

Unlock the potential of quality management in your life sciences organization

A modern offering from KPMG and Sparta Systems, a Honeywell Company

Enable your quality organization with a truly digital and connected experience

Do you envision your quality function transforming from a cost center to a value-adding unit of your life sciences organization?

Enabling this change requires a paradigm shift to establish quality as an enabler of enterprise value creation. As outlined in our forward-thinking thought leadership article “Quality 2030: quality inside,”¹ one of the key pillars to enabling a truly digital and connected quality organization is implementing innovative technology platforms to automate processes.

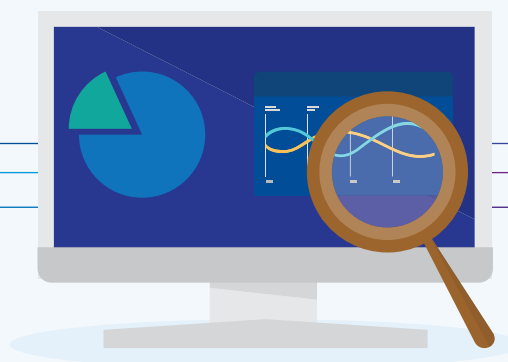
Traditional technology platforms for managing quality operations are often siloed across various processes, resulting in reactive practices and a lack of insights to support effective, proactive operations. If you are like most organizations, your quality management system (QMS) is likely a custom-built, on-premises solution augmented by paper processes. You might also have multiple instances of the same or different platforms due to mergers and acquisitions. As a result of these disparate, custom-built, and dated systems, organizations are often stuck in a reactive state, led by unreliable and disconnected data.

The next generation of QMSs need to:

Simplify and standardize processes

Fully integrate digital quality processes

Drive proactive insights from quality metrics



Enables technology integration and digital connectivity

Support internal and external collaboration

Be agile, mobile, and user friendly

So, how do you transform your quality organization, shift from a reactive state to a proactive state, become more agile, and drive value within your organization?

The answer: implement a digital and connected QMS with help from KPMG and Sparta Systems. KPMG provides the framework—based on domain knowledge and industry-leading practices—to

implement TrackWise Digital®, Sparta’s next-generation, cloud-based quality management SaaS solution. With redesigned processes to meet business needs and an agile, flexible technology platform, you can drive efficiency, improve quality, achieve compliance, reduce risk, enhance decision-making, and lower cost of ownership.

¹ Source: KPMG US <https://institutes.kpmg.us/healthcare-life-sciences/articles/2019/quality-2030.html>

A solution for next-generation quality management

Working closely with Sparta, KPMG has developed an offering designed to deliver digital quality management capabilities to life sciences companies. With deep experience providing business transformation services to leading life sciences companies, KPMG examines current processes and then designs a target operating model to meet your business needs. Integrated services—including process redesign, program management, TrackWise Digital deployment, system testing and validation, systems integration, data migration, change management, training, and postimplementation support—enable you to achieve your goals.

Built on the trusted Salesforce platform, TrackWise Digital brings quality management to the cloud. It can be quickly implemented, updated, and accessed anywhere on any device. With reporting and analytics across all processes, your teams can leverage data to impact performance. Finally, TrackWise Digital is the industry's first quality management solution with artificial intelligence (AI)-augmented decision-making capabilities through the QualityWise.ai platform, enabling proactive—not reactive—quality management.

A KPMG team of functional professionals, project managers, business analysts, and skilled Salesforce technologists supports you from project planning to implementation of TrackWise Digital modules and beyond. Together, KPMG and Sparta bring an out-of-the-box, enterprise-grade, leading QMS that can be configured for your specific needs.

Key steps of the offering include the following:



Align business processes.

KPMG defines a target operating model and realigns business processes for complaints handling, change controls, corrective and preventive action (CAPA), audits, and supplier quality.



Define requirements.

Collaborative workshops define business and functional requirements.



Design and implement the solution.

KPMG works with you to define a future state and a roadmap that includes solution architecture, design, configuration, implementation, and deployment support.



Migrate data.

KPMG plans and executes data migration from legacy systems to TrackWise Digital.



