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GRC Vendor Analyzer: QUMAS Compliance Platform Delivering GRC Value to Life Sciences

Meeting the Diverse Compliance Needs of Life Sciences

Effective compliance management in life sciences requires the ability to meet regulatory requirements, achieve efficiency in compliance and business processes, and meet the demands of a dynamic business environment.

Compliance technology delivers a process, technology and information architecture that addresses a range of initiatives throughout the life science organization. The right solution enables a better performing, cost-effective, more flexible business environment. Organizations should not assume that all software platforms labeled GRC or compliance deliver on this vision.

Life science organizations face a multitude of business and regulatory challenges, this includes:

- **A dynamic and distributed business environment:** The modern life science organization is a network of business relationships that demand collaboration and information sharing while requiring strict oversight, documentation and control of processes.
- **Highly regulated environment:** Virtually every aspect of life science faces regulatory oversight — from research and development, to manufacturing, to clinical trials, all the way to marketing and sales. Fragmented approaches to compliance documentation and process burden the organization.
- **Defensible data:** The life science organization has to have detailed documentation and validation of business processes and be ready to provide audit trails, evidence and documentation at a moment’s notice.
- **Documented policies, standards and procedures:** To be compliant, the organization must have written policies, standards, and procedures across the organization. Deviations and exceptions must be recorded, approved and monitored. The organization must show individuals understand what is required of them and are trained appropriately.
- **Corrective actions and preventative actions:** Organizations must have established procedures in place to correct noncompliant conditions and prevent further issues from happening. This requires a detailed issue management and resolution process be established.
- **Business risk and regulatory intelligence:** Like any organization, the life science organization needs to ensure it is managing its business according to strategy, performance and objectives as it addresses compliance in a constantly changing risk and regulatory environment.

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- **Effective document management:** The organization must manage and process documents and ensure nothing slips through the cracks, as well as address the risk of unauthorized access to documents with full traceability through version control and workflow.
- **Faster time-to-market:** The modern life science organization requires agile business processes that deliver fast time-to-market for new products. Document completion time has to be fast and accurate.

To meet the demands of business and compliance processes, the modern life sciences organization needs to:

- ✓ Shorten approval times
- ✓ Enhance user satisfaction
- ✓ Reduce complexity and redundancy
- ✓ Decrease the time needed to complete critical business processes
- ✓ Reduce the number of documents, templates, workflows and processes
- ✓ Handle documents in a consistent manner regardless of where they are in the world
- ✓ Cut time spent manually processing documents
- ✓ Decrease office and document storage space and costs
- ✓ Diminish or eliminate transfer and carrier costs of routing paper documents
- ✓ Provide a single integrated truth of business processes and compliance documentation
- ✓ Enable full traceability through audit trails, version control and workflows

Life science organizations cannot manage business and compliance processes with point solutions and meet demands to be agile, efficient and effective in a distributed and dynamic business environment. Organizations need an integrated process and compliance platform. Successes in the modern life science organization depends on the ability to efficiently and effectively manage the large number of documents required to comply with numerous regulations. Paper approaches fail: they are time-consuming, inefficient, ineffective and not agile in response to the demands of a dynamic and distributed life sciences environment.

QUMAS Compliance Platform Delivers Efficiency, Effectiveness and Agility

QUMAS is a GRC vendor that Corporate Integrity has researched, evaluated and reviewed with users of the QUMAS Compliance Platform and its integrated components. QUMAS delivers on the vision of GRC in life sciences to provide a robust technology and information architecture that enables risk and compliance processes to be agile, efficient, and effective in managing regulatory requirements while maintaining ease of use. The QUMAS Compliance Platform provides a framework to manage the unique challenges of a life science organization through integrated compliance management of documentation and processes while delivering analytical tools needed to implement, manage and monitor. Clients deploy the QUMAS Compliance Platform to understand and manage risk exposure, ensure compliance with obligations, improve efficiencies, enhance transparency, and manage GRC in the context of business change.

With a leadership position in life sciences, QUMAS has nearly 20 years of experience delivering innovative GRC technology. They have more than 80 life science clients with a combined total of over 250,000 users of the platform across 29 countries. Corporate Integrity has interacted with and engaged several QUMAS customers and finds them to be very satisfied with the platform and its ability to deliver value to manage GRC in a highly regulated environment. While many vendors stretch themselves thin by attempting to be all things to all industries — often promising more than they deliver — QUMAS demonstrates its focus on life science with a platform addressing the unique business problems in this industry.

QUMAS clients report achieving value in their implementations of the QUMAS Compliance Platform through reduced time in gathering and reporting on GRC, reduction in fees paid to external resources, clear accountability of GRC tasks, and a strong stance to demonstrate that the organization has sound practices in place for GRC. In particular, QUMAS has enabled clients to efficiently manage documents electronically whether they are in the hundreds or tens of thousands as well as electronically managing business processes such as deviations and CAPAs. The QUMAS Compliance Platform provides an integrated process, information and technology architecture that bring GRC activities together through clear accountability in workflow, task, project, and program management.

