testing is required to confirm therapeutic characteristics discovered during Research, to identify and optimize formulations for production and scale-up, and to release active ingredients and products.

With long product development times, Life Sciences organizations must accelerate the pace and quality of innovation for long-term success. As a result, they are re-evaluating the entire product lifecycle from research through development to manufacturing and are adopting advanced information technology (IT) systems capable of supporting today’s dynamic business ecosystem. As products move from discovery and development to manufacturing and commercial operations, Life Sciences organizations are investing in the latest tools and technology to improve insight, accelerate innovation, reduce costs, and speed time to market. Faster innovation is a direct result of greater productivity with digital solutions in the lab, as researchers spend less time on documentation and leverage existing experimental data to make better decisions faster.

## MOVING TOWARDS THE DIGITAL LAB

Laboratory organizations need an environment that facilitates and optimizes collaboration, experiment execution, documentation and data management in the different labs from R&D through manufacturing to commercialization. But today many laboratories are still working on paper or have a legacy system of some kind that digitally stores experimental data. This can be a database that includes anything from scanned PDF documents to word documents to spreadsheets. It can also be a commercial solution that is not fully leveraged because of usability or implementation issues. Many organizations that adopted early commercial ELNs now find themselves missing needed features with a system that is difficult to upgrade or has not been widely embraced by laboratory staff. The deployment of different (legacy) solutions in different areas or working fully or partially with paper often results in workflow inefficiencies, errors due to manual work, high total cost of ownership and difficult collaboration.

To collaborate more efficiently and productively, organizations are moving from paper lab notebooks and legacy systems that can be tedious to implement and update, to flexible ELNs that are cost-effective, easy to deploy and adopt across disciplines and global sites. Multi-disciplinary, generic ELNs will help drive continuous, rapid innovation and improved research efficiency, quality and compliance as well as making experimental information easier to read, search, share and reuse.

The ultimate goal is a fully integrated scientific enterprise where information flows from research and development to manufacturing and commercialization as seamlessly as possible. The integration of the ELN with other laboratory systems will eliminate time-wasting, error-prone manual data transfer and streamline data sharing across systems.

Key capabilities of an ELN are:

- Executing and documenting experiments, methods, procedures and tasks
- Storing, sharing and protecting lab data and results
- Managing chemicals, materials, equipment, personnel and related processes
- Developing, adapting and managing recipes generated throughout the product lifecycle

## SCIENTIFIC DATA-DRIVEN DECISION-MAKING

Product research, development and manufacturing organizations need to manage lab data effectively if scientists and engineers are to extract full value for decision-making and innovation. This applies to operational reporting and release processes as well as data mining, trending and feedback into product development processes and initiatives.

Leveraging an ELN is especially beneficial for scientists and engineers. Capturing experiments and data within a unified ELN provides access to historical data, allowing scientists and engineers to build on their colleagues’ work and expertise by easily searching for prior experiments and data to supplement their own experiments. As a result, teams can leverage common procedures and make incremental changes to optimize variations based on changing specifications, regional suppliers and manufacturing capabilities—as opposed to designing each experiment from scratch. At the manager level, the ELN makes it possible to quickly review the division of labor in collaborative experiments and assign new tasks based on a clear understanding of lab priorities and utilization. Additionally, standardized experimental processes and data entry gives scientists and engineers a common language for communicating and interpreting data from across the organization. This unified environment minimizes unused “dark data” and needlessly repeated experiments, streamlining the R&D network so that scientists and engineers can develop new products faster than ever before.

In this way, an ELN does much more than just digitize experimental documentation and existing workflows; it can be a powerful force for transformation within Life Sciences R&D. For example, capturing scientific data within a common technology framework makes it easier to apply cutting-edge technologies like 3D modeling/simulation and predictive analytics. Teams can virtually screen drug candidates, and search for optimal structures, fostering a culture of iterative innovation that reduces development costs and shortens time to market.

### **BENEFITS OF DIGITAL EXPERIMENTAL DOCUMENTATION**

An ELN brings a number of immediate benefits upon implementation and adoption in a science-based organization. The quality of experimental documentation is greatly improved, as it is easy to capture data according to ALCOA principles: namely that the data is Attributable, Legible, Contemporaneous, Original and Accurate. Eliminating handwritten notes also makes the data much easier to read, as well as making it searchable across the organization. Data can be copied and pasted directly from instruments, saving time and frustration, and eliminating transcription errors.

