BIOVIA

3DEXPERIENCE

# THE 21ST CENTURY LAB

Reinventing laboratory informatics
to accelerate drug discovery and innovation

DASSAULT SYSTEMES

## TRANSFORM FROM ELECTRONIC TO DIGITAL

Life Science companies face major challenges to continued operations and profitability from patent expirations, low R&D productivity, increased competition, decreased margins, inefficient processes, and mounting compliance constraints.

> **70% of life sciences companies are moving from individual and separate applications to comprehensive platform solutions.**

Labs need a technology infrastructure capable of integrating and automating critical processes, so scientists can capture and share critical information. In this context, the phrasing should be "data across the entire scientific product lifecycle."

It requires a scientifically aware informatics foundation that integrates critical capabilities with existing systems and information sources—speeding "science to compliance" for organizations that rely on scientific innovation to differentiate themselves.

This eBook outlines why you should stop relying on point solutions addressing individual problems in the lab, how an intelligent scientific platform can accelerate innovation, and how to move seamlessly between different dimensions to integrate and standardize everything across the entire organization.

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# CREATE DIGITAL CONTINUITY

Labs are under pressure to deliver products, analysis, and results of high performance and quality as quickly and cost-efficiently as possible.

Traditional disconnected, paper-based, and error-prone processes cause:

### Lack of Productivity

**Up to 40%** of experiments repeated needlessly
**Only 0.5%** of data fully analyzed and utilized

### Compliance Issues

**25%** of lab expenses spent finding and correcting errors
**49%** of FDA warning letters cite data integrity issues

### Increased Costs

**45%** of R&D materials ultimately wasted
**50%** of pre-clinical studies with irreproducible results, wasting $28B/year

Today, workflows are becoming more digital and connected, and companies are working to harmonize and standardize environments to help lab scientists collaborate seamlessly across the globe.

Technologies to meet the requirements for life science laboratories require true digital continuity, holistic solutions, and data standards for compliance and consistency, all in the cloud.

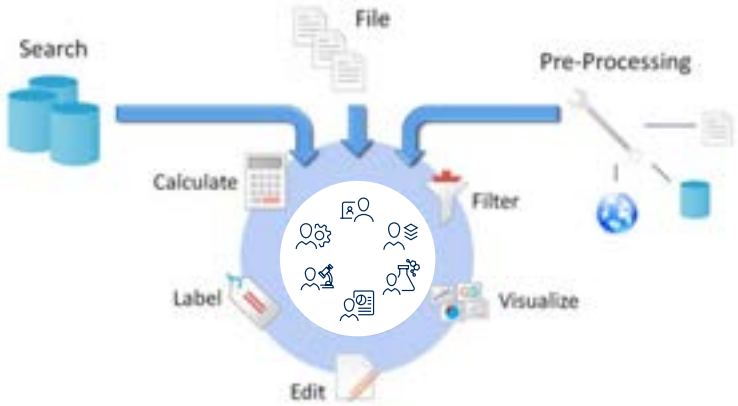
An intelligent scientific platform delivers better scalability, usability, increased compliance, and lower total cost of ownership. It will accelerate innovation, leverage marketplaces, and allow 21st century labs to move to new horizons for innovation and efficiency.

# MANAGE DARK DATA

Dark data results from users' interactions across different devices and disconnected systems, and includes everything from instrument data to server log files to unstructured data derived from social media and offline sources.

Although often considered incomplete, redundant, too old to provide value, or in inaccessible formats across tools, dark data may be an organization's biggest untapped resource. Data is a major asset, and competitive organizations need to tap into its full value. Stringent data regulations also increasingly require complete traceability of any organization's data.

By removing paper and dark data from the lab using centralized and unified digital recordkeeping, scientists can manage all data across fast-moving and simultaneous projects. Data generated by scientists, instruments, and manufacturing equipment is automatically ingested, stored, tagged, processed, and formatted for use. It becomes available to other systems and scientists for reporting, prediction and modeling, and analysis without requiring tedious transcription to other analytics tools.




Cloud-based data management and analysis systems help uncover, organize and leverage dark data to keep project progress on track. Scientists access information easily to generate insights from this data, helping to accelerate the product development pipeline and respond to regulatory inquiries quickly.

# IMPROVE TECH TRANSFER

Tech transfer is a complex process, whether it occurs between R&D and manufacturing within a single company, between a services lab and a corporation, between manufacturing sites, or between a manufacturer and a contract development and manufacturing organization. It is a bidirectional process that feeds R&D with critical data to help continuously improve quality and drive down cost, and manufacturing sites to optimize their processes.

Compounding complexities, each tech transfer must gather hundreds of documents and supporting data from different disconnected systems, making knowledge transfer slow and incomplete.

Tech transfer, though, is the bridge between innovation and profits, and a growing number of life sciences companies are using new technology to help improve its integration and speed.