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QUMAS Compliance Platform Capability Analysis

Through one of the most complete and integrated process and compliance platforms, the QUMAS Compliance Platform delivers operational effectiveness, human and financial efficiency, and agility to life sciences organizations. The QUMAS Compliance Platform is ideally suited for organizations that operate in highly regulated, dynamic and distributed environments. The QUMAS Compliance Platform achieves this through the following core capabilities:

- **Central repository for documents:** Organizations implement a single cohesive system for managing the document management lifecycle that provides ease of use with the capability to manage access and audit trails needed for compliance.
- **Business and compliance lifecycle management:** QUMAS delivers a complete system to integrate business processes with the compliance oversight needed for life science. This involves controlling processes and documents throughout business and document lifecycles across processes.
- **Business process automation and workflow:** The QUMAS Compliance Platform delivers workflow and task management to ensure controls are implemented and followed throughout business processes and operations.
- **Full traceability and accountability:** The QUMAS Compliance Platform provides a robust audit trail to document who viewed, reviewed and approved documents and submissions, what the key decision points were, and highlights the sign-offs and certifications.
- **Forms processing and management:** QUMAS enables creation and use of forms to automate business and compliance processes, and routes requests and information for approval and other authorizations.
- **Integrated learning management:** Through integration of learning content into business processes and compliance documentation, the QUMAS Compliance Platform enables the life science organization to deliver consistent and compliant business operations to ensure individuals have access to learning modules and are properly trained.
- **Dashboard and reporting:** The QUMAS Compliance Platform delivers robust and configurable reporting and dashboards to give business, process and compliance personnel the information they need when they need it.
- **Track and interpret regulations:** Life science organizations face constantly changing laws, rules, regulations and enforcement actions around the world and need to ensure business processes are current and relevant to changing business and regulatory requirements.
- **Capture exceptions and deviations:** QUMAS has a complete system to capture issues, incidents, exceptions and deviations and ensure they are responded to.
- **Audit and investigate:** Through integrated audit, assessment, and management capabilities the QUMAS Compliance Platform provides a consistent application to manage the assessment, audit, monitoring and investigation processes across the life science organization.
- **Measure, assess and implement change:** Life science organizations are constantly changing. Business, technology, employees, relationships as well as the regulatory and risk environment are in a constant state of flux. The QUMAS Compliance Platform profiles and manages change to keep the organization compliant and on track to hit its objectives while staying out of hot water.

The QUMAS Compliance Platform is a cohesive system to manage the complexities of business within life science organizations. While designed to help life science companies be compliant, the QUMAS solution is more than that; it enables effective business management in the context of a highly regulated, dynamic and distributed business environment. From a pure compliance perspective it is a worthy candidate for any compliance program — combined with its breadth of process and document capabilities the QUMAS Compliance Platform provides information, analytics and insight to deliver value beyond compliance and to the business. QUMAS enables agility, efficiency and effectiveness in operations and processes supporting the modern life science organization.

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About QUMAS . . .

QUMAS delivers a closed-loop compliance model that standardizes and integrates the common elements of compliance tasks across the organization. Enterprises are able to effectively converge all of their compliance programs onto a single platform, radically reducing the cost of compliance and creating competitive advantage. With its proven track record in two of the most stringently regulated industries - financial services and life sciences - QUMAS has proven that it is best positioned to provide centralized compliance for any company, regardless of industry. Its solutions ensure corporate compliance with the full spectrum of global regulations.

The QUMAS solution facilitates an informed, risk-based response to compliance challenges across any business. The QUMAS Compliance Framework channels and focuses resources, providing certainty to a company's state of compliance as well as meaningful reporting to stakeholders. The result is an optimized closed-loop compliance environment.

With the QUMAS closed-loop compliance environment, the goal is to provide organizations with a complete and comprehensive view of compliance and serve as the compliance system of record when dealing with regulatory bodies.

About Corporate Integrity . . .

Corporate Integrity, LLC is a GRC strategy advisory firm providing leadership in education, research, analysis, and advisory services by monitoring the challenges and trends in business for corporate governance, risk management, and compliance (GRC).

Through ongoing research, interactions, and analytics, Corporate Integrity is the authority in understanding how organizations can foster a culture that "walks the talk," where integrity is central to GRC practices. Corporate Integrity educates organizations — and GRC professionals within those organizations — on achieving sustainability, consistency, efficiency, and transparency in their corporate GRC practices to maintain a position of integrity aligned with corporate values and business performance.



About Michael Rasmussen . . .

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Michael Rasmussen is an internationally recognized pundit on the topics of business ethics, corporate culture, policy management, and compliance. With more than 18 years of experience, Michael helps organizations understand their culture and improve related governance, risk, and compliance (GRC) strategies, processes, and technologies that deliver business agility, efficiency, and effectiveness. He is a sought-after keynote speaker, author, and advisor on compliance and risk management strategies. He is noted for being one of the earliest advocates for a collaborative and integrated approach to GRC.