DASSAULT SYSTEMES

BIOVIA

BIOVIA ONE QUALITY LAB INDUSTRY PROCESS EXPERIENCE

BUILDING COMPLIANCE AND OPERATIONAL EXCELLENCE INTO YOUR QUALITY LAB OPERATIONS

Solution Brief

The BIOVIA ONE Quality Lab is a field-proven, fully validated approach to:

- Data acquisition
- Method execution
- Compliance documentation
- Review and reporting
- Instrument and IT systems integration

This dedicated informatics system integrates easily and seamlessly with your current IT infrastructure, so you see tangible results quickly.

Designed for analysts, reviewers and supervisors to manage the entire development and QA/QC process in a paperless, compliant environment, the BIOVIA ONE Quality Lab automates your analyst's method execution and integrates all lab instruments within the context of each test method.

The system saves money, saves time and frees resources — it's that simple!

Save time by:

- Preventing errors and virtually eliminating rework
- Minimizing the need for reviews and investigations
- Accelerating the review and approval process
- Facilitating audits
- Eliminating the need to create, maintain and search paper records

THE SOLUTION FOR YOUR QA/QC TEAM

Every member of your Analytical Development and QA/QC team benefits from the BIOVIA ONE Quality Lab.

Lab Analysts enjoy less paper, more science

- Methods are delivered "under glass" with no need for paper.
- Instrument data is automatically captured within the context of the test method — no writing required!
- All calculations and experiment documentation are performed inside the method and are fully validated.
- Review all data on a simple dashboard with forwarding of results to BIOVIA LIMS or ERP systems — no more paperwork!

Faster reviews, easier compliance with a paperless dashboard

- No more paper data packets, forms or binders to review
- Electronic access to all lab data, instrument reports and analyst notes with the touch of a mouse
- "Compliance flags" on review dashboard enable review-by-exception for fast approvals and reduced cycle times
- Meets all technical requirements for 21 CFR Part 11

Mimics familiar paper-based processes but offers the advantages of computer-driven automation including:

- Secure access to approved methods/SOPs, files and systems on your network
- Reliable data capture from PC and RS-232 lab instruments
- Data exchange with your other IT systems, i.e., BIOVIA LIMS, ERP, EDMS, CDS
- Sensible organization and search of data in the event of an audit
- Technical controls for Part 11 compliance
- Built on industry-standard tools

QUANTIFIED BENEFITS

"Approximately 40-60% reduction in document review time."

"96% of employees prefer BIOVIA ONE Quality Lab to the old testing system."

"100% of reviewers agree that BIOVIA ONE Quality Lab saves time and increases productivity."

"Average 30 minute cycle-time reduction for method execution."

FREEDOM FROM PAPER DOCUMENTATION:

- Instrument data captured completely
- Calculations performed automatically
- No more paperwork

