

BIOVIA MANAGEMENT CONSULTING

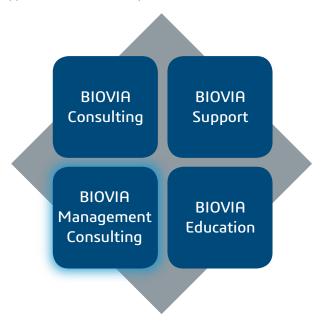
HOLISTIC, PROCESS-ORIENTED CONSULTING ACROSS THE LAB-TO-PLANT VALUE CHAIN

DATASHEET

Today pharma and specialty chemicals are focused primarily on innovation, while generics, consumer goods and bulk manufacturers look to reduce costs with predictable quality. BIOVIA Management Consulting addresses both of these industry priorities by providing a single consulting service extending from R&D through late-stage quality control and GxP manufacturing.

Along with solution-based Consulting, Technical Support and Education, BIOVIA Management Consulting is a key component of the extensive services offerings that enable BIOVIA customers to optimize their processes and achieve their goals by maximizing their investment in BIOVIA software solutions.

BIOVIA Management Consulting brings together professional consulting services in business analysis, laboratory process excellence, multimoment analysis, business case justification, vendor solution selection, integration consulting and solution support. This breadth of expertise enables customers to:



- Increase lab productivity and efficiency by up to 30%
- Minimize risk while improving quality, compliance and data consistency
- Optimize laboratory data management and boost profitability on a sustainable basis
- Shorten development time and improve collaboration
- Implement consistent processes throughout the organization
- Reduce existing IT complexity

The BIOVIA Management Consulting Group combines unparalleled lab-to-plant business consulting services with unique, multidisciplinary domain expertise enabling on-time/on-budget delivery of consistent processes throughout your organization.

OPTIMIZING PROCESSES ACROSS THE VALUE CHAIN

Companies in the life sciences, food & beverage and chemical materials areas need to optimize their business processes in order to become or stay competitive. To do this, they are looking into optimizing their processes across the value creation chain. For laboratory-dependent organizations, this also includes the laboratory space. But laboratory processes are complex, highly variable and interdependent. Additionally, laboratories in the Development, QA/QC and Manufacturing spaces must adhere to regulatory regulations. Therefore, they are difficult to optimize and standardize, and workflow redesign is challenging. Investment decisions also require hard facts and numbers. A clear view of the status quo and a realistic definition of the potential for process improvement are both required to project a credible return on investment.

BIOVIA Management Consulting supports the entire business process optimization project for laboratories including:

- Evaluation of the current process with metrics
- Definition of the desired future state of an optimized, harmonized and integrated lab process
- Evaluation of the IT landscape
- Calculation of the financial benefit
- Validation and regulatory advice

Typical Laboratory Tasks	Disrupted Manual Process	Possible Applications for Paperless Lab
Test Request	Excel	ERP
Sample Reception	Manual	LIMS
Test Preparation	Manual	ELN/LES
Test Execution	Paper	LES
Data Processing	Instrument Software	Instrument Software
Result Transfer	Manual	SDMS
Approval	Manual	LIMS/LES
CoA & Reporting	Excel, Word	LIMS
Data Management	Manual	SDMS

PSM Analysis PSM (Process System Metrics) Analytics: Includes analysis of the process and the systems and workshops with system experts; process and system descriptions are developed.

MMA

MMA (Multi Moment Analysis): Results of time and resource measurements are used for statistical calculations to calculate efforts for every step; effects of various new scenarios are forecasted.



Concept: A new optimized concept is developed based on identified gaps, required functionalities and a SWOT analysis; business, user and technical perspectives are considered.



Business Case: Calculation of the business benefits, Return-on-Investment (ROI) and payback timebased on current costs and future target value.



Paperless Lab: To-be ("future") process definition, creation of User Requirements Specification (URS), independent vendor selection support and pilot, interfacing and validation services, on-going support.

MOVING TOWARDS THE PAPERLESS LAB

Usually the outcome of such an analysis is the recommendation to reduce time-consuming and error- prone manual steps (mostly paper-based) by integrating devices and systems and automating processes, essentially moving towards a Paperless Lab. The key principle of the Paperless Lab is the "self-documenting process" that eliminates unnecessary tasks from the workflow and automatically produces GxP-compliant documentation. Automated data collection and transfer eliminates redundant or fragmented data, while implementing a "single-source of-truth" principle makes data available to every authorized user in realtime. This leads to improved processes, increased efficiency, faster decision-making and better teamwork.

Applications used to achieve a Paperless Lab are BIOVIA LIMS (Laboratory Information Management System), BIOVIA Electronic Laboratory Notebook (ELN), Laboratory Execution Systems (LES); Electronic Batch Record (EBR) Systems; Scientific Data Management Systems (SDMS); and specialized applications for instrument, device and system integration. Increasingly, software that was not originally laboratory-specific such as Product Lifecycle-Management (PLM) systems or Enterprise Resource Planning systems (ERP) are also used in the Paperless Lab environment.

BIOVIA MANAGEMENT CONSULTING PROCESS

BIOVIA Management Consulting is performed by a team of experienced industry and process experts with extensive system know-how and up-to-date and in-depth knowledge of the laboratory data management industry and market.

As shown above, the BIOVIA Management Consulting team typically follows a 5-step Management Consulting process with the fifth and last step culminating in the final selection and implementation of the optimum Paperless Lab solution for the customer.

BENEFITS OF BIOVIA MANAGEMENT CONSULTING

- Successful project with requirements and goals met, on budget, on time
- Quantitative process assessment compared to industry benchmarks
- Customer-centric holistic solution proposals
- Optimized laboratory management
- Implementation of consistent processes throughout the organization
- IT landscape aligned with business objectives
- Increased overall business efficiency providing a firm platform for long-term success

BENEFITS OF PAPERLESS LAB

- Up to 30% increased lab productivity and efficiency
- Improved collaboration and teamwork
- Shortened development/lead time
- Faster decision-making
- Improved knowledge management and retention
- Minimized risk while improving quality, compliance anddata consistency

BIOVIA provides a wide range of dedicated services performed by trained engineers who have a deep understanding of the solutions and applications as well as of the information management industry to support customers in the best way possible. The service offerings include solution-based Consulting, Education and Support as well as the processrelated Management Consulting described in this document. An extensive partner program completes the cooperation ecosystem for and with our customers.

For more information on BIOVIA Management Consulting, go to accelrys.com/amc.

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