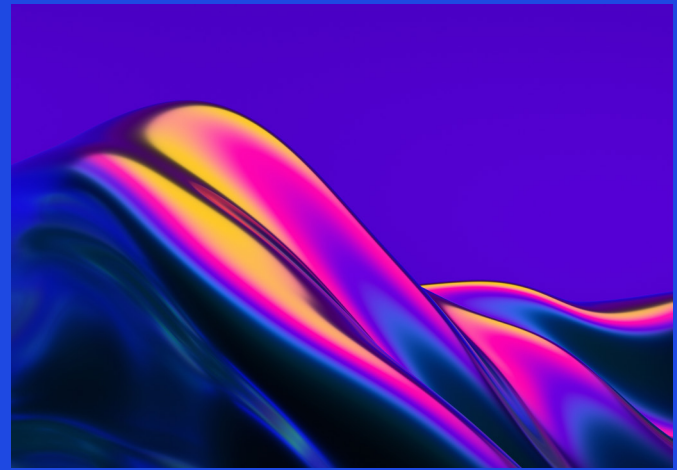




Enabling Quality for the Future

The move from compliance to competitive advantage



Unlock the power of quality

Quality alignment with corporate strategy, innovative risk-based processes and technology enablement is required to increase the value of quality and unlock its power. With the life sciences industry's transition to customer centricity, personalized medicine, and direct product delivery models, an effective Quality Management System (QMS) directly impacts product quality, customer satisfaction and achievement of corporate market share objectives.

At KPMG, we support our clients quality journey from a compliance function to a competitive advantage:

- Our regulatory and industry knowledge and our technology solution capabilities, move clients from reactive compliance to proactive quality monitoring that generates business insights.
- Leveraging data-driven analysis, value stream mapping, and advanced methodologies, we develop impactful and sustainable solutions while keeping compliance and agility as critical attributes.

KPMG helps clients address the needs of today while anticipating those on the horizon and unlocking the power of quality.

Quality Transformation Opportunities

- **Regulatory Changes** – Adoption of new global regulations and data-driven remediation activities
- **Technology Advancement** – Automate and monitor quality in real time to support continuous improvement
- **Quality Management Systems (QMS) Reimagined** – Design and process aligned to leading practices and technology enabled
- **Quality Organization** – Alignment of organization process, activity, and structure to business strategy
- **Product Innovation** – Accelerate the development of new products and services through risk-based processes

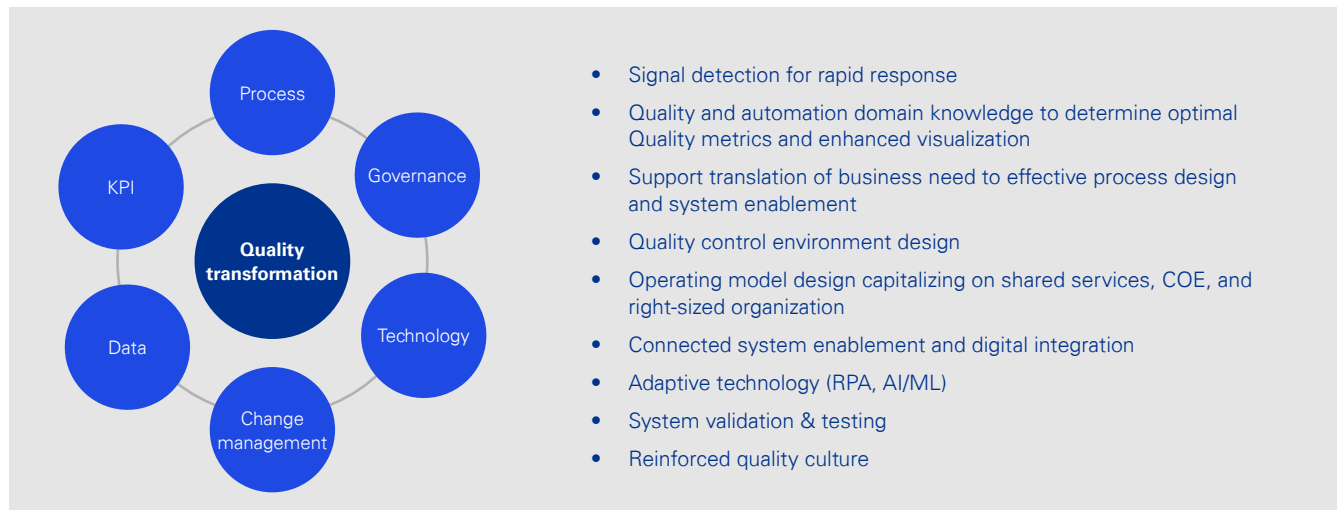
Quality Service Offerings

<p>Quality Strategy</p> <ul style="list-style-type: none"> • Strategy development • Organization alignment • Maturity model assessment • Key performance indicators (KPI) for monitoring quality • M&A readiness and transaction support 	<p>Quality Operations</p> <ul style="list-style-type: none"> • Process evaluation with industry leading practices • Development of robust and sustainable quality controls • Data integrity assessment and mitigation • Remediation support for regulatory findings 	<p>Quality Management System</p> <ul style="list-style-type: none"> • QMS framework assessment, design, and remediation • CAPA and Deviation management process, evaluation, design, and execution support • Complaint management evaluation, design, and execution support • Quality manual, policy, and SOP development
<p>Computer System Validation</p> <ul style="list-style-type: none"> • Validation strategy assessment, design, and remediation • Validation execution support: Protocol development, testing, technical writing • Validation strategies for new technologies and standards 	<p>Quality Audit</p> <ul style="list-style-type: none"> • Assessment/Audit of quality management system across process, product, and systems • Mitigation development, prioritization, and roadmap to support continuous process improvement and risk reduction 	<p>Quality Technology and Digitization</p> <ul style="list-style-type: none"> • Business process and requirements definition • Technology vendor selection • Solution architecture and design • Solution implementation and deployment support • Application rationalization and upgrade support

“Move the Dial” on your Quality Management System



Quality Transformation – Focus on Delivering Business Value



Why KPMG

Experience and Knowledge

We provide real-world responses to real-world problems leveraging our experience in business, technology acumen, and consulting capabilities.

Industry Insights

Our professionals bring insights to enhanced methodologies with industry domain knowledge, and maintain a pulse on changes in regulations.

Quality Value

We focus on building flexibility into the organization to adjust to changes in business needs, optimize delivery, and manage costs.

Connect the Dots

We align KPIS to business strategy providing visibility into health of the quality organization and identify opportunities for continuous improvement.

Trusted collaborator

Our subject matter professionals apply optimal practices to achieve consistency across the supply network while accounting for required local variants.

Innovation

Our teams help organizations leverage intelligent systems to drive business decisions based on objective data.

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KPMG insight

The KPMG knowledge base of articles and publications demonstrates our understanding of the complex business challenges faced by companies around the world. Check out our thought leadership at <https://institutes.kpmg.us>.

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