With all scientists and engineers capturing data in the same system, it is easier to gain an overview of all activities which are being performed. At the same time, visibility into all existing data helps improve awareness of the knowledge already contained in the organization, reducing or eliminating the potential for unnecessary repeated work or extra reporting. Scientists can easily find work which has already been completed, and build upon it, rather than having to start from scratch, and there is less time spent chasing information from other colleagues.

### **CLOSING THE GAP BETWEEN INNOVATION AND COMMERCIALIZATION**

Faced with revenue erosion resulting from patent expiration and increased competition, Life Sciences organizations are looking for new ways to drive innovation, improve productivity and control costs. For decades, most data has been paper-based, requiring numerous non-value-added checks to ensure end-to-end data integrity and quality from product development through commercialization. These legacy paper-based systems are becoming even more difficult to manage as Life Sciences companies expand their global reach.

An ELN also allows for further integration with other Digital Lab capabilities throughout the lab. For example, a chemical inventory management system allows scientists and engineers to see what materials are available and request them as needed from within their ELN. Likewise, stockroom managers can simplify inventory management with real-time updates on stored substances including amounts, expiration dates, locations and changes in safety data. They can order new materials only when needed—reducing inventory, lowering costs and creating a safer and more sustainable enterprise overall.

Today's technology can replace paper systems with efficient electronic environments supporting "innovation to market." Starting from an ELN, the informatics environment in the Digital Lab supports quick technology transfer of robust, automated test methods to quality operations and process parameters to manufacturing facilities. When a product goes into full commercial production, the Digital Lab also enables recursive data access supporting continuous product/process improvements.

#### **CURRENT STATE - PAPER LAB**

- **Slow pace of innovation**
- **Lab work too slow and projects are difficult to track**
- **Repeat experiments due to lost data and inconsistent test procedures**
- **Slow, manual documentation**
- **Data trapped in notebooks and difficult to share**



#### **FUTURE STATE - DIGITAL LAB**

- **Faster innovation and time to market**
- **Shorter project completion times**
- **Reusable data**
- **Less time on documentation**
- **Easily collaborate and share across sites and locations**

By bridging the innovation and productivity gaps in research, development, manufacturing and quality, and enabling successful technology transfer across new product development and production operations, the Digital Lab supports:

- Enhanced productivity through streamlined workflows and simplified reporting
- Better collaboration within globalized R&D and across dispersed teams through easy data access and standardization
- Informed decisions through optimized experimentation and sample processing with real-time results
- Faster time to market through shorter cycle times and reduced latencies between cycles
- Improved compliance through ALCOA – experimental data that is Attributable, Legible, Contemporaneous, Original and Accurate

## WHY ADOPT AN ELECTRONIC LAB NOTEBOOK?

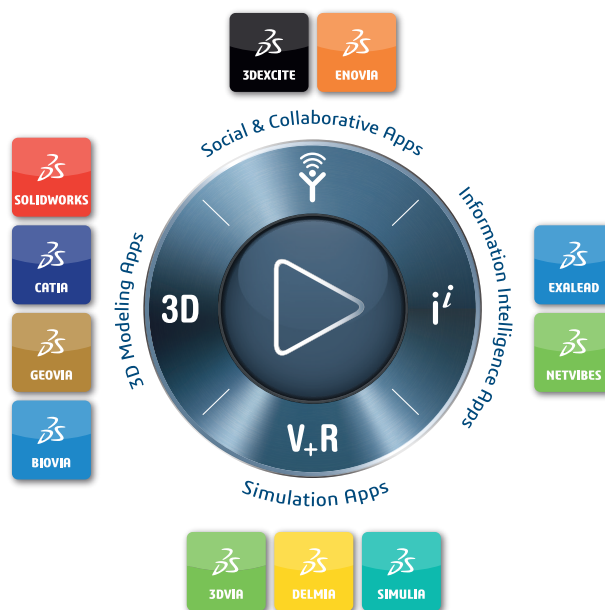
In summary, paper-based Life Sciences labs are inefficient because data is “siloe” on bookshelves, experiments are needlessly repeated and information cannot be shared. As a result, innovation slows to a crawl.

An ELN accelerates innovation by reducing unnecessary work, improving data access and facilitating collaborative data sharing. Life Sciences organizations have reported qualifying breakthrough innovations in half the time, with improved metrics in many underlying tasks supporting faster innovation and productivity including:

- As much as 20% faster project completion
- Up to 40% reduction in time spent recording information
- Up to 95% faster data aggregation
- A 20% improvement in formulations innovation

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