BIOVIA LIMS

AN ENTIRELY NEW PROCESS- AND EXECUTION-CENTRIC APPROACH TO LIMS IMPLEMENTATIONS

DATASHEET

The BIOVIA Laboratory Information Management System (LIMS) is purpose-built to manage 21st-century product and process informatics requirements with a specific focus on scale-up, manufacturing and compliance that eliminates the complexities, excessive customization and lengthy associated validation requirements inherent with traditional LIMS. The result is streamlined deployment, substantially lower total cost of ownership and rapid return on investment.

BIOVIA's new approach to laboratory information management provides a workflow software layer to manage critical lab-to-plant experimental, procedure and SOP execution needs during downstream scale-up, manufacturing and compliance. With BIOVIA LIMS, out-of-the-box, commercial LIMS capabilities can be deployed as independent, free-standing, web-based applications or integrated with other BIOVIA solutions such as BIOVIA Electronic Lab Notebooks (ELNs), BIOVIA Lab Execution System (LES), BIOVIA Electronic Batch Records (EBR), and BIOVIA Discoverant to create a comprehensive, paperless informatics solution from scale-up through manufacturing and compliance. In addition, BIOVIA Foundation enables integration with lab instrumentation and existing software systems including legacy LIMS, as well as facilitating data aggregation, analytics and reporting.

BIOVIA's process- and execution-driven approach to LIMS deployments is fundamentally different from the sample-driven approach of traditional LIMS and eliminates the complexities, excessive customization and lengthy validation requirements inherent with them.

NO CUSTOM CODING

Each BIOVIA LIMS application includes workflow editors that eliminate traditional software custom-coding processes, enabling internal system administrators to deploy the needed applications, workflows and procedures using a simple drag-and-drop process and dialog interface with automatic procedure validation. Organizations can start with one of the BIOVIA LIMS applications and simply add the others as needed.

By eliminating the need for external consultants and programmers, this approach speeds system deployment while also lowering total cost of system installation and ongoing ownership.

AUTOMATIC WORKFLOW VALIDATION

When finished with the workflow editing, a single mouse click generates a complete validation document for the application, workflow or procedure. Built-in compliance at the core technolgy level turns qualification/validation into simple, fast document reviews with no need for external validation consultants, even in regulated environments.

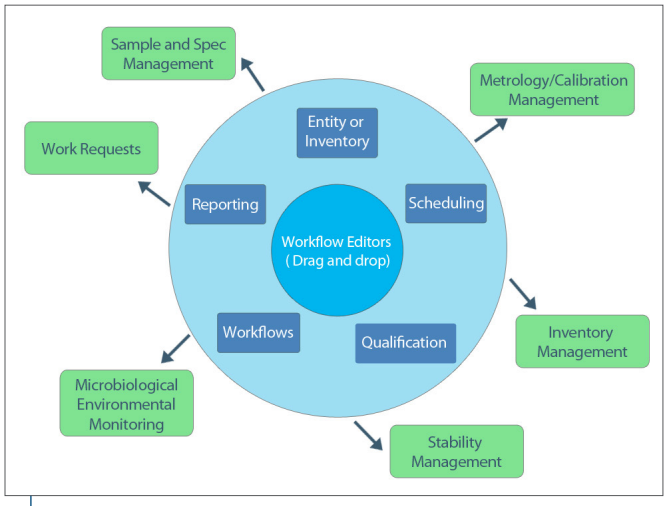

Figure1: At the heart of the BIOVIA LIMS are unique workflow editors that allow internal IT/IS groups to create precise business workflows through a simple drag-and-drop process and dialog interface. As a workflow is created, the system automatically creates the validation/qualification document for fast and easy implementation even in regulated environments.

FLEXIBLE, FAST DEPLOYMENT

The key capabilities of BIOVIA LIMS provide one of the fastest "go-live" times in the informatics industry. With only a few IT resources, plus a BIOVIA implementation team, BIOVIA LIMS solutions can be running and validated in only a few weeks or months. The system's purpose-built workflow and compliance technologies, enabled by BIOVIA's deep history in R&D, Quality, and Manufacturing operations, reduce or eliminate LIMS customization and configuration issues, making the applications truly easy to install and validate without external consultants or programmers.

