



QUALITY ANALYTICS IN LIFE SCIENCES

Manage Key Quality Drivers and Ensure Continued Global Compliance

Quality analytics measures are increasingly being recognized by Global Health Authorities as a necessary mechanism for monitoring compliance across regulated companies. The United States FDA is pursuing standards of quality metrics to create a more flexible and rationalized review and continuous inspection system. Use of these metrics will facilitate the agency's intended transition from an inspection mode to proactive surveillance under a risk-based approach.

Industry groups are proactively working with the FDA to develop best practices for identifying and reporting key quality metrics, evaluation criteria, and managing related electronic submissions. A well-developed and transparent system promises to add value in terms of greater understanding and control of internal processes, as well as by reducing the need for traditional inspections and providing for a streamlined review of supplemental filings.

Successful companies invest in analytical capabilities to support the following business drivers: launch of new products, introduction of new facilities, processes improvements, technology monitoring, growth of the supply chain, expanding markets, complexity of specialty business models, internal manufacturing and external supplier/partner integration.

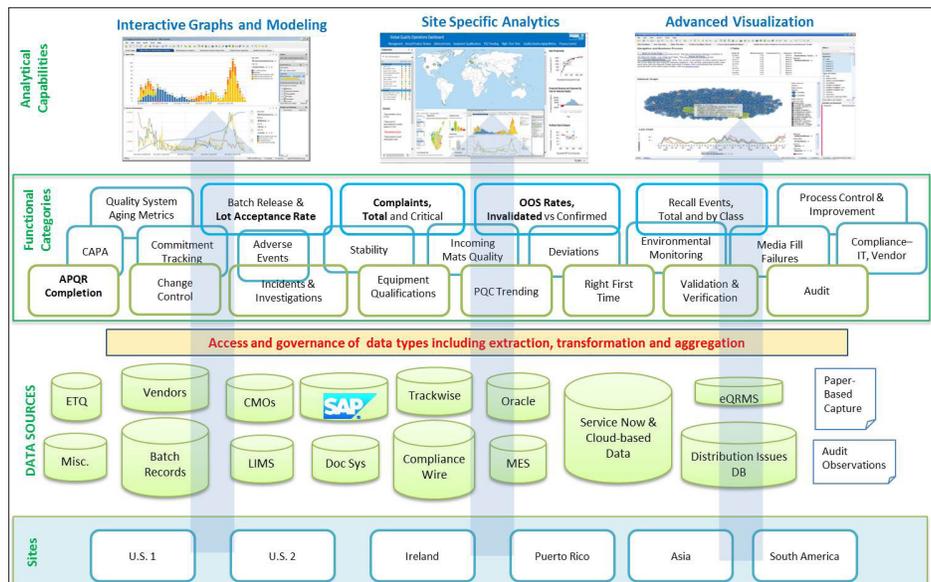
Paragon's Quality Analytics Solution

Paragon takes an integrated approach to quality analytics that includes industry best practices, FDA priorities and critical metrics, and Paragon's target state POV that delivers an analysis set of capabilities, business design and a robust analytics foundation. Paragon will work with your team to:

- **Realize and design** the target state, the competitive roadmap and set the foundation for global health authority compliance.
- **Develop and implement** a flexible and scalable process and system to monitor quality-related KPIs, data sets and metrics.
- **Enable** global proactive management that supports continuous improvement of product availability and quality systems.
- **Prototype** key capabilities and processes with real data to ensure a full understanding of the business requirements.

Integrated Information, Quality Analytics and Informed Management

Provide for integration of data from disparate sources to enable insight and better decisions across the supply chain.





Ensuring Quality Excellence

Ensure proactive measurement and management. Per the FDA, the goal for the industry is, “A maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces high quality drugs without extensive regulatory oversight.” Success will require:

- Alignment with industry initiatives and regulatory guidance.
- Data standardization with global access and availability.
- Timeliness and accuracy of critical quality reports.
- Modernized reporting, analytics and collaboration capabilities.

Paragon can develop a comprehensive analytics platform to enhance decision-making with respect to manufacturing quality and field-based information, including corrective actions. Being a leader in quality analytics, monitoring and reporting stands to add significant value to the current supply chain as well as future product line expansions, thereby delivering competitive advantage.



Successfully Completing the Picture

Paragon has worked with major life science partners to design and develop innovative quality-based analytics solutions. Our success stories include the full life cycle of implementation. From establishing organizational priorities to delivering full road maps, design and capability integration, we help our clients better analyze what they manage. We adeptly manage operational needs including:

- Expanding therapeutic product lines.
- The complexities of integrating many sites, sources, and formats of analytical data.
- Working across a global organization to develop a comprehensive set of capabilities.
- Enabling compliance with multi-national regulatory expectations.



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**
- **Bausch & Lomb**
- **Bayer**
- **Bristol-Myers Squibb**
- **Celgene**
- **CSL Behring**
- **Daiichi-Sankyo**
- **GSK**
- **Lilly**
- **MedImmune**
- **Merck**
- **Novo Nordisk**
- **Otsuka**
- **Roche**
- **Shire**
- **Chiltern**
- **inVentiv Health**
- **Worldwide Clinical Trials**
- **Regeneron**