BIOVIA

3DEXPERIENCE®

BIOVIA
BATCH RELEASE
Solution Brief

DASSAULT SYSTEMES

BIOVIA Batch Release is part of BIOVIA's Unified Lab offering and a field-proven, fully validated approach to:

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

This dedicated informatics solution 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, BIOVIA Batch Release 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 BIOVIA Batch Release.

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 Samples 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 Samples, 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

FREEDOM FROM PAPER DOCUMENTATION:

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

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

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

" 100% of reviewers agree that BIOVIA solution saves time and increases productivity."

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

THE BIOVIA PROCEDURE EXECUTION AT WORK

Raw Materials

BIOVIA Batch Release 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.

Lab Calibration

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

"88% report that BIOVIA 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 Samples, ERP, CDS and other corporate IT systems.
- Our Installation/Operation Qualification (IOQ) documentation suite lets you "go-live" quickly.

Integrates with Your IT Environment

BIOVIA Batch Release 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 Unified Lab module or CDS system.

BUSINESS BENEFITS OF BIOVIA BATCH RELEASE

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 BIOVIA BATCH RELEASE

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

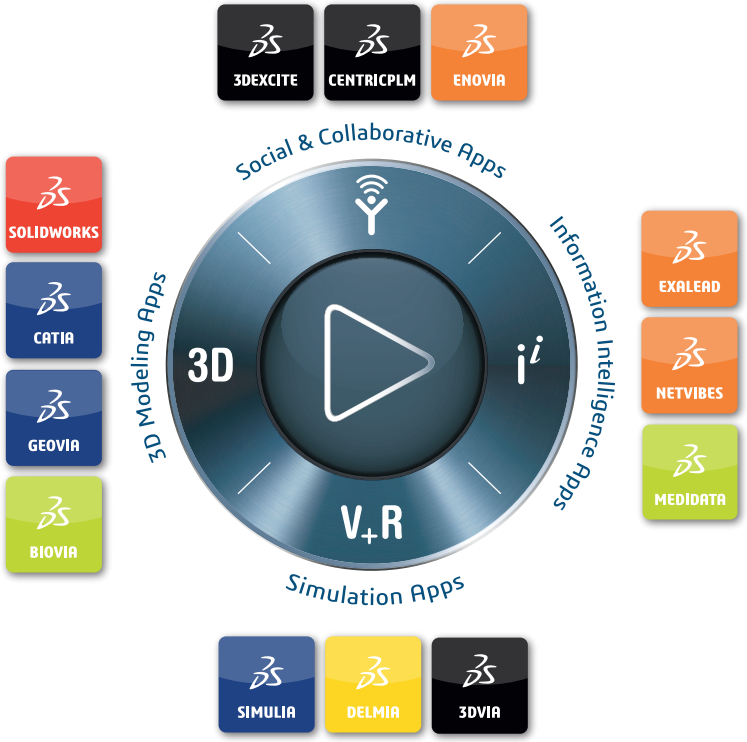
In fact, industry estimates indicate that up to 70% of laboratory resources are now devoted to compliance. This is largely because the pharmaceutical community relies on outdated, manual, paperbased systems to achieve mandated security and audit trails — the same processes that have been used for decades.

Leverage scientific resources to meet compliance regulations while:

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

BIOVIA Batch Release eliminates tedious manual paperwork while providing a common data exchange capability. Deployed in global pharmaceutical companies, generics and contract organizations, BIOVIA Batch Release:

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



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