



GXP CONTENT SERVICES

Enabling Efficient and Compliant Management of Quality Documents

Life sciences organizations struggle to provide effective ways of finding, using and compliantly managing controlled GxP quality content (such as Standard Operating Procedures (SOPs), methods, specifications, etc.) and information to meet the needs of stakeholders both within and outside the organization. This content is sometimes stored in more than one content management system, or in systems that are outdated or no longer supported. Multiple or outdated systems are not only costly to maintain, they increase the potential for non-compliance and do not provide the visibility into quality processes or collaboration capabilities that are required in today's increasingly outsourced manufacturing environment.

Life sciences organizations need systems in place to effectively manage quality information as required by health authority regulations. Those that do not risk serious compliance penalties and fines resulting from:

- The inability to produce documents requested during an audit
- Difficulty for employees to find SOP, spec and test method documents needed to do their jobs
- Employees managing content via email and file shares to avoid outdated quality systems that are not user-friendly

Specialists in Managing Quality Content

Paragon has extensive experience working with quality organizations to establish and implement a strategy that effectively manages controlled quality content. Paragon's industry experts know the latest leading industry standards, process efficiencies and technologies. We can help define efficient quality management processes and business requirements, as well as assist in the evaluation and selection of a Quality Content Management (CM) system that enables the company to manage quality content across the organization and comply with health authority regulations. Once we have helped you define your Quality CM strategy and roadmap, we will leverage our reusable assets to help you quickly implement Quality CM capabilities. Paragon can help you establish a path forward to more efficiently and effectively:

- Collaborate with contract manufacturers and labs
- Efficiently and effectively manage GxP Quality Systems documentation throughout the life of your products
- Reduce the cost of quality operations and systems, while enhancing compliance and process efficiencies

Paragon's Model for Ensuring Quality Operations and Compliance

GxP Content Management is only part of Paragon's comprehensive, leading practice Quality Operations framework. This framework facilitates quick and effective development of a future state strategy and roadmap for achieving quality information management while ensuring alignment among executive and business leaders. Our framework addresses the people, process, information and technology aspects of an overall Quality CM vision.

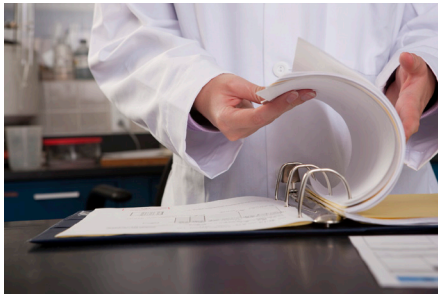




Benefits of Implementing a GxP Content Management System

Below are just some of the benefits that can be achieved by implementing Quality CM capabilities and optimizing compliance document management:

- **Enhanced GxP compliance** – provides accessibility to the documents employees need daily to do their jobs and ensure compliance.
- **Increased Collaboration** – enables tighter interoperability to work with outsourced partners, such as contract manufacturing organizations (CMOs) and labs.
- **Higher user-adoption** – a modern and supported Quality Content Management solution that is user-friendly will encourage adoption and eliminate compliance risk of managing content outside the quality CM system.
- **Greater business productivity** – optimizing quality business processes frees-up time to focus on other activities and simplifies interactions with external service providers.
- **Reduced cost of ownership** – purpose-built, off-the-shelf solutions are less costly to maintain than older, heavily customized systems that are expensive to update and require more user training.



Paragon's Relevant Capabilities

What sets Paragon apart is our investment in specialized industry practices, our commitment to our client partnerships, and a willingness to apply our industry knowledge and integration expertise to every solution we deliver. Whether it's a global deployment of a solution or a focused strategic engagement, Paragon can address your needs. Our delivery model features solution frameworks, reusable accelerators and methodologies that not only ensure fast and efficient delivery, but through repeatability, help manage costs.

Below are some of other areas where the Paragon team can help:

- GxP Quality Systems Analytics
- Quality Management Systems
- Content Imaging/Scanning Solution Implementation
- Information Governance
- Content Migration/Integration
- Regulatory Information Management
- Electronic Trial Master File Optimization
- eSubmissions/eCTD
- Promotional Materials Management
- Enterprise Content Management Strategy and Implementation
- Big Data Analytics
- Cloud Readiness

About Paragon

Paragon is a consulting firm that helps health and life sciences companies become high-performing, compliant, and digitally connected. Paragon powers business transformation and delivers better business outcomes by providing valuable consulting services as a trusted partner to our clients. We do this by building long-term client relationships based on our domain expertise, creative ideas, pragmatic consulting services, and quality delivery of solutions.

For more information, please visit us online at www.consultparagon.com or call 1.800.462.5582.

Paragon Client Roster

Paragon's client roster includes life science industry leaders such as:

- AbbVie
- AstraZeneca
- Bayer
- Bristol-Myers Squibb
- Celgene
- Chiltern
- CSL Behring
- GSK
- inVentiv Health
- Lilly
- Merck
- Novo Nordisk
- Otsuka
- Regeneron
- Roche
- Sanofi
- Shire
- Valeant
- Worldwide Clinical Trials