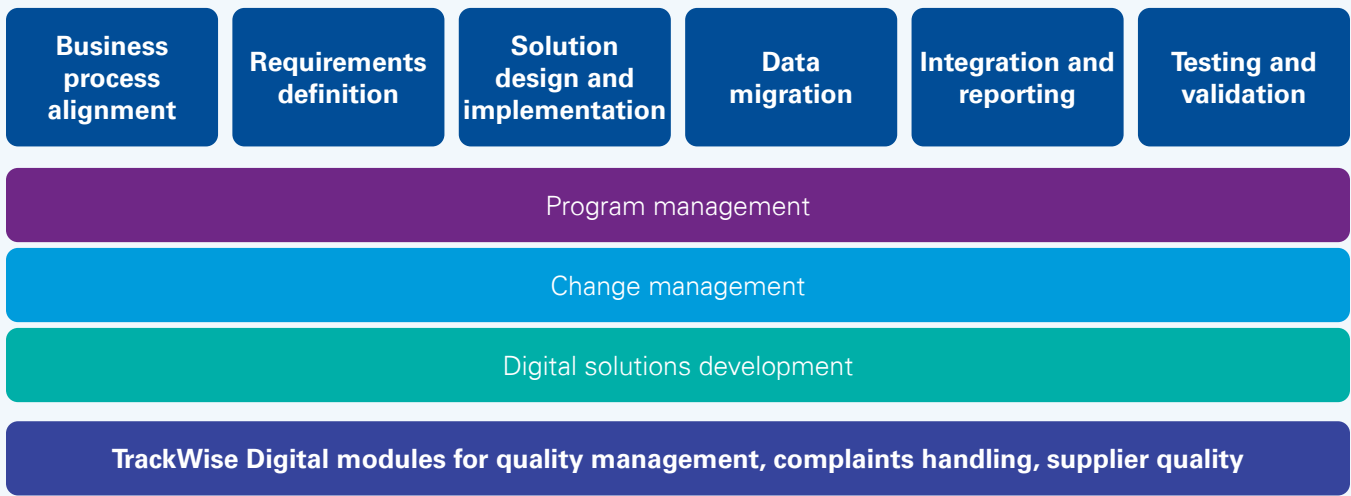
Build integrations and reports.

With Salesforce-trained professionals, KPMG supports integration with other systems and interface design. Reports and analytics dashboards are designed and developed based on defined quality metrics and KPIs.



Conduct testing and validation.

KPMG develops a validation strategy then executes protocols to help you validate the overall solution.



Quality assurance for audits, changes, complaints, CAPA, risk, and suppliers

The KPMG transformation offering addresses modern quality management capabilities across three key areas:

Quality management

Modern quality management means a fully integrated CAPA system—with automated routing, notification, delivery, escalation, and approval capabilities—as well as change control processes initiated by either planned or spontaneous deviations. An integrated tracking system and a powerful workflow engine automate all the steps in internal, external, and regulatory audits. It captures meaningful quality metrics that can provide actionable insights to predict and mitigate potential quality issues.

Complaint management

With modernized complaint management, you can manage the entire complaint lifecycle—from complaint to investigation, root cause analysis, and regulatory reporting. The offering gives you the ability to track, triage, escalate, and share records in a centralized and validated platform. Configurable questionnaires and

decision trees can be used for complaint, reportability, and safety assessments. In addition, you can easily submit adverse event reports to the FDA electronically. The use of prebuilt accelerators and AI modules, simplifies the case management process, allowing configuration to client’s requirements and specifications while complying with regulatory standards.

Supplier quality management

With enhanced supplier quality management processes, quality teams can collaborate with suppliers and contract manufacturers across the supply chain. You can manage onboarding, audits, incidents, corrective action, and more. In addition, reliable supplier data powers analytics for surfacing insights.

Each of these areas can be implemented separately, but they are also interconnected. A single, unified platform for all quality processes makes it easier to get closed-loop feedback and see the full picture on quality issues. For example, the root cause of an issue tracked in the complaint processes might be tracked back to an issue with raw materials flagged in the supplier quality processes. By eliminating disparate processes and systems, KPMG can help you see the big picture.

Determine by transforming quality management

Combining skills, experience, and technology, the KPMG offering powered by TrackWise Digital delivers the following determine.

- Flexible, adaptable processes and workflows
- Compliance with regulations
- Improved quality metrics
- Lower risk of supply disruptions
- Powerful business insights
- Ability to react to a changing environment
- Efficient integration of new business lines
- New digital capabilities for managing audits, changes, complaints, CAPA, risk, and suppliers
- Ability for different business units to modify core processes to meet unique requirements
- Long-term value for investment

Deploy quality operations across the enterprise

Life sciences companies need modern quality management processes and systems to drive efficiency, improve quality, achieve compliance, and reduce risk. With KPMG services and TrackWise Digital, you can address challenges such as tougher compliance requirements, supply chain disruptions caused by quality issues, tighter budgets, greater product portfolio complexity, higher customer expectations, increased product quality, and patient safety. This offering—spanning quality, complaint, and supplier quality management—can help you bring safe, high-quality products to market so you can stay competitive and foster growth.

Bring quality into the digital era

Increased regulatory scrutiny and the rapid pace of change impact life sciences organizations everywhere. The quality management transformation offering from KPMG can help you design a strategy and accelerate implementation of TrackWise Digital to improve efficiency and compliance. With multiple deployments of TrackWise Digital at leading pharma and medical device companies, KPMG possesses the implementation methodology, end-to-end process flows, requirement mappings, and accelerators for integrations, reporting, and system validation to modernize how you manage quality. Contact us to learn more.

Contact us

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