

QUMAS Cloud

Regulatory, Quality & Compliance Management in the Cloud, From a Trusted, Proven Leader in EDMS and EQMS for Life Sciences

The QUMAS Cloud delivers a **qualified** environment for regulatory, quality and compliance management across life sciences.

QUMAS is the only Cloud provider offering full EQMS capabilities, not just EDMS for regulated content, but also for critical processes such as Deviations, CAPAs, Change Control, Customer Complaints & Audits.

The QUMAS Cloud leverages the trusted QUMAS EDMS and EQMS solutions, in the cloud, to meet all of the global regulatory requirements mandated for the life sciences industry. Delivered in a SaaS model, the QUMAS Cloud enables you to migrate from legacy systems to a trusted, qualified environment, built on 20 plus years' experience of regulated environments.

Enterprise Document Management Solution (EDMS)

- Regulated Content
- Submission Documents (eCTD)
- QA Documents & Content
- Learning Management (LMS)
- External Collaboration

Enterprise Quality Management Solution (EQMS)

- Deviation Management
- CAPA Management
- Customer Complaints
- Audit Management
- Change Control



QUMAS Cloud Benefits

- Access your controlled, regulated content and processes, anywhere/anytime via a web browser
- Instant, elastic scalability, with the ability to spike for periods of high utilization
- Optimize the utilization of your Regulatory, Quality and Compliance Solutions, with 'Always On' access
- Outsource the burden of maintenance/operation of infrastructure/applications to QUMAS compliance experts and our SSAE 16 SOC 1 Type II Certified Sungard Data Center
- Leverage efficient management of service portfolio, options for additional Professional Services support
- Avoid costly interruption of business with a system availability of 99.999, as well as multi-layered redundancy and fault tolerance
- Ensure the availability and integrity of your data through multi-level backups, with sophisticated Disaster Recovery (replicating between Sungard Data Centers)
- Control the system configuration and upgrade cycle – you dictate which upgrades are applied and when
- Leverage regulatory compliance expertise and technology of market leader QUMAS, inside your own organization; Improve quality and compliance by leveraging industry standard configurations

QUMAS Cloud

Retain and prove control over your critical content and processes in a cGxP environment, while leveraging the latest in Cloud technologies.

The QUMAS Cloud delivers all essential Regulatory, Quality and Compliance capabilities, and uniquely offers a range of options so that you can tailor our Cloud to suit your business perfectly:

Capabilities

Options

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| Tenant | Single tenant application servers (dedicated client application servers). Users connect to server farms; security is maintained through individual, independent data repositories and through a strict permission set. Option to share certain services. |
| Redundancy | State of the art hosting facility with redundant fault tolerant networks and server farms Option Redundant Fault Tolerant Server Farms, with active offsite DR environment for full business resiliency. |
| Licensing | Volume licensing models available based on client requirements (250-499, 500-1000 users etc.) currently scaling from 50 to 120,000+ users. Option to purchase user licenses on a perpetual, subscription or SaaS model, and to add users instantly as the business requirements grow. |
| Upgrade | Upgrades are included in the licensing models, and you choose the timing of upgrades, retaining control over which upgrades, at what time. Option to sign up for one standard upgrade per year (additional upgrades available on request), with related costs included in the model. |
| Qualification | QUMAS can perform IQ, you can perform OQ/PQ as required, with templates from QUMAS. Option If you select a QUMAS Packaged Solution (meeting GAMP 5 Category 3 definitions), you can leverage the OQ that has already been completed by QUMAS and you only need to execute the PQ. Alternatively, QUMAS can provide validation as a service. |
| Environments | Two environments are provided as standard, one for 'test' and one for 'production'. Option Additional DR environments can be provided as standard – other additional environments available on client request, for example for training. |
| Support | 24/7/365 support is available from QUMAS, additional support services available from Professional Services as required. |

Contact Us for More Information

www.qumas.com or info@qumas.com

Freephone US 800-577-1545, NJ Phone: 973-805-8600, Europe Phone: +353-21-491-5100

QUMAS is the leader in Enterprise Compliance Solutions with more than 270 global customer deployments and 20 years of experience helping companies in highly regulated industries.

For more information visit www.qumas.com.

