Overview

With increasing pressure on costs and margins across Life Sciences, the industry must move away from tackling regulatory compliance with legacy or point solutions that cannot efficiently address the broad range of regulations and standards. QUMAS ComplianceSP on Microsoft SharePoint 2010/2013 is a closed-loop enterprise application that combines all the elements of a comprehensive regulatory compliance program. It delivers critical capabilities around document and process management, presenting these through the familiar Microsoft SharePoint user interface.

Why QUMAS ComplianceSP?

With domain expertise gained from providing quality, regulatory and compliance management solutions to Life Sciences since 1994, QUMAS now delivers these capabilities on the SharePoint platform. With ComplianceSP, companies can draw on the QUMAS best practices for regulatory compliance management, leveraging them on the latest technologies. Collaboration is a core element of electronic document management and QUMAS extends this key SharePoint capability to ensure full compliance with 21 CFR Part 11 regulatory requirements. ComplianceSP delivers unique and verifiable solutions that provide pre-configured software for managing documents (SOPs), processes (CAPA, Deviation, Change Control, Complaints) and tasks on SharePoint. ComplianceSP is fully web-based, ensuring anytime/anywhere access to your critical compliance activities, all secured by role and permission based access. It integrates seamlessly with the wider Microsoft environment, including Word, Excel, Outlook, etc.

QUMAS ComplianceSP Value Add for Controlled Content Management

ComplianceSP utilizes the rich functionality of the SharePoint 2010/2013 platform to create the additional compliance capabilities listed in Figure 1 below. For organizations who must comply with regulatory mandates and who are considering or committed to SharePoint 2010/2013 as their platform of choice, the unique value add provided by QUMAS ComplianceSP makes it a compelling application to optimally meet business needs.

<table>
<thead>
<tr>
<th>Content Management Value Add</th>
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</thead>
<tbody>
<tr>
<td><strong>QUMAS ComplianceSP</strong></td>
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<tr>
<td><strong>SOP/QA Documents</strong></td>
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<tr>
<td><strong>CAPA</strong></td>
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<tr>
<td><strong>Deviation</strong></td>
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<td><strong>Complaint</strong></td>
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<tr>
<td><strong>Change Control</strong></td>
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<tr>
<td><strong>R&amp;D Regulatory Documents</strong></td>
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**Figure 1: ComplianceSP ‘Value Add’**
QUMAS ComplianceSP Core Capabilities

- Full Enterprise Content Management including document check-in/check-out, version control, enterprise-level security, integrated Active Directory, rich metadata and document tagging, advanced search capabilities and more
- Rich Collaboration environment for exchanging documents and data and supporting co-authoring, document approval and distribution
- Comprehensive Document Lifecycle Workflows providing configurable control of documents throughout their lifecycle of create, review, edit, approve, release and distribute
- 21 CFR Part 11 Support including Electronic Signatures (Figure 2), extensive Audit Trail, Controlled Tasks, Read & Understood with user verification providing Irrefutable Accountability
- Extended Audit Trail to provide full traceability and accountability – including who reviewed and approved documents, key decision points and sign-off on compliance processes
- PDF Renditions, including watermarking and overlays, providing permission-based access to relevant formats of content for viewing and printing
- Electronic Forms for automation & processing of regulatory events such as CAPAs, Deviations, Complaint Handling and Change Control
- Configurable Segregation of Duties to ensure that only the appropriate users can access certain information and be selected to carry out particular compliance tasks
- ‘Compliance Center’ (Figure 3) that contains and displays all relevant compliance information for instant decision making
- Controlled content creation using configurable document templates with workflow automation, auto-naming and metadata support
- Tight integration with both SharePoint 2010 & 2013, leveraging and extending the default user experience
- Integration to leading Submission Management publishing tools for Regulatory Affairs, with built in templates
- Automated Notifications, Reminders & Escalations via e-mail, to ensure critical tasks are addressed

Figure 2: Electronic Signature in QUMAS ComplianceSP
Quality Management Solutions on ComplianceSP for SharePoint 2010 & 2013

As well as the control of critical content, ComplianceSP delivers control over critical quality processes (Figure 4) and offers a unique set of best practice configurations.
Quality Process Management with QUMAS ComplianceSP

All key Quality Management activities in ComplianceSP are critically linked with Content Management to ensure a closed-loop of compliance. Each of the ComplianceSP Quality Management solutions contains advanced, out-of-the-box business process management.