COMMERCIAL, OFF-THE-SHELF APPLICATIONS

The BIOVIA LIMS applications described below can be used as standalone applications, or they can be integrated with existing BIOVIA ELNs or BIOVIA LES to improve documentation efficiency, ensure compliant procedure documentation and reduce manual transcription errors.

The applications provide an out-of-the-box environment that can be readily configured to meet specific needs without the extensive and expensive modifications seen with traditional LIMS. These applications can also be easily integrated with existing commercial LIMS installations.

BIOVIA Environmental Monitoring

BIOVIA EM (environmental monitoring) automates workflows and paperless record keeping in microbiological environmental monitoring tasks including materials qualification, inventory management, sampling plans, scheduling and reporting. The application increases productivity, minimizes errors and reduces regulatory compliance risks that arise with traditional manual documentation.

Developed in collaboration with some of the largest pharmaceutical companies in the world who were seeking a comprehensive solution to the paperwork-intensive processes traditionally used in their aseptic environments, BIOVIA EM manages all aspects of a paperless microbiological environmental monitoring program including:

- Sampling plan creation
- Sampling plan scheduling and execution
- Materials and device qualification
- Sample collection
- Sample processing and tracking
- Reporting and trending

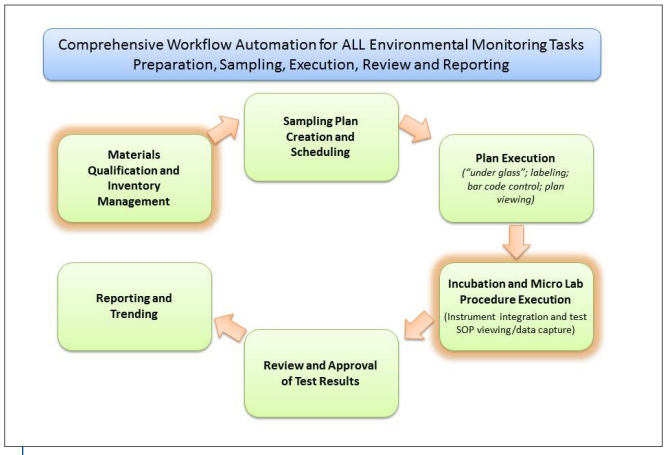

Figure 2: Environmental Monitoring—Comprehensive workflow automation for all environmental monitoring tasks including preparation, sampling, execution, review and reporting.

BIOVIA Inventory Management

Preparation, storage and control of consumable laboratory supplies such as chemical reagents, standards and working reagents are common activities in all GLP/GMP laboratories. Maintaining proper documentation for these supplies using paper notebooks, logbooks or forms, as well as monitoring the training and adherence to SOPs for materials management is time and resource intensive.

BIOVIA CISPro is an enterprise software application for the paperless management of consumable laboratory supplies. BIOVIA CISPro workflows can capture all data and SOP execution steps during the preparation, storage and control of consumable laboratory supplies. Offering full audit trails and comprehensive, dynamic and static management reports, the application meets all technical requirements to support 21 CFR Part 11 compliance.

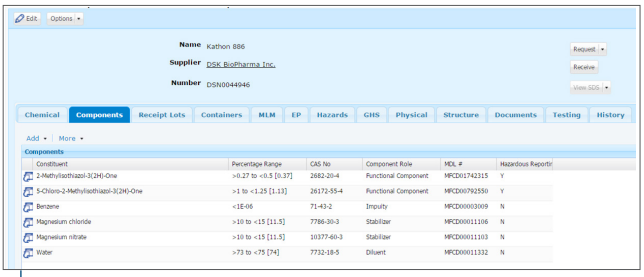

Figure 3: BIOVIA CISPro—Any chemical, reagent, working standard or device (HPLC column) can be inventoried with full BIOVIA Metrology history for efficient cGxP environments.

BIOVIA Metrology Management

BIOVIA Metrology is a web-based application for compliant performance verification and routine calibration of laboratory instruments, equipment and devices supporting inventory management, scheduling, protocol/test method execution, data capture and reporting in lab-to-commercialization operations.

