BIOVIA ONE QUALITY

Datasheet

The overall challenge for Quality is to ensure both Regulatory Compliance and Operational Excellence through high quality processes, documents, materials and products underpinned by meaningful metrics. At the same time processes need to be streamlined and cost efficient to reduce compliance costs and cost of poor quality. BIOVIA One Quality will help customers increase productivity and enhance Quality while ensuring compliance.

Today's science-based organizations are very aware of the relevance of Quality in conducting a successful business and sustaining competitive advantage. Therefore, many enterprises do have a Total Quality Strategy in place that includes all areas of the organization but there are some challenges that make the implementation difficult.

Those can include:

- Quality procedures and processes must be developed and followed consistently.
- Enforcing the execution of procedures can be very demanding, especially as it can lead to time-consuming, non-value-add check box activities.
- The Quality process needs to ensure that the right input materials of the right quality are used for the right purpose; different purposes may require different specifications of the material used.
- All documents need to be managed and maintained throughout their lifecycle in accordance with regulations mandating version control, review, approval, distribution and lifecycle management.
- The required data from the different documents and sources need to be quickly aggregated in order to measure and analyze Quality-relevant metrics.

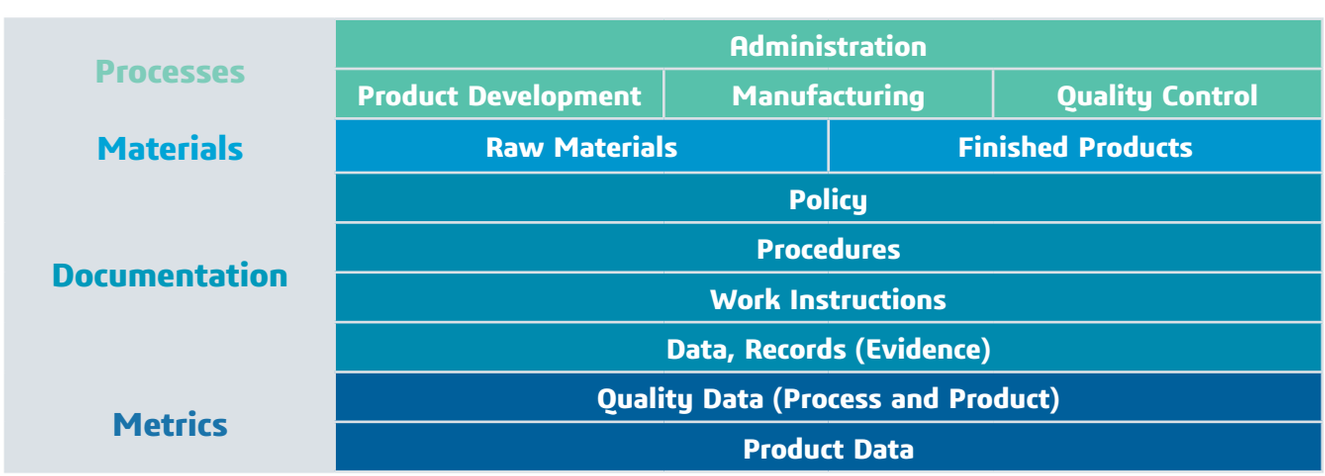
SUPPORTING SOLUTION FROM BIOVIA

BIOVIA One Quality solution includes capabilities for Quality Process Management, Quality Control and Testing, Materials Quality Management, Quality Document Management and Quality and Process Data Analytics.

Quality Process Management helps organizations to standardize and automate business processes that manage the collection, tracking and analysis of information and the resolution of related issues. Capabilities include SOP and content management with all quality management processes for CAPAs, deviations, audits, validation, customer complaints and other events management processes and multi-site change control. Core components are a rules-based workflow engine, data dictionary, business rules engine, audit trail, forms manager and advanced reporting.

Product Lifecycle Specific Processes are supported by dedicated solutions for Method and Procedure Development, for Batch Execution/Electronic Batch Record (EBR) for Manufacturing and Lab Management/Lab Execution for Quality Testing. Each of the three areas is supported by the specific workflows and helps manage the plethora of different Quality-relevant data that are generated.

