



## Quality Management System (QMS) Strategy & Roadmap

Delivered an implementation-ready roadmap for the deployment of a QMS system that ensures compliance with commercial GMP standards.

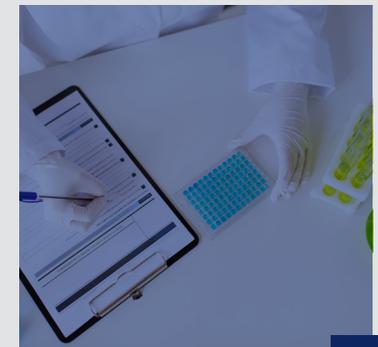
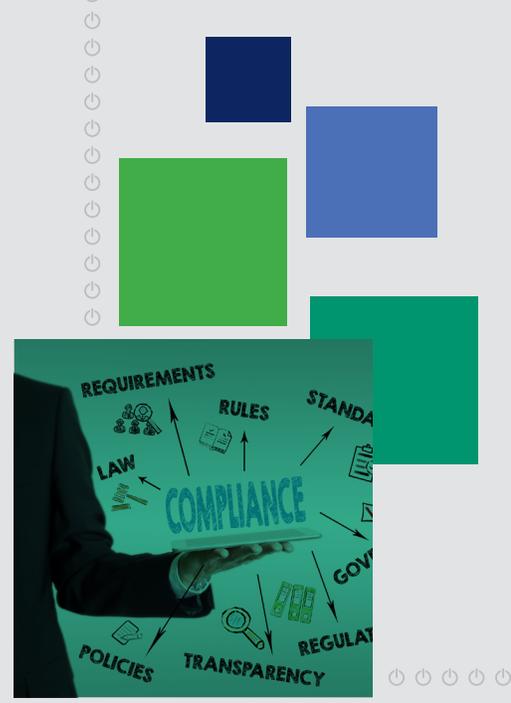
### Business Challenge

A biopharmaceutical company that was accustomed to collaborating with other corporations on product launches was preparing to introduce its own commercial product. In preparation for product approval, the company recognized the need for a harmonized Quality Management System (QMS) to support commercial-scale Quality processes and workflows and provide internal capabilities to manage and monitor product quality with the contract manufacturing organizations (CMOs) they collaborate with.

### Client Objective

The client engaged Paragon to create a prioritized QMS roadmap that would define actionable steps that could be taken to implement an efficient and scalable QMS, capable of maintaining compliance against commercial GMP standards. The initiative included:

- Envisioning the future of quality management
- Developing a two-year roadmap and QMS implementation plan to implement the vision
- Defining future quality management business processes and high-level user requirements to support Product Realization, State of Control, and Continuous Improvement
- Assessing the QMS vendor landscape to arrive at a short list of technology vendors for evaluation



**“The client engaged Paragon to create a prioritized QMS roadmap... to implement an efficient and scalable QMS, capable of maintaining compliance against commercial GMP standards.”**

## Paragon Approach

Paragon worked with the client to create a comprehensive, realistic plan to organize project tasks, activities, and business interaction to achieve the project goals. Through Voice of the Customer (VOC) interviews and workshops, Paragon gained an understanding of the client's current state of quality management, their pain points, and global future business needs. Analysis of the VOC data was used to prioritize various business capabilities that would be enabled by the new QMS platform. The desired QMS capabilities were then evaluated against business importance and business readiness. A future state vision was developed which included: QMS business and technical capabilities and maturity levels; strategic business and solution architectures; high-level process, RACI, and requirements; and strategy recommendations that aligned with the company's business plan. A QMS vendor landscape and short list was provided, as well as a Strategy Roadmap that included a timeline, implementation plan and task prioritization.

## Client Results

Paragon delivered a tactical, implementation-ready roadmap for the deployment of a new QMS system to achieve the client's goal of establishing the best path to a more efficient, scalable, and manageable future state, capable of maintaining compliance against commercial GMP standards.

The roadmap depicted the key initiatives laid out across a high-level project plan, including:

- Optimizing Quality Business Processes
- Verifying requirements and conduct the QMS Vendor Assessment & Selection process
- Installing, configuring and rolling-out QMS solution software
- Integrating supporting systems
- Migrating legacy data to new QMS system
- Establishing a framework for ensuring harmonization across enterprise projects
- Implementing a comprehensive Change Management program



**“Paragon delivered a tactical, implementation-ready roadmap... to a more efficient, scalable, and manageable future state, capable of maintaining compliance against commercial GMP standards.”**