

# BIOVIA QUMAS iX FOR INTELLIGENCE XCHANGE

## COMPLIANT COLLABORATION ACROSS THE GLOBAL SUPPLY CHAIN DATASHEET

### 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.

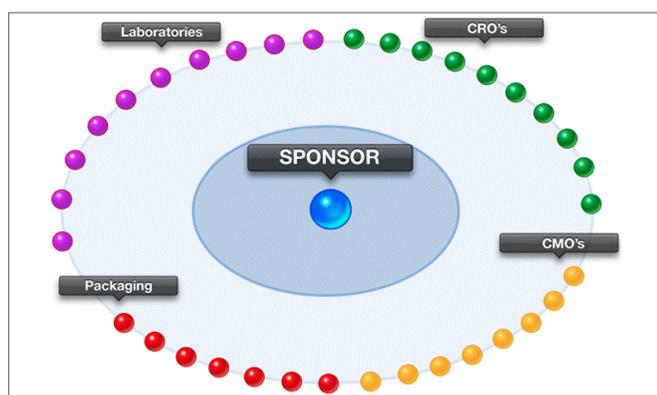


Figure 1: The Collaborative Ecosystem in Life Sciences

### 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 BIOVIA QUMAS iX FOR INTELLIGENCE XCHANGE

BIOVIA 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 BIOVIA QUMAS iX site based on Microsoft SharePoint.

BIOVIA QUMAS iX provides compliant collaboration across your regulated Life Sciences ecosystem of partners, including CROs, CMOs, suppliers, vendors and sponsors. BIOVIA 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.

BIOVIA 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

BIOVIA 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 BIOVIA QUMAS EDMS/BIOVIA QUMAS Portal User Interface
- Provide sharing via BIOVIA QUMAS Cloud or Sponsor-controlled system



## Access All Microsoft SharePoint features including:

- Calendar
- Task lists
- Address lists
- Collaboration
- Micro-blogs
- Blogs
- Wikis...
- Flexible & Configurable

Leverage this functionality immediately with BIOVIA QUMAS iX

## HOW DOES BIOVIA QUMAS iX WORK?

### SIMPLE SET-UP ECOSYSTEM ACROSS PARTNERS, SUPPLIERS & CONTRACTORS:

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

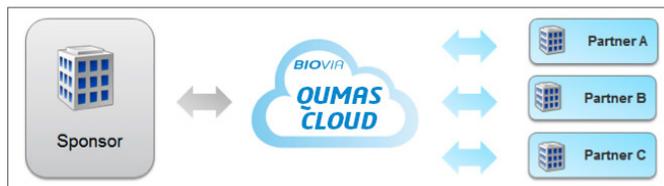


Figure 2: Ecosystem Set-Up

### SHARING FOR COLLABORATION AND EFFECTIVE COMPLIANCE

Sponsor users can:

- Share approved documents directly from BIOVIA QUMAS EDMS (see Figure 3) with a pre-approved list of partners that displays in a pop-up selection box (the BIOVIA QUMAS EDMS automatically show a list of all partner sites created in BIOVIA 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:** BIOVIA QUMAS EDMS is required to use BIOVIA QUMAS iX. BIOVIA QUMAS EDMS is the underlying electronic document management system.



Figure 3

Partner users can:

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

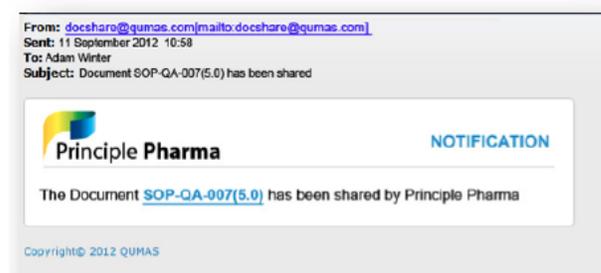


Figure 4: Partner Notification of Shared Content

## SUMMARY

BIOVIA 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. BIOVIA QUMAS EDMS or others via SDK
- Validated System in compliance with regulatory requirements

## No Longer Required!

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

Use a Qualified Environment to Control Sharing!



## BUSINESS ADVANTAGES OF BIOVIA 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 BIOVIA 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!

## IMMEDIATE BENEFITS!



Speed



Agility



Trust



Certainty

### ABOUT BIOVIA

Dassault Systèmes Biovia Corp. (BIOVIA) provides global, collaborative product lifecycle experiences to transform scientific innovation. Powered by Dassault Systèmes' 3DEXPERIENCE® Platform, BIOVIA solutions create an unmatched scientific management environment that can help science- and process-driven companies create and connect biological, chemical, and material innovations to improve the way we live. The industry-leading BIOVIA portfolio integrates the diversity of science, experimental processes and information requirements across research, development, QA/QC and manufacturing. Capabilities include scientific data management; biological, chemical, and materials modeling and simulation; open collaborative discovery; scientific pipelining; enterprise laboratory management; enterprise quality management; environmental health and safety; and operations intelligence. BIOVIA solutions are used by more than 2,000 companies in the pharmaceutical, biotechnology, energy, chemicals, aerospace, consumer packaged goods and industrial products industries, as well as academic and government entities.

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