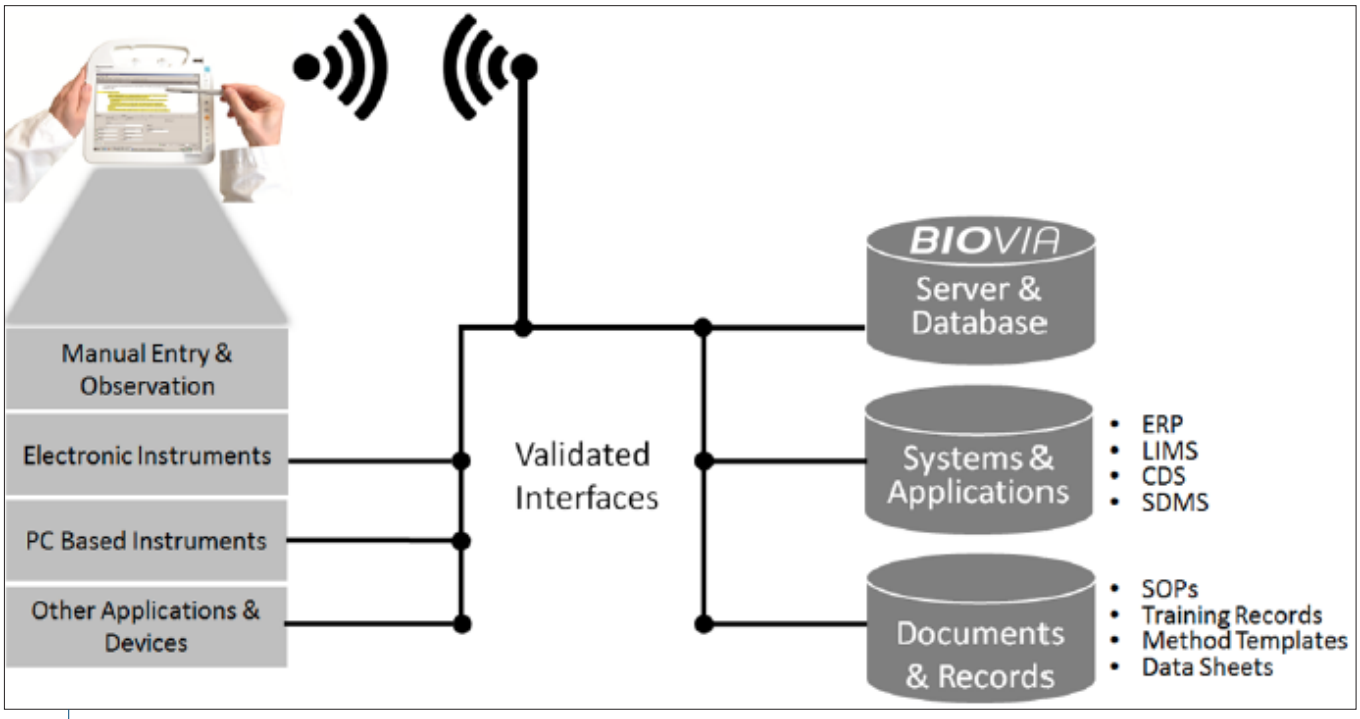

Figure 1: The BIOVIA ONE Quality Lab consolidates the wide variety and sources of data that power your organization, automating data collection and inventory management while applying current SOPs to experimental design. The result: higher quality products advancing through the pipeline faster and with minimized compliance risk.

THE BIOVIA ONE QUALITY LAB

Raw Materials

The BIOVIA ONE Quality Lab automates standard USP-based test methods for raw materials testing.

Final Product and Stability Testing

A series of final product test templates including Content Uniformity, Dissolution Testing, ID and Assay are configured with instrument integration and system validation. The method templates represent Best Practices from pharmaceutical industry leader deployments and are 95% complete — with specific product configurations finalized for your individual methods.

BIOVIA ONE Quality Lab Calibration

The system automates the routine method execution and data capture validation and calibration tasks required for instruments in cGMP operations. Chromatography Data Systems

The system automates sample data input and post-run evaluation, calculations, reporting and IT integration for commercial Chromatography Data Systems (CDS).

> “88% report that BIOVIA Quality Testing has positively impacted data recording productivity”

> “7-week time savings from method development to NDA report”

> “50% time savings in QA reviews”

SEAMLESS INTEGRATION INTO CURRENT IT ENVIRONMENTS

Fast connection to IT systems and lab instruments

- Leverage your IT investments - our Commercial off the shelf (COTS) system means fast installation, integration and validation.
- System connects with all instruments without additional computers or programming.
- Library of network connections allows integration with BIOVIA LIMS, ERP, CDS and other corporate IT systems.
- Our Installation/Operation Qualification (IOQ) documentation suite lets you “go-live” quickly.

Integrates with Your IT Environment

The BIOVIA ONE Quality Lab integrates with other IT systems and all instruments in the lab.

The System contains an XML-based data exchange module that provides an input and output structure to interoperate with other IT systems. The system is configured easily to any BIOVIA LIMS or CDS system. Some of our customers bypass the BIOVIA LIMS layer and have direct interaction with their ERP systems. In fact,

BIOVIA offers a large library if integration templates for fast deployment with most commercial BIOVIA LIMS.

- For “simple” instruments (balances, pH meters, titrators, etc.), an inexpensive protocol converter attaches to the instrument to allow for a network-compatible data stream.
- For more “complex” PC-driven instruments (HPLCs, spectrophotometers, etc.), BIOVIA ONE Quality Lab utilizes a dedicated print driver. The system captures the printout as a pdf image and parses the needed QC method data to the BIOVIA database. In addition, it saves the entire pdf for review purposes.
- For other IT systems (such as BIOVIA LIMS, ERP, metrology or document management systems), our database-to-database interface provides a seamless communication portal for quality data workflow requirements.

BUSINESS BENEFITS OF THE BIOVIA ONE QUALITY LAB

Management sees faster cycle times and reduced costs

- 80% correct first-time submissions
- 50% time savings in QA reviews
- 7-week time savings from method development to NDA report
- 50% reduction in report writing hours
- QC errors reduced or eliminated with "right first time" initiative
- Increased capacity with no increase in headcount

SEE FAST, POWERFUL RESULTS WITH THE BIOVIA ONE QUALITY LAB

Compliance-related activities don't have to be a bottleneck in the drug development and commercialization cycle

In fact, industry estimates indicate that up to 70% of laboratory resources are now devoted to compliance. This is largely because the pharmaceutical community relies on outdated, manual, paperbased systems to achieve mandated security and audit trails — the same processes that have been used for decades.

Leverage scientific resources to meet compliance regulations while:

- Increasing staff productivity
- Reducing operational costs
- Moving finished product off the shipping dock faster

The BIOVIA ONE Quality Lab eliminates tedious manual paperwork while providing a common data exchange capability. Deployed in global pharmaceutical companies, generics and contract organizations, the BIOVIA Quality Testing:

- Reduces compliance risks
- Liberates valuable resources
- Adds value to existing informatics resources by integrating with current IT infrastructures including ERP, BIOVIA LIMS, CDS and Document Management platforms

For additional information, visit the BIOVIA ONE Quality Lab product page at **www.biovia-quality.com**

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