# BIOVIA LAB EXECUTION SYSTEM

## STREAMLINE CYCLE TIMES AND REDUCE COSTS

DATASHEET

**BIOVIA Lab Execution System is a complete automated compliance system that drives continuing process efficiencies in compliant environments, ensuring 'right-first-time' execution and rapid notification of quality and production issues.**

The pharmaceutical industry is facing major challenges in satisfying compliance regulations while increasing productivity. Meeting compliance requirements is mandatory and reallocating resources from compliance activities to developing new candidates is critical to new product development. Meeting these goals is becoming increasingly difficult using paper-based compliance management systems. Moving from paper to electronic lab execution is the only way to achieve confident compliance with breakthrough productivity. Changing the paradigm will help pharma achieve the ultimate goal of electronic submissions, audits, reviews and investigations.

It is estimated that 70% of all laboratory resources are dedicated to compliance activities. Evolving from a paper-based system to an automated compliance system must initially mimic existing policies and procedures in order to minimize disruptions to current operations. Once electronic lab execution systems are implemented, organizations can optimize Standard Operating Procedures (SOPs) and test methods with key elements that improve both quality levels and productivity.

BIOVIA LES is one of the most advanced, yet easy-to-use environments for procedure execution, eliminating paper documentation, simplifying QA review/approval and enabling organizations to:

- Reduce quality operational costs by 20%
- Reduce review and reporting cycle times by 50%
- Reduce rework loops by eliminating lab errors
- Increase capacity without adding headcount

### Procedure Management

Procedures are retrieved from existing document management systems, assuring the correct procedure and version are assigned or retrieved for each task.

### Sample Management

Perform sample administration in the laboratory and easily create work orders for individual tests or test suites, assign to individual analysts and review requests.

BIOVIA Lab Execution System is included in the BIOVIA Process Management and Compliance Suite, a comprehensive informatics platform for capturing, managing, and analyzing development and process data for operational excellence in new product development and commercial quality operations.

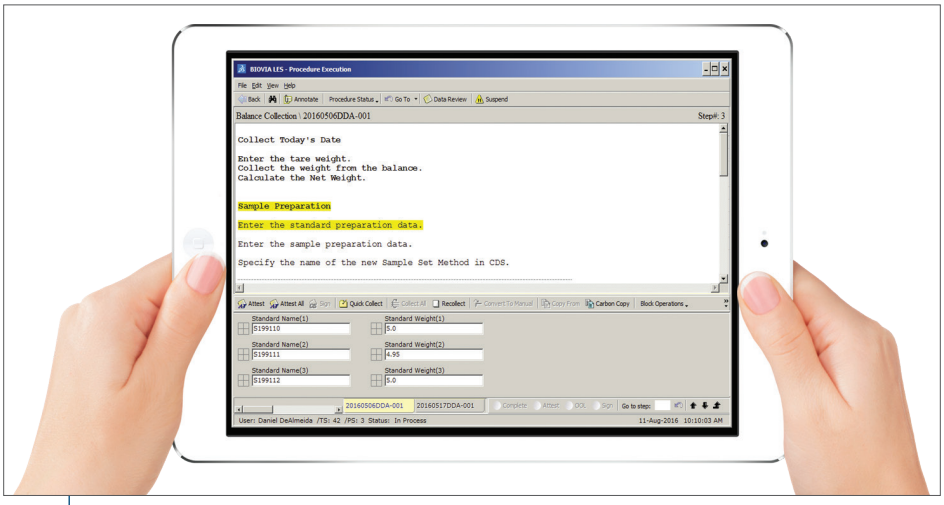


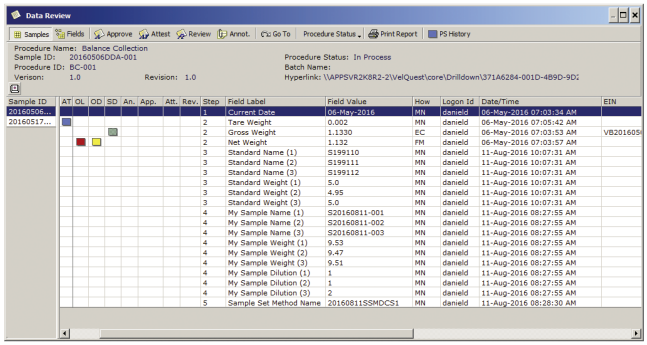

**Figure 1:** Technicians follow the procedure plans "under glass" through a handheld or cart-installed tablet.

## Instrument Management

Instrument and System Libraries are provided to facilitate installing and validating most common laboratory instruments. Central administration facilitates implementation and improves compliance.

Data is automatically transferred from validated instruments and systems to the operator's LES session, eliminating transcription errors and increasing productivity. Through direct data capture there is no need for secondary verification operators.