ComplianceSP processes provide for the electronic capture, management, and reporting of all incidents and occurrences that may affect regulatory compliance, as well as the root cause analysis of incidents and the required follow up. Each element of the ComplianceSP solution is seamlessly integrated and offers a unique combination of best & common practice configurations for all compliance initiatives, including:

- Deviation Management
- CAPA Management
- Change Control
- Complaint Handling

Figure 5: QUMAS Quality Management with ComplianceSP

QUMAS ComplianceSP adds Value to SharePoint, delivering an end-to-end Quality Management Solution (QMS)

As with the Controlled Content capabilities outlined earlier, the Quality Management capabilities in ComplianceSP enables you to leverage SharePoint 2010/2013 to meet regulatory mandates with regards to Quality Management across the enterprise.

<table>
<thead>
<tr>
<th>Quality Management Solution Value Add</th>
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<tbody>
<tr>
<td><strong>Business Relevance</strong></td>
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<tr>
<td>Analysis &amp; Investigators</td>
</tr>
<tr>
<td>Impact &amp; Risk Determination</td>
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<tr>
<td>Root Cause Analysis</td>
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<tr>
<td>Effectiveness Verification</td>
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</table>

Figure 6: Quality Management Solution Value Add
**Deviation Management**

Regardless of whether your organization calls them Deviations, Non-Conformances, Incidents, or Out Of Specification results, the issues that arise in the day-to-day operation of your organization must be dealt with in a way that will meet with regulatory approval. In fact, some deviations are planned when testing a new formula or operating process. In order to properly manage Deviations and Non-Conformances, quality measures must be in place to ensure the root cause of any problem is addressed. Specifically, a Deviation and/or Non-Conformance must be recorded if anything out of the ordinary occurs during a regulated process.

The essential information regarding the Deviation is recorded and verified before an analysis of the cause is initiated. The solution must ensure that a consistent, prescribed protocol is followed where an issue is investigated, it is validated as an issue, and a Corrective Action Plan initiated. The resolution actions and disposition are approved before any action takes place (see Figure 7).

**QUMAS ComplianceSP Deviation Management**

- Capture & Investigate any deviation from approved procedures or specifications
- Evaluate all issues to identify the Root Cause & Escalate
- Record results of investigation & actions
- Disposition impacted Product appropriately
- Verify effectiveness of resolution before closure

**Corrective and Preventative Actions (CAPA) Management**

FDA inspectors and ISO auditors view CAPA - the Corrective Action / Preventive Action process -- as critical to investigating and correcting quality issues, and ensuring there is no recurrence. When implemented properly, a CAPA system improves product quality and patient safety and increases customer satisfaction.

The QUMAS ComplianceSP CAPA Management solution is easily configurable and offers a closed-loop process for effectively managing the corrective action/ preventive action process and integrating it with other processes critical to regulatory compliance, such as Change Control, Deviations and Customer Complaints (see Figure 8).

**QUMAS ComplianceSP CAPA Management**

- Correct issue or implement control to prevent issues
- Evaluate & Investigate root cause
- Identify & Implementation appropriate CAs / PAs
- Effectiveness Verification

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*Figure 7: Deviation Management*

*Figure 8: Corrective and Preventative Actions (CAPA)*
Complaint Handling

The FDA considers customer complaint handling an essential process for life sciences companies as well as a critical component for assuring compliance. Whereas in less regulated industries, customer complaints may indicate mere dissatisfaction, in life sciences they can point to serious product patient safety issues.

The ComplianceSP Complaint handling solution initiates a compliant process following receipt of a complaint. It captures the key details of the complaint and the problem either with product or documentation to be routed for analysis and impact. During analysis, further information or an investigation can be sought before a response is defined including whether a CAPA is required (see Figure 11).

QUMAS ComplianceSP Complaint Handling

- Record complaint details & ensure patient/product details are captured
- Evaluate & assess complaint
- Create investigation & record results
- Verify effectiveness of resolution and ensure root cause addressed
- Keep complainant informed of progress and outcomes

Change Control

Change Control is a critical component of a quality management system. Regulated organizations are expected to establish a change control procedure as a means of maintaining product quality, safety and assuring FDA and ISO compliance.

QUMAS helps organizations simplify and effectively manage their change control process, extending to product, process, equipment, facilities and computer system changes. Providing a solution to automate the change control process of assessment, plan, build, implementation, verification, and close of project, the ComplianceSP Change Control solution facilitates compliance with FDA regulations (21 CFR Parts 210, 211, 820, 600) and ISO standards (9000, 1400, 13485, etc.) (see Figure 9).

