Global Trends in Life Sciences and Growth of the Partner Ecosystem

The trend toward virtual pharma is accelerating, and as it does, the life sciences industry is undergoing a profound structural transformation. What once was done within the confines of one company is now being done collaboratively across an ecosystem of many companies. The vertically integrated approach that supported the old order is giving way to hugely **distributed, diverse, outsourced,** and **collaborative** organizational chains of events. These event chains encompass such activities as looking for and tracking compounds, managing many clinical trials through multiple third parties, and contracting out manufacturing. The result is the new, dynamic collaboration ecosystem illustrated in Figure 1
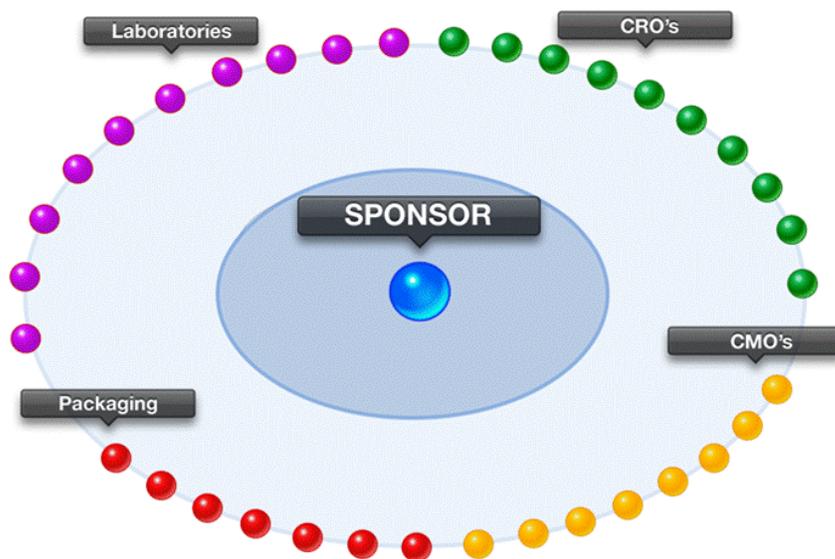

Figure 1: The Collaborative Ecosystem in Life Sciences

Implications for Quality and Compliance:

To promote productive collaboration while maintaining regulatory compliance, your compliance strategy must extend beyond your organization and its firewall to flexibly manage your entire supply chain - bearing in mind that each ecosystem partner not only carries a piece of your brand, but also extends your compliance obligations into their operations.

Introducing QUMAS iX for Intelligence Xchange

QUMAS iX is a purpose built solution that creates a bridge between an organization's internal document management system and a qualified environment for exchanging controlled regulatory and GxP information with third parties that is safe, secure and scalable. Third party users can view, search, print and collaborate on shared information by accessing the content through a web browser that directs them to a dedicated cloud-based QUMAS iX site based on Microsoft SharePoint 2010.

QUMAS iX provides compliant collaboration across your regulated Life Sciences ecosystem of partners, including CROs, CMOs, suppliers, vendors and sponsors. QUMAS iX allows you to simply yet effectively share (and segregate) the essential documents and other IP that is the focal point of each relationship.

QUMAS iX delivers full Sponsor/Partner Collaboration capabilities, including:

- Chinese Walls to segregate multiple parties with independent content backup, restore and content management
- Critical Document Exchange (of content that has been approved with Electronic Signatures containing Meaning of Signature and Time&Date Stamp)
- Full FDA 21 CFR Part 11 support
- Partner site management & reporting

QUMAS iX goes far beyond traditional electronic document management systems (EDMS) that reside on-premise behind firewalls, to extend your proven quality approaches across your supply chain. It is the first purpose built solution that allows you to bridge your internal document management systems and processes to a safe, secure, and scalable exchange, all in a qualified environment:

- Provide Document sharing to External Partners
- Allow Documents to be shared in a controlled and secure manner
- Audit of shared events
- Maintain visibility on whom Documents have been shared with
- Retract shared Documents
- Provide integration with QUMAS DocCompliance MyQUMAS User Interface
- Provide sharing via QUMAS Cloud or Sponsor-controlled system

Microsoft® SharePoint® 2010

Access All Microsoft SharePoint features including:

- ✔ Calendar
- ✔ Task lists
- ✔ Address lists
- ✔ Collaboration
- ✔ micro-blogs
- ✔ blogs
- ✔ wikis…
- ✔ Flexible & configurable