Digitalizing and integrating lab and manufacturing systems improves agility and quality. It allows companies to be efficient and respond quickly when issues arise.

It also makes processes more consistent and helps prevent errors, in particular when applying globally standardized processes for both horizontal and vertical tech transfer, even when there is some local variation.

"Digitalizing Tech Transfer," Tech-Clarity Survey, 2019

**Digitalization and integration accelerates Life Sciences tech transfer by:**

- transforming from document-centric to data-centric workflows
- creating more structured data that improves quality and efficiency
- simplifying the flow of information between departments
- improving both horizontal and vertical integration across the organization

Digitalization is the key to improving tech transfer performance, helping to get products to market faster and reach quality and yield targets sooner than the competition. Adopting digital processes, data, and platform-based integration will drive better tech transfer and business performance.

# OPTIMIZE PROCESSES

The next-generation lab is integrated both horizontally and vertically, and then end-to-end.

Horizontal integration requires standardized methods that can be shared across different labs, ensuring the same procedures, taxonomies, and ontologies are applied.

Vertical integration is sharing those methods across the different stages of the product life cycle, for example from development to manufacturing. Standardized procedures help build and execute those methods, which can then be utilized as the product moves.

By implementing an integrated lab solution, companies can streamline workflows in the lab, automating non-value adding steps, while standardizing processes and data for improved quality, compliance, and efficiency.

**50% experiment reuse increase with improved data management**

**30% less raw material use with enhanced inventory management**

**Simplified data searching and sharing across labs and sites**

**Real-time analytics and reporting**

Leverage an integrated lab solution to improve productivity and bring rapid, game-changing innovation to market faster.

## CUSTOMER USE CASE

### Streamlining Lab Execution at a Global Pharma Company

This customer was challenged by: manual data handling; data not available for planning/decisions; information buried in scattered documents; knowledge kept at individual level; excessive late-stage lab work.

### Solution

A unified cloud-based Chemistry, Manufacturing, and Controls lab informatics built with BIOVIA ONE Lab.

### Benefits

- Enabled growth through scalable collaboration processes
- Created foundation for systematic knowledge management
- Reduced risk with better-informed decisions
- Removed bottlenecks to growth
- Eliminated redundant work
- Accelerated time to market

# REDUCE COMPLIANCE RISK

To comply with guidelines outlined by current GxP regulations, life sciences organizations must ensure that personnel will view, follow, and document all written procedures. Regulatory agencies require that manufacturers a) document what they are going to do, b) follow the document while they are doing it, and then c) document what they did.

Minimizing the risks of compliance is critical to costs, resulting from non-value adding work, production delays, or halts. This ultimately leads to shut downs, product recalls with potential fines or consent decrees, and potential impacts.

Automating and standardizing processes across sites and projects enables organizations to increase quality and compliance. At the same time, it increases efficiency and productivity, resulting in fewer complaints and observations against existing products and faster commercialization of new products.

### Digital Quality and Compliance Best Practices

- ↑ **85%** improvement in data traceability
- ↓ **50%** reduction in FDA on-site inspection time
- ↓ **20-30%** in observations

### Global Operational Efficiency

- ↓ **16%+** reduction in time to market
- ↑ Global compliance
- ↓ Variances between sites

By utilizing an automated procedure management system, the resulting paperless environment assures that step-by-step compliance with procedures is followed, all data and metadata are captured and cataloged, and review and approvals are streamlined.

Significant benefits improving operational excellence include 50 percent to 75 percent cycle-time reductions, reduced compliance risk, and harmonization of procedure/method/SOP best practices across the enterprise.

## CONCLUSION

Companies that are adopting a digital approach that effectively connects innovation and commercialization cycles will achieve high fidelity data that retains contextual information as projects move through R&D into manufacturing.

Support your product development and commercialization with a comprehensive, scientifically aware informatics foundation that captures and harmonizes data along the end-to-end product lifecycle continuum. By bridging the innovation and productivity gaps in research, development, manufacturing, and quality companies will drive successful technology transfer across the entire organization. Companies that have adopted this proven integrated informatics approach have experienced:

- Enhanced productivity through integration and streamlined workflows
- Improved compliance through automated data transfer and support of execution and 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

# THE 21ST CENTURY LAB

It is clear that labs in the 21st Century can no longer operate with a patchwork of point-based informatics systems. Companies are increasingly turning to integrated, platform-based solutions to solve their challenges and accelerate product development and commercialization.

The leaders in the Life Sciences industry are partnering with BIOVIA, a Dassault Systèmes brand, to transform their lab operations with BIOVIA ONE Lab. ONE Lab enables full digitalization, standardizing data and procedures while automating workflows and removing non-value added tasks. ONE Lab leverages the power of the 3DEXPERIENCE platform for a unified experience, and true end-to-end business transformation which is completely unique in the marketplace.

For more information, visit **www.3ds.com/life-sciences-healthcare**.