QUMAS ComplianceSP Change Control

- Manage all types of change that influence Product/Process/Equipment/System
- Evaluate & Classify impact associated risk
- Determine actions for implementation of the change
- Review and approval by appropriate people

Change Control

Initiate
Categorize & Plan
Implement
Review
Closed

Figure 9: Change Control

Figure 10: Complaint Handling
Validation and Implementation of QUMAS ComplianceSP

QUMAS has successfully implemented validated systems since 1994 with a sophisticated and proven methodology. At QUMAS, we implement solutions and support the client through the full project delivery life cycle. We transfer our knowledge to the client team to facilitate continued compliance success. Our highly experienced project delivery teams provide guidance throughout the project, using the following activities and deliverables:

- SharePoint Architecture and Deployment Guidelines
- Validation Master Plan Assessment
- Risk-based Assessment
- User Requirements Review
- Traceability Matrix
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Production Qualification (PQ)
- Validation Summary Report
- Migration Templates

Validation Accelerator Pack

| ✓ Validation Plan | ✓ OQ Test Scripts |
| ✓ System Requirements Specification | ✓ PQ Protocol |
| ✓ Risk Assessment | ✓ Traceability Matrix |
| ✓ IQ Protocol | ✓ Validation Summary Report |
| ✓ OQ Protocol | ✓ IQ Scripts |

QUMAS ComplianceSP Benefits

- Complete quality management system for SOPs (documents), Deviations, Change Controls, Complaints, and CAPA's (forms) from QUMAS thus lowering your total cost of ownership, simplifying validation, and reducing maintenance costs and complexity
- Optimum content management practices in accordance with FDA regulatory requirements, driving enterprise-wide consistency and compliance for creating, managing and securely storing all controlled content and processes electronically
- Using electronic workflows for Quality Process Management allows tight control over all quality issues, with built in Controlled Content Management as a critical element of all activities
- Deviation investigations and Complaints resulting in CAPAs tracked and managed from cradle to grave with built in reporting
- Standardized and automated regulatory and business processes, ensuring all incidents are logged, investigated, and remediated in an accountable way that drives efficiency and accuracy across all related activities
- Regulatory compliance with Read and Understood and Electronic Signature functionality (21 CFR Part 11)
- Workflows and other automations (such as electronic signature) with minimal number of third party solutions being utilized, greatly benefiting upgrades and support
- Seamless integration to Microsoft Office, with full enterprise collaboration capabilities
- Greater user satisfaction through the familiar Microsoft interface: High user adoption rates increasing business productivity, reduced user error and reduced compliance risk, simplified end-user training, reduced internal support demands and requirements
- Ease of implementation maximizing use of SharePoint functions, reducing deployment time and lowering the total cost of ownership, and accelerating the return on investment
- Fully scalable solution as the enterprise or requirements grow
## SUMMARY

QUMAS ComplianceSP delivers a fully integrated, quality-focused system that meets the Compliance and Quality pressure coming from regulatory bodies and new FDA initiatives for a risk based approach.

<table>
<thead>
<tr>
<th>Designed as ONE Product</th>
<th>Delivered by ONE Vendor</th>
<th>Lower Total Cost Ownership</th>
</tr>
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<tbody>
<tr>
<td>✓ Content &amp; Quality Management in one product</td>
<td>✓ Single support desk</td>
<td>✓ Use shared configuration across multiple Business Units</td>
</tr>
<tr>
<td>✓ Consistent qualification process</td>
<td>✓ deploy new features or applications quicker, with less validation overhead than multi-vendor deployments</td>
<td>✓ Optimize support effort</td>
</tr>
<tr>
<td>✓ Consistent look and feel</td>
<td>✓ Faster deployment and staff training</td>
<td>✓ Minimize validation effort = lower total cost of ownership</td>
</tr>
</tbody>
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**QUMAS**

✓ Highly Automated Quality Process Management
✓ Highly Configurable Electronic Forms
✓ Connected Quality Processes and Content
✓ Advanced Task Management
✓ Flexible Panel Options
✓ All on one Platform

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About QUMAS

QUMAS is the leader in Regulatory, Compliance and Quality Management Solutions for the Life Sciences industry, with more than 270 global customer deployments and domain expertise in regulatory compliance since 1994.

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