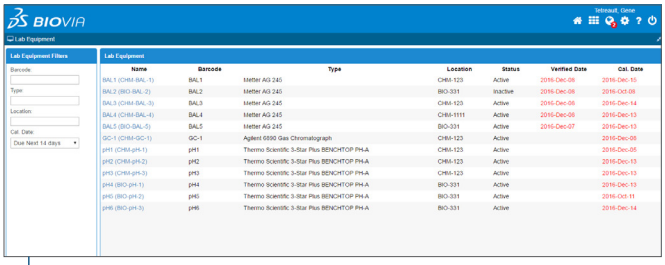

Figure 4: BIOVIA Metrology—All data is automatically captured and presented in a dashboard for review and approval.

BIOVIA Metrology automates all traditional paper, manual and semi-automated tasks associated with the performance of routine calibration and maintenance for simple and complex instruments.

Key capabilities include:

- Inventory list and management of all instruments, devices, equipment and parts
- User-defined workflows for each instrument, part or device type with full audit trail history
- Bar-code labeling for all inventory items for easy track-and-trace
- Calibration and maintenance scheduling and tracking
- Track-and-trace links to calibration weights and standard solutions
- Comprehensive track-and-trace history and reporting with dashboard reviews
- Optional integration with BIOVIA ELNs and BIOVIA LES for compliance verification prior to operator or analyst use (all in real-time)
- Automatic lookups and insertion of metrology data into BIOVIA ELNs and BIOVIA LES
- Real-time compliance alerts for analysts and operators when using BIOVIA ELNs and BIOVIA LES

BIOVIA Sample Management

The flexible BIOVIA Samples application supports a variety of ways to manage the following laboratory workflows in a secure web-based environment:

- Inspection lot management
- Specification management
- Sample chain of custody management
- Test execution and result entry
- Result review and reporting

As samples are collected and submitted, they become visible to the system. Samples are assigned testing workflows and lab location/destination parameters, and the optional BIOVIA ELN or BIOVIA LES core application features for assigning/managing analytical procedures can then become active.

Lab staff can easily define any sample type, assigning typical workflow rules and properties for consistently capturing supporting data such as customer account, lot ID, product and/or internal specifications and more. You can use the functions for scheduling or managing ad hoc or on-receipt/request samples. The same sample tracking, audit history, assignment and method execution procedures used by other BIOVIA LIMS applications are used for managing routine samples.

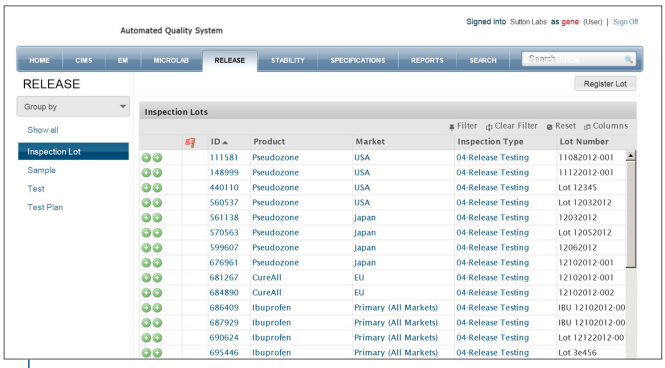

Figure 5: Sample Management—View of Inspection lots by distribution area/country

BIOVIA Stability Management

The web-based BIOVIA Stability application provides an intuitive, drag-and-drop workflow editor enabling stability study owners to add user-defined properties, schedules and process steps to stability workflows in a simple layout. These properties, shown as icons, link to lot materials, specifications, time-point definitions and the general workflow of the study.

Permissions and workflow actions can be set up to match the business rules of the organization, e.g., who may activate a study (such as study owner, lab manager or lab staff member), whether unscheduled pulls are allowed, how and if a study may be extended and if tests can be added or removed. All changes and edits are fully audited from the initial definition and saved through the approval, activation, use and final closure/archiving of the study.

