



QUMAS SOP Solution™

SOP Management: The Cornerstone of an Effective Compliance Program



Powerful SOP Management Addresses All Lifecycle Phases

Standard Operating Procedures (SOPs) are the cornerstone of an effective compliance program. In R&D and manufacturing, SOPs define the business processes and procedures for everything from pre-clinical research, clinical development and equipment operation to the release of new products. As with any other business-critical information, SOPs must be managed effectively. Poor capture, review, and distribution of these assets routinely cause expensive production delays and errors.

In fact a large percentage of FDA 483 citations are related to documentation that is not current or easily accessible to employees. Moreover, paper-based methods of maintaining regulated information are costly and extremely difficult to manage with the increasing complexity of R&D and manufacturing processes. Competence is fundamental to mitigating fines and to protect brand equity and market position.

Avoiding reputation-damaging incidents can deliver financial rewards as well, including higher margins, lower perceived risk and cheaper capital. A company without compliance problems attracts customers and shareholders who prefer a more trustworthy brand. While many firms mistakenly believe their storage-based intranet site will

suffice, it typically fails when you need it most — during an inspection.

Powerful SOP Management Addresses All Lifecycle Phases

Implementing the QUMAS SOP Management Solution assures compliance with all cGMP requirements for procedure management and with 21 CFR Part 11. The SOP Solution builds on the QUMAS DocCompliance product to efficiently address all content lifecycle phases — Create, Edit, Review, Approve, Distribute, Retire — and in a manner designed specifically for compliance and quality professionals.

In fact, reliance on the QUMAS closed-loop quality management process assures employees have immediate access to the most recent SOPs while providing an audit trail that validates the SOP delivery and change process.

Critical features include:

- Advanced lifecycle management — configurable states and permissions.
- Automate and standardize the creation, review, distribution, revision and approval of SOPs across a global network -- minimize compliance exposure and the opportunity to introduce human error.

- Sophisticated role-based access control - users can access only information that is related to their role and that they have permissions to view, edit or approve.
- Automated notification & distribution — enables rapid notification of document changes and expedited approvals.
- Role-based electronic signatures — ensures the meaning of electronic signatures match user intent.
- Read & Understood — traceable accountability throughout the organization.
- Comprehensive, independent audit trail — more than 270 auditable events.

A Web-based Storage System is Not Enough

An uncontrolled system reveals vulnerabilities during audits — no audit trail of approvals, no point-in-time reporting, no attestations, no systemic analysis of the impact of any changes. Ultimately, an ad-hoc system is a waste of a smart compliance professional. The time spent shepherding documents through the review/approval lifecycle; struggling to retrieve historical information for audits, and manually attempting to



Point-in-Time Reporting

conduct impact assessments could have been better spent on proactive compliance activities.

Point-in-Time Reporting

Point-in-time reporting capabilities ensure you have a proactive and robust regulatory defense and can more easily isolate problems and identify the root cause of a customer complaint or deviation. Using the SOP Solution, you have on demand access to all of the notifications of a new SOP on any date in the past. You can run a report detailing which employees received the notification and when they received it, and when they actually marked the SOP as 'read and understood'. The QUMAS software helps you support the following common audit requests to provide secure, on-demand copies of any and all existing SOPs including:

- Documenting the effective date of all SOPs.
- Documenting the dates and times of SOP distribution.
- Documenting the individuals to whom all such SOPs were distributed.

Document Loading

The QUMAS SOP Solution includes an advanced import/export utility to move large collections of legacy documents and/or file folders from a file system

and into DocCompliance, from where they will be controlled and managed going forward.

Delivering Lower Total Cost of Ownership

The QUMAS SOP Solution is configurable and deploys without a heavy IT footprint. Implementation and training are included in the initial cost of ownership. Deployments typically take place in a two to four month time frame, depending on the size of the organization. Expert test scripts are provided, which can help to further accelerate implementations and optimize performance.

Benefits:

- Automates the creation, sharing, distribution and management of SOPs across a global network with an electronic workflow for review, and approval.
- Reduces the expense related to the creation, review, approval and distribution of business-critical content by 20 to 40 percent — expedites the review cycle by eliminating the time a typical worker spends looking for information (estimated at 20 to 30 percent of the work day by AMR Research).

- Tracks SOP lifecycles — the SOP, who needs to review and approve it at any time, when is it mandated for a periodic review.
- Versioning assures reviewers always have the "right" document - version compare facilitates the easy identification of updates between versions.
- Controlled viewing and printing including watermarks and overlays.
- Hard copy management ensures that printed copies of old versions of documents are destroyed when new versions are available.
- Delivers rapid search capability by displaying only the most current SOP, rather than multiple versions.
- Adheres to the 21 CFR Part 11 password and audit trail requirements.
- Role-based permissions ensure content and IP security.
- Reduces submission time when integrated with eCTD builders.
- Pre-defined, fixed-deliverable configurations available for biotechs and other firms with rigid requirements.
- Readily accessible information regarding the distribution and receipt of all SOPs across the organization.





Collaborative Review and Authoring

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The SOP Solution provides a secure, structured and controlled review environment — this truly collaborative review environment allows everyone to comment on the SOP in its native format (MS Word, PowerPoint, Image Collections) or in PDF. Reviewers can see each other's comments and changes and reply in real-time.

- Authors can decide which comments and changes to accept.
- Authors get a single document with consolidated comments and changes.
- Simple "point and click" browser environment.

About QUMAS

With over 15 years experience in highly regulated industries, QUMAS is recognized as a leader in Enterprise Compliance Management. QUMAS works with global leaders in Life Sciences (including five of the top ten companies) and Financial Services, and has more than 250 customer deployments, some with up to 120,000 users globally. QUMAS is unique in offering solutions that enable these organizations to achieve complete, enterprise-wide compliance with a broad range of regulations and initiatives.

QUMAS provides highly configurable solutions for document and process management, ready for validation and deployment within these regulated environments. Based on open systems platforms, QUMAS technology integrates seamlessly with existing corporate databases, third party applications, operating systems and hardware from most major vendors.

For more information visit www.qumas.com.

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