



KPMG Life Sciences–Quality and Regulatory Consulting

Regulatory Affairs



- Operating model and process redesign
- RIM technology implementation support
- Automation and AI solutions
- Regulatory strategy enablement
- Support for adoption of new regulations, standards and regulatory requirements

Quality



- Quality strategy
- Quality operations transformation
- Quality management system
- Computer Systems Validation
- Quality audit
- Quality technology, automation and AI

M&A Support



- Pre-deal Quality & Regulatory assessments
- Future state operating model definition
- Day 1 readiness support
- Market authorizations and regulatory submission execution support
- Manufacturing cutover and supply continuity enablement

Helping our clients bring products to market more quickly, while reducing risk and enabling a sustainable approach to regulatory activities

Helping our clients transform the Quality function for the next generation of life sciences products, from strategy through execution

Helping our clients enable uninterrupted continued market access globally during mergers, acquisitions



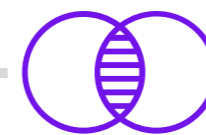
Extensive experience on complex projects—and we can scale as needed to meet your needs



Deep industry expertise and comparators—we have tailored approaches specific to RA and Quality



Highly-trained team members—our team has professional and software certifications



Combination of business and technical expertise—we can help you solve a wide variety of challenges



Toolkits and playbooks—we can help accelerate value and onboard quickly to drive impact