Key functional capabilities include:

- Stability sample management
- Stability specifications and business rules
- Stability chambers and inventory management
- Stability study and protocol execution (schedules, workflows)
- Stability testing/result entry (manual to direct from ELN/LES)
- Data review and reporting (internal or using commercial statistical packages)

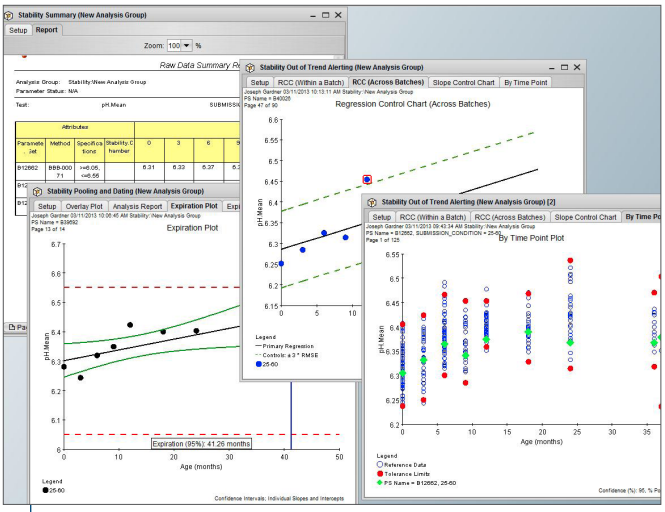

Figure 6: Reduce errors from manual data management tasks, and improve process performance predictability with an intuitive and flexible solution for product Stability and Expiration Dating Studies. BIOVIA LIMS provides a validated environment to calculate statistically accurate expiration dates, receive automated alerts of deviations from historical batch performance and get easy access to all stability and upstream process data from multiple sources for analysis and reports.

BIOVIA Work Request Management

The web-based BIOVIA Request application is a project management and communication/reporting tool. The application streamlines laboratory processes, eliminates workflow bottlenecks, reduces cycle times and improves project communication by routing tasks, samples and results to colleagues directly in an electronic lab environment.

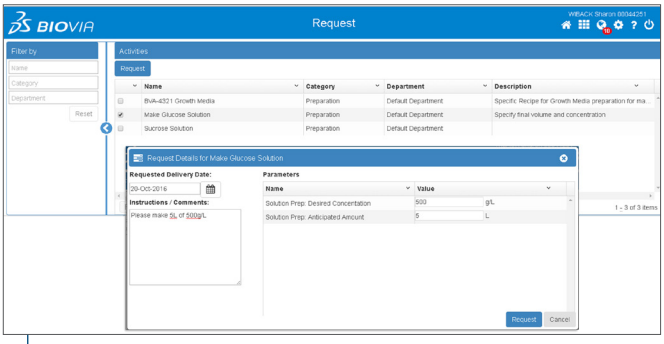

Figure 7: Request Management—Analysts can easily review, sort, group, filter and view task details. Managers can monitor, re-prioritize and re-assign tasks as needed.

With BIOVIA Request, scientists and collaborators can electronically manage the submission, routing, receiving, tracking and reporting of results originating from lab work requests and test orders. Flexible activity templates enable organizations to configure and manage activities that map to critical lab workflows including analytical tests, mechanical tests, chemical synthesis processes, biological testing and processes, formulations and more. Business rules such as approvals, email notifications and routing can all be defined in accordance with organizational needs.

Key organizational benefits include:

- Formally agreed-upon definition of work
- Direct collaboration between requestor and executor of the work
- Support for tracking, generating and labeling samples
- Ability to manage projects across the organization or with CRO/CMO partners
- Direct links to the results recorded in the BIOVIA ELN or BIOVIA LES
- Inbox notifications that link directly to activity requests
- Visibility into laboratory resource utilization and bottlenecks

To learn more about BIOVIA LIMS,
go to 3dsbiovia.com/lims

Our **3D**EXPERIENCE Platform powers our brand applications, serving 12 industries, and provides a rich portfolio of industry solution experiences.

Dassault Systèmes, the **3D**EXPERIENCE Company, provides business and people with virtual universes to imagine sustainable innovations. Its world-leading solutions transform the way products are designed, produced, and supported. Dassault Systèmes' collaborative solutions foster social innovation, expanding possibilities for the virtual world to improve the real world. The group brings value to over 170,000 customers of all sizes in all industries in more than 140 countries. For more information, visit **www.3ds.com**.

3DEXPERIENCE®

DASSAULT SYSTEMES | The **3D**EXPERIENCE® Company

Dassault Systèmes Corporate
Dassault Systèmes
175 Wyman Street
Waltham, Massachusetts
02451-1223
USA

BIOVIA Corporate Americas
BIOVIA
5005 Wateridge Vista Drive,
San Diego, CA
92121
USA

BIOVIA Corporate Europe
BIOVIA
334 Cambridge Science Park,
Cambridge CB4 0WN
England