

Quality Management System (QMS) Strategy & Roadmap

Implementation-ready roadmap for QMS system deployment ensures compliance with commercial GMP standards.

Business challenge

A biopharmaceutical company accustomed to collaborating with other corporations on product launches was preparing to introduce its own commercial product. In preparation for product approval, the company needed a harmonized 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) with which they collaborate.

Client objective

The client desired a prioritized roadmap defining 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 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

CGI's approach

CGI worked with the client to create a comprehensive, realistic plan to organize project tasks, activities, and business interaction to achieve project goals. Through Voice of the Customer interviews and workshops, CGI gained an understanding of the client's current state of quality management, pain points, and global future business needs. Analysis of the 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, including: 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.

Founded in 1976, CGI is one of the world's largest IT and business consulting services firms, helping clients achieve their goals, including becoming customer-centric digital organizations. Project profile originally from Paragon, which merged with CGI in December 2017.



Value delivered

CGI delivered a tactical, implementation-ready roadmap for the deployment of a new QMS 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 the new QMS
- Establishing a framework for ensuring harmonization across enterprise projects
- Implementing a comprehensive change management program