BIOVIA EM (Environmental Monitoring) automates workflows in environmental monitoring including materials qualification, inventory management, sampling plans, scheduling and reporting to enhance productivity, minimize errors and reduce FDA compliance risks arising from traditional manual documentation.

Monitoring the state of environmental control in aseptic processing operations is critical, not only for release of high-quality products that are safe for the public, but also for compliance reasons. In accordance with 21 CFR Part 211.188, all in-process steps and laboratory control results for aseptic product manufacture must be included in batch record documentation. Environmental monitoring program documentation should define, execute and report all parameters that allow for reproducible detection of microorganisms, such as sampling location, frequency, timing, duration, size, equipment, techniques and alert/action levels.

BIOVIA EM is an enterprise software application for the paperless management of sampling plans for microbiological environmental monitoring. The application was developed in collaboration with some of the largest pharmaceutical companies in the world that were seeking a 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
- Sample Collection
- Sample Processing
- Reporting and Trending

**SCHEDULE, CONTROL AND EXECUTE ENVIRONMENTAL MONITORING PROGRAMS**

**Materials Qualification and Inventory Management**

With BIOVIA EM providing track-and-trace inventory management of all environmental monitoring materials, consumables, instruments and devices, environmental monitoring groups can be assured that needed supplies are available and any environmental monitoring device can be inventoried and verified for compliance status.

**Plan Design and Scheduling**

Sampling plans can be configured for specific frequencies depending upon your Standard Operating Procedure (SOP) and presented to technicians for execution. Plans can be easily updated with drag-and-drop functionality. BIOVIA EM provides an easy overview of sample plans per day and month being able to filter by location, date, and status. It provides quick access to information and menu items and allows for in-line editing and updating.

**Plan Execution**

Technicians follow each step in the SOP “under glass” and all materials, equipment, locations and rooms are bar-coded and scanned for tracking and tracing in real-time, allowing easy monitoring for management and resource planning.

**Incubation & Lab Procedure Execution**

All post-sampling activities are timed and monitored by BIOVIA EM, allowing quick identification of any negative findings and flagging for identification testing methods. BIOVIA EM is designed to be used on devices like tablets and small laptops to enable mobility.
Lab & Device Integration
Integration of any PC-based or RS-232-based instruments into BIOVIA EM facilitates a truly paperless system with direct-to-database capture of environmental monitoring test results.

Review & Approval of Test Results
The onboard Procedure Execution System shortens the data approval process by over 50% compared with manual systems, presenting all result data and metadata in an easy-to-read dashboard for supervisory review and approval.

Reporting & Trending
All BIOVIA EM plan data and metadata reside in an Oracle database, which can be presented and displayed with onboard widget reports for quick visual reference. Typical reports include:

- Sample size and location
- Sampling frequency
- Timing/duration of sample collection
- Sampling equipment and techniques
- Limits
- Contaminate ID
- Trending
- Procedures to address out-of-limit results or trends

BIOVIA EM provides a seamless integration with the industry leading BIOVIA Pipeline Pilot Reporting Collection.

BIOVIA UNIFIED LAB MANAGEMENT
BIOVIA EM is a component of the BIOVIA Unified Lab Management suite, a comprehensive software offering that optimizes operations, maximizes quality and drives innovation. As a collection of standardized solutions built on a single, unifying technology foundation, the BIOVIA Unified Lab Management suite provides unique, role-based user experiences for the lab.

To learn more about BIOVIA EM, go to accelys.com/products/unified-lab-management/biovia-lims/biovia-environmental-monitoring.html

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