Leverage this functionality immediately with QUMAS iX

How does QUMAS iX work?
Simple Set-Up Ecosystem across Partners, Suppliers & Contractors:

Figure 2: Ecosystem Set-Up

1. Each Partner is (Virtually) Separate (see Figure 2)
2. Partner Staff may administer their own Sites (sponsors choice)
3. Partner Setup is Quick and Easy from Templates
4. Unlimited Partner Projects can be Supported

Sharing for Collaboration and Effective Compliance

Sponsor users can:
- Share approved documents directly from QUMAS DocCompliance (see Figure 3) with a pre-approved list of partners that displays in a pop-up selection box (the QUMAS eDMS automatically show a list of all partner sites created in QUMAS iX EDMS)
  - If a previous version of this document has already been shared with a partner, the version of the shared document will also be displayed per partner
- Retract shared documents (for example if an updated version of a shared document becomes available)
  - The Retract Document pop-up lists all of the partners the document is currently shared with and the version of the document shared with the partner

Note: QUMAS DocCompliance is required to use QUMAS iX. DocCompliance is the underlying electronic document management system.

Figure 3

Partner users can:

- View the shared documents in a web browser accessing the Cloud-based QUMAS iX interface, based on Microsoft SharePoint 2010 (See Figure 4)
- Print shared documents and search for shared documents
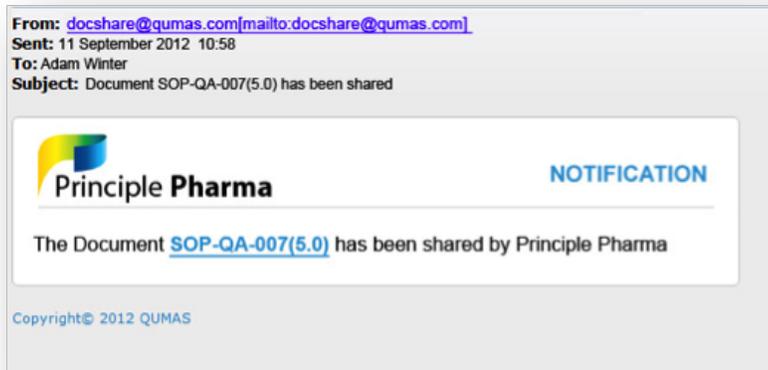- Collaborate on content

Figure 4: Partner Notification of Shared Content

Summary

QUMAS iX delivers a QUALIFIED ENVIRONMENT for

- Secure Document Sharing with Multiple Partners
- Ease of Use, Familiar Intuitive Interface – Microsoft SharePoint
- Increased Efficiencies – Time, Cost, Resources
- Self Service Administration for Partners
- Extensive Audit Trail and Reporting
- Ability to integrate with current DMS system e.g. DocCompliance or others via SDK
- Validated System in compliance with regulatory requirements

Business Advantages of QUMAS iX

- Speed of updates between parties
- Ease of Audit
- More "Evidence", less "Expectation"
- Faster adoption on projects, changes
- More predictable Supply Chain
- Access to full collaborative features of Microsoft SharePoint

Gain Strategic Advantages from QUMAS iX

- Ability to assess and compare various parties, suppliers, contract organizations and partners
- Far greater predictability on execution/delivery across all partners
- Joint Ventures operating seamlessly and collaboratively
- Run your partner ecosystem as you run your own company!

No Longer Required!

CDs / FTPs are no longer required to share content with partners

Use a Qualified Environment to Control Sharing!

Immediate Benefits!

- ✔ Speed
- ✔ Trust
- ✔ Agility
- ✔ Certainty

QUMAS **ComplianceSP**™

QUMAS iX enable you to share content in a controlled way. When you are ready for your partner to take the next step, and become involved in the creation of content, you need to ensure they create, review, edit, consume and retire content in a compliant way, using an EDMS. QUMAS ComplianceSP is a proven EDMS based on SharePoint 2010, that delivers full document lifecycle management, electronic signatures, audit trail and process management for CAPAs, Deviations, Change Control, Complaints and Audit.

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, Audits) and tasks on SharePoint 2010. 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 Office and Outlook.

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, 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, Change Control and Audits, both internal and external
- 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' 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 the SharePoint 2010 environment, 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 Microsoft Outlook, to ensure critical tasks are addressed

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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QUMAS is a Microsoft Certified Partner :

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Gold Content Management

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CONTROL · COMPLY · PERFORM