QUMAS Cloud
Datasheet

A Quality Management System is the core of any quality strategy of organizations. It helps organizing and documenting any quality efforts to ensure quality processes, operations and products as well as regulatory compliance, which is relevant for any regulated industry. While quality is often perceived as a costly burden, an integrated cloud-based Quality System is easy to deploy, contains costs and efforts, and contributes to better and more efficient processes.

Built on QUMAS' 25 years of expertise in Quality and Document Management, customers can now leverage the benefits of QUMAS' deep functionality combined with a modern cloud deployment and a data-centric approach. The application is easily implemented and updated and accessed from any device and its scalability makes it possible to adapt the solution from small to large enterprise deployments.

With QUMAS Cloud, customers can focus on the usage of the application rather than on its Management. With an infrastructure managed by BIOVIA and built on Amazon Web Services (AWS) the responsibility for security, application access, operations, and maintenance will be removed from your IT organization freeing up valuable time, resources, and budget.

> QUMAS Cloud delivers comprehensive regulatory, quality and compliance management capabilities on a single integrated platform.

COSTS

QUMAS Cloud also provides easy control of costs and low Total Cost of Ownership (TCO). The cloud solution is easy to configure, to deploy and to integrate without a heavy IT footprint. The subscription on a yearly basis includes the costs of upgrades, support, enhancements, scalability, performance improvements and testing providing full control of costs. QUMAS Cloud can scale from a 25 users to over 100,000 with the ability to rapidly deploy additional infrastructure as need arises.

> QUMAS Cloud allows organizations to standardize and automate business processes managing the collection, tracking and analysis of information and helping the resolution of Quality related issues.

RISK

BIOVIA takes care of delivering application and security updates and ensuring performance. You will realize reduced risk, reduced IT burden, and increased flexibility while retaining full control over frequency and timing of updates and upgrades for alignment of your own Computer System Validation (CSV) strategy. For complete privacy, your data remains completely separate from other customers. There is no risk of data being comingled with other customers' data.

> QUMAS Cloud ensures that regulatory content is managed in a consistent and compliant manner throughout the organization.

COMPLIANCE

All of the components provide built-in compliance management and support the most stringent requirements such as: 21 CFR Part 11; 210; 820; 600, ISO standards (9000; 1400), Annex 11 and GxP practices. The solution also provides immutable audit trails and full support for Electronic Signatures as per the US Food & Drug Administration (FDA) 21 CFR Part 11 requirements.

SECURITY

BIOVIA has heavily invested in cloud security as Pharmaceutical companies of all sizes require complete assurance that confidential and proprietary information remains that way-and the systems in place to safeguard data are certified to an accepted industry standard. QUMAS Cloud has undergone a certification process with Securastar, an information security consulting firm specializing in ISO 27001 (one of the most widely recognized and internationally accepted best practice standards for information security management), and Bureau Veritas that verified that a detailed framework for security design, implementation and management are in place, continuously monitored and improved. The certification process also verifies that a robust framework exists for information security risk assessment, threat identification, and rapid response. This comprehensive standard, which includes regular follow up surveillance audits, assures BIOVIA clients and partners around the world that rigorous security controls are in place to protect the confidentiality, integrity, and availability of their information.

CAPABILITIES

Based on decades of expertise and best practices QUMAS Cloud is an integrated cloud-based solution for quality management and document control providing a single source of truth. The data-centric approach allows for easy data access, re-use and insight for knowledge-based decision making.

QUMAS Cloud is a complete, closed-loop Enterprise Quality Management solution. Through its intuitive end-to-end work- flow engine QUMAS enables organizations to create, manage, and securely store documents, using built in password policies to protect against unauthorized access. Best practice document management workflows ensure that the correct content is created, reviewed, approved, consumed, distributed, and retired. Drag and drop of content like Word documents onto the user interface simplifies document creation and check-in.

QUMAS Cloud provides process management for all quality activities including: Corrective Action Preventive Action (CAPA), Deviations, Change Controls, Customer Complaints, and Audit Management. Workflows for each of these and additional processes can be created, reviewed, processed, and approved through this interface. It provides a configurable, rules-based workflow engine, including automated triggers and escalations. Advanced search and retrieval capabilities allow you to generate searches on SOPs and quality events.

QUMAS is tightly integrated with a Learning Management System. This enables customers to leverage GxP training related compliance content and documents to launch, track, and manage their corporate as well as GxP compliance training. QUMAS provides integrated Search and Analytics for your Quality data delivering Quality intelligence for easier and better decision making.

QUMAS Cloud is a modern data-centric solution in line with current digitalization strategies.

VALUE

Costs – minimized IT costs with full cost control

Flexibility – adaptability to changing business requirements

Efficiency – streamlining and automation of workflows and documentation

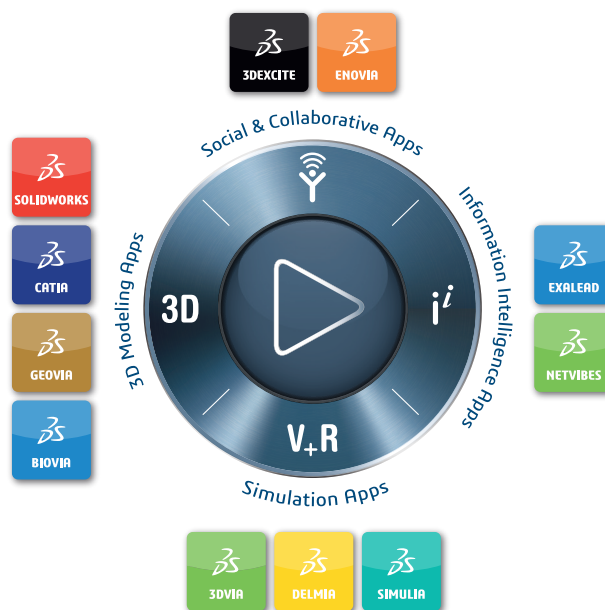**Oversight** – easy data access, control, re-use and insight

Risk - Single-source-of-Truth with immediate availability of remediation-relevant information

Compliance – validation-readiness, data integrity, electronic signatures, audit trails

Culture of Quality - comprehensive, data-centric approach with reporting and analytics

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