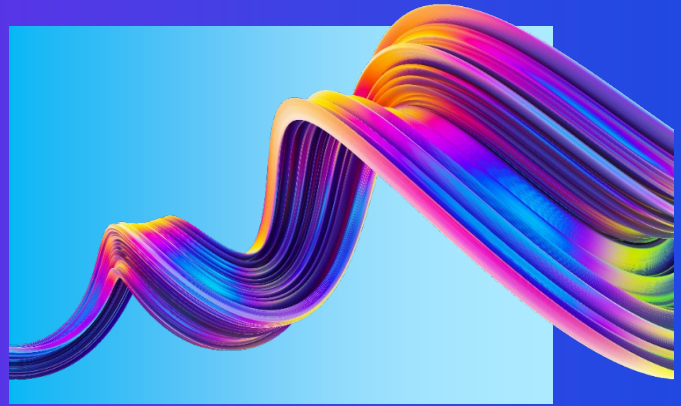




# Quality Solutions

Accelerating the future of quality and delivering business value



## Strategic Alignment

The Quality function alignment with corporate strategy and business direction is required to increase the value of Quality while reducing the overall cost of Quality. With the Life Science industry accelerated transition to customer centricity, personalized medicine, and direct product delivery models, the Quality Management System (QMS) tightly interweaves with customer service and market share objectives.

A Quality function with flexibility to adjust to the changing business environment and that leverages modernized tools and advanced analytics, provides the requisite competitive advantage through fostering innovation, integration and collaboration while accounting for the changing compliance imperatives.

## The Future of Quality

At KPMG, we support our clients in their holistic Quality journey from Quality strategy development to digital solution implementation. Data driven analysis, value stream mapping and assessments, allow KPMG to develop achievable, sustainable and impactful solutions.

Leveraging our regulatory and industry knowledge, as well as technology capabilities, we move clients from reactive compliance to providing proactive business insights. KPMG helps clients address the needs of today while anticipating those on the horizon.

## Quality Transformation Opportunities

- Support clients to efficiently adopt new global regulations and address remediation activities
- Empower clients to digitally re-imagine their business by leveraging digital and emerging technologies
- Capitalize on technology advances and leading practices in quality to achieve a competitive advantage
- Development of achievable, right sized and flexible quality practices that can be leveraged across the supply chain network
- QMS design and process remediation to align to leading practices

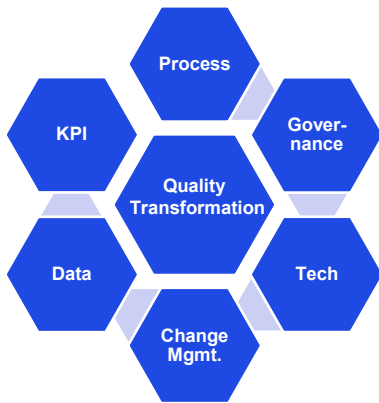
Quality Strategy	Quality Operations	Quality Management System	Computer Systems Validation	Quality Audit	Quality Technology and Digitalization
<ul style="list-style-type: none"> <li>• Strategy development</li> <li>• Organization alignment</li> <li>• Key Performance Indicator for monitoring Quality</li>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



# "Drive Measurable Improvement" on your Quality Management System (QMS)



## Quality Transformation - Focus on Delivering Business Value



- Signal detection for rapid response
- Quality and automation domain knowledge to determine optimal quality metrics and enhanced visualization
- Support translation of business need to effective process design and system enablement
- Balanced control environment design
- Operating model design capitalizing on shared services, COE and right sized organization
- Connected system enablement and digital integration
- Adaptive technology (RPA, AI/ML)
- System validation & testing
- Reinforced quality culture

### Why KPMG

#### Experience and knowledge

Providing practical approaches to complex business challenges, leveraging our experience in business, technology acumen and consulting capability

#### Industry insights

Bring insights to enhanced solutions with industry domain knowledge, and maintaining a pulse on changes in regulations

#### Quality value

Flexibility built into the organization to adjust to changes in business needs, enhance delivery effectiveness and manage the cost

#### Connect the dots

KPI's aligned to business strategy providing visibility into health of the quality organization and identify opportunities for continuous improvement

#### Professional relationship

Determine optimal practices to achieve consistency across the supply network while accounting for required local variants

#### Innovation

Leverage intelligent systems to drive business decisions based off objective data

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### KPMG Insights

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 [Insights & Resources](#)