## Data Review




| Sample ID | AT | OL | OD | SD | An. | App. | Att. | Rev. | Step | Field Label | Field Value | How | Logon Id | Date/Time | EIN |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 20160506-... | | | | | | | | | 1 | Current Date | 06-May-2016 | MN | danield | 06-May-2016 07:03:34 AM | |
| 20160517-... | | | | | | | | | 2 | Tare Weight | 0.002 | MN | danield | 06-May-2016 07:03:42 AM | |
| | | | | | | | | | 2 | Gross Weight | 1.1330 | EC | danield | 06-May-2016 07:03:53 AM | VB201605 |
| | | | | | | | | | 2 | Net Weight | 1.132 | FM | danield | 06-May-2016 07:03:57 AM | |
| | | | | | | | | | 3 | Standard Name (1) | S199110 | MN | danield | 11-Aug-2016 10:07:31 AM | |
| | | | | | | | | | 3 | Standard Name (2) | S199111 | MN | danield | 11-Aug-2016 10:07:31 AM | |
| | | | | | | | | | 3 | Standard Name (3) | S199112 | MN | danield | 11-Aug-2016 10:07:31 AM | |
| | | | | | | | | | 3 | Standard Weight (1) | 5.0 | MN | danield | 11-Aug-2016 10:07:31 AM | |
| | | | | | | | | | 3 | Standard Weight (2) | 4.95 | MN | danield | 11-Aug-2016 10:07:31 AM | |
| | | | | | | | | | 3 | Standard Weight (3) | 5.0 | MN | danield | 11-Aug-2016 10:07:31 AM | |
| | | | | | | | | | 4 | My Sample Name (1) | S20160811-001 | MN | danield | 11-Aug-2016 08:27:55 AM | |
| | | | | | | | | | 4 | My Sample Name (2) | S20160811-002 | MN | danield | 11-Aug-2016 08:27:55 AM | |
| | | | | | | | | | 4 | My Sample Name (3) | S20160811-003 | MN | danield | 11-Aug-2016 08:27:55 AM | |
| | | | | | | | | | 4 | My Sample Weight (1) | 9.53 | MN | danield | 11-Aug-2016 08:27:55 AM | |
| | | | | | | | | | 4 | My Sample Weight (2) | 9.47 | MN | danield | 11-Aug-2016 08:27:55 AM | |
| | | | | | | | | | 4 | My Sample Weight (3) | 9.51 | MN | danield | 11-Aug-2016 08:27:55 AM | |
| | | | | | | | | | 4 | My Sample Dilution (1) | 1 | MN | danield | 11-Aug-2016 08:27:55 AM | |
| | | | | | | | | | 4 | My Sample Dilution (2) | 1 | MN | danield | 11-Aug-2016 08:27:55 AM | |
| | | | | | | | | | 4 | My Sample Dilution (3) | 2 | MN | danield | 11-Aug-2016 08:27:55 AM | |
| | | | | | | | | | 5 | Sample Set Method Name | 20160811SSMDCS1 | MN | danield | 11-Aug-2016 08:28:30 AM | |

Reduce time for data reviews by 80% with "review by exception" and a series of step-by-step compliance flags indicating and issues or notations that need review. This allows operators to focus on exceptions quickly to create a more effective quality review.

## Data Reporting

BIOVIA LES allows use of standard report writers to create configurable reports with trending information including number and types of samples each analyst has completed, environmental monitoring results, people and instrument performance, vendor and materials tracking metrics as well as compliance procedures by monitoring and displaying the number of unplanned deviations.

- Standard Reports for instruments allow key elements of instrument management to be tracked and trended. Every instrument sample run is easily identified and linked to the system, enabling on-demand availability of meta data.
- Instrument Trending Reports review performance of an individual system against validation and calibration criteria. Easily evaluate and apply corrective action for performance of a single system in relation to all other identical systems.
- People Trending Reports review performance of an individual analyst against expected procedure performance metrics. Deviations, whether pre-planned or unplanned, can be used as indicators of required procedure changes or additional training.

## Data Security & Access Control

All data is maintained on a secure, Part 11 compliant server. Access controls allow rights and permissions to be set for performing laboratory tasks and accessing existing data.

## Data Exchange

A Unified Data Exchange Manager using industry-standard XML language allows seamless transfer of data into existing networks, data archives, BIOVIA LIMS and knowledge management systems

## Archiving

BIOVIA LES provides capabilities for Data Archiving and Restore. Data previously captured in LES can be moved into the archive for secure, long-term storage and improved system performance. The archived data can be restored for review, reuse and viewing.

## Pipeline Pilot Integration

BIOVIA LES permits lab analysts to extract data using BIOVIA Pipeline Pilot protocols, creating a real-time data exchange with web services, databases or file-based systems. While running an LES method, an analyst can launch a Pipeline Pilot protocol to send and retrieve data from external systems, collect information from files or perform complex calculations. This powerful combination facilitates and expedites common QA/QC workflows such as material testing for recipes, stability testing, product release testing and post-release quality testing in GxP operations.

Pipeline Pilot can also be used individually to run reports based on LES data.

To learn more about BIOVIA LES, go to
**accelrys.com/lab-execution-system**

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