Method and Procedure Development provides the flexibility as well as the compliance capabilities needed for route design, method development and formulation design. It accelerates the design, documentation, storage and secure sharing of formulations with templates for standardized protocols, powerful searching and experiment cloning capabilities. The solution supports IP, 21 CFR Part 11, GLP and GMP with document versioning, forms-level audit trails and signatures.



Quality Testing builds compliance and Operational Excellence into quality lab operations. It includes capabilities for lab management and execution supporting the full workflow of quality testing from test requests to the creation of certificates of analysis including direct data transfer from an Enterprise Resource Planning (ERP) System and/or Laboratory Information Management System (LIMS), from a consumables and instrument inventory and the lab equipment itself up to the transmission of results for final release.

Electronic Batch Record (EBR) provides an electronic environment for procedure execution and electronic batch recording to efficiently and compliantly document the execution of any procedure or recipe. The solution provides improved batch record keeping and compliance for a low cost of ownership without the large overheads of a complex Manufacturing Execution System (MES).

Materials and Sample Management helps organizations manage their evolving materials and sample processes and workflows. Capabilities include the accurate managing, tracking and reporting of materials and sample quantity, location and safety data while meeting safety and regulatory requirements, including barcode labelling, remote inventory control and Material Safety Data Sheet (MSDS) management. The solution helps to maintain a listing of all the materials in a facility while also keeping track of where they are in real-time quantity and monitoring usage.

Sample Management supports the workflow of samples from collection and submission to disposal. Capabilities include inspection lot management, specification management, sample chain of custody management, execution of quality testing and verification of fitness for purpose as well as genealogy, result review and reporting.

Quality Document Management helps organizations to create, manage and securely store documents, using built-in password policies to protect against unauthorized access and support Electronic Signatures per FDA 21 CFR Part 11 requirements. It ensures that the correct content is created, reviewed, approved, consumed, distributed and retired.

The solution includes Content Management and advanced search and retrieval, flexible process control and configurable reports, built-in system administration, secure audit trail, automated version control, and automated PDF rendering. Supported documents are policies, procedures, Standard Operating Procedures (SOPs), work instructions, R&D documentation (clinical, regulatory and manufacturing), legal documentation, sales and marketing collateral, HR policies and reports including Corporate Integrity Agreements (CIAs).

Data Monitoring, Analysis and Reporting helps organizations to utilize the abundance of process and quality data in a more user-friendly, organized (contextualized) form for improved process knowledge supporting initiatives like QbD (Quality by Design), PAT (Process Analytical Technology), PR (Process Robustness) and CPV (Continued Process Verification). It provides process development, quality and manufacturing users with a validated environment for self-service, on-demand access to process and quality data from disparate databases and paper records. It automatically aggregates and contextualizes the data and enables ad hoc statistical investigations and analysis with automated validation-ready workflows.

BENEFITS OF THE BIOVIA ONE QUALITY SOLUTION

The BIOVIA One Quality solution allows customers to:

- Have a comprehensive approach for Total Quality that ensures Compliance and Quality Excellence in all Quality relevant areas throughout the entire product lifecycle
- Reduce compliance costs and costs of poor quality with a solution that allows for pre-emptive action
- Standardize and automate quality processes, increase efficiency and accuracy of business processes and activities and proactively improve business performance
- Remove bottlenecks and compliance risks from laboratory-related processes in Development, Manufacturing and Quality through integration, automation and harmonization
- Accurately manage materials and samples from receipt to disposal, address EH&S lab safety requirements and reduce regulatory and quality risks, hazards and costs
- Ensure enterprise-wide consistency of all quality documentation as well as compliant lifecycle management
- Reduce errors, minimize non-value-add manual tasks and improve efficiency by replacing disconnected and/or paper- and spreadsheet-based systems with a solution that integrates key components of the corporate Quality strategy
- Improve product and process quality throughout the entire product lifecycle with improved consistency and reliability through enhanced process understanding and knowledge sharing

BIOVIA One Quality increases efficiency, reduces costs and improves quality and compliance by addressing all relevant aspects of an organization's corporate Quality strategy. When properly implemented, the solution can reduce time-to-market, increase sustainability, protect brand reputation, and enhance competitive advantage.

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