



Intelligent compliance for Life Sciences

Turning regulatory obligation
into operational advantage



In an era of unprecedented innovation, the life sciences industry faces a unique set of challenges. From pioneering new therapies and navigating complex regulations to optimizing global supply chains and attracting specialized talent, the path to growth is intricate. Life sciences executives need a trusted advisor with the deep industry experience and global reach to not only mitigate risk but also to unlock new opportunities and drive sustainable value.

The KPMG Life Sciences Risk Advisory team leads with AI-driven, data-powered insights to help organizations confidently navigate this dynamic landscape. Our technology-enabled approach helps you manage risk, ensure compliance, and optimize operations in support of a patient-centric future.

Why KPMG?

Our deep compliance and operations insight

Our deep commitment to the Healthcare & Life Sciences (HCLS) industry:



Global reach and experience

With over 40 accredited forensic practices and over 3,600 forensic professionals across the globe (over 800 in the US), we bring a world of life sciences experience to your doorstep.



Demonstrated industry leadership

We are proud to serve all of the top 25 global life sciences and Medical technology companies, as well as emerging biotechnology companies, giving us a broad perspective on the challenges and opportunities shaping the industry.



Dedicated regulatory insight

Our Center for Healthcare Regulatory Insights provides real-time monitoring and analysis of regulatory changes from Washington and around the globe, helping you stay ahead of the curve.



Executive peer network

Through our exclusive Chief Compliance Officer (CCO) Exchange and Forum, we connect industry leaders to discuss trends, risks, and leading practices in a confidential, peer-to-peer setting.



AI-powered, digital-first approach

We lead with an AI-first approach to transform compliance. By combining advanced analytics, strategic partnerships, and deep big-data expertise, we deploy technology solutions aligned with your compliance and IT priorities, unlocking significant enterprise value.

Third-party risk and commercial contract compliance audits



We empower organizations to proactively manage their third-party vendor risk landscape through AI-powered applications. Our approach allows organizations to shift from periodic assessments to continuous, real-time monitoring, leveraging data-driven insights to identify and prioritize risks presented by third-party vendors before they impact the business. By automating due diligence, facilitating vendor audits, and orchestrating remediation, we enable a more resilient and compliant ecosystem for your third-party vendor population, including but not limited to those vendors that support:

- Patient services
 - Specialty pharmacy, patient support programs/hubs, patient assistance programs
 - Independent charity patient assistance programs, commercial copay programs
 - Patient advocacy program assessments
- Speaker program vendors
- Contract research organizations
- Managed care
 - Pharmacy benefit manager, wholesalers, 340B, plan sponsor
- International distributors

Our forensic, risk, and operations services



We serve as support for our clients' compliance teams and provide outsourced managed services. Our goal is to help businesses navigate the operational requirements, costs, and risks associated with new regulations and industry-specific compliance mandates. We leverage AI-enabled technology solutions to drive efficiencies in manual compliance tasks, thus freeing up our clients to focus on more strategic activities. The services we deliver and technologies we implement are designed to be extensive, scalable, and tailored to the unique needs of each organization.

Regulatory compliance support



We help life sciences organizations by identifying process efficiencies and gaps in their existing compliance risk coverage, enhancing line of sight into trends and outliers, designing new controls to mitigate risk and enhance efficiencies, and implementing AI-driven technologies to streamline workflows and promote process automation. Our proprietary technology solutions have prebuilt requirements and workflows that can be utilized to baseline your processes and customized to support the future-state design of a variety of compliance areas, including:

- HCP/O Engagement
- Ongoing transaction monitoring and testing
- Transparency reporting (state and federal reporting)
- Risk Evaluation and Mitigation Strategy Program Audits

Investigations and eDiscovery



We support our clients' teams when investigations arise from identified compliance misconduct. We leverage proprietary solutions to increase efficiencies in the collection, storage, and review of data that relates to investigations and litigation.

- On Call Investigation support
- eDiscovery services

Compliance solutions



KPMG, LLP delivers next-generation technology solutions that modernize critical functions across commercial contracting, regulatory compliance, and core operations. Powered by AI, automation, and advanced analytics, our platforms help clients streamline workflows, enhance accuracy, and gain real-time insight into performance. The result: smarter decisions, stronger compliance, and more capacity to focus on advancing health and earning the trust of the communities they serve.

- KPMG Healthcare Professional Engagement Assist™
- Covered Entity — 340b
- Pharma Commercial Contracting Automation
- Health Authority Inquiry
- KPMG Enterprise Risk Management
- Transparency Reporting

Life sciences operations



We help transform and optimize quality and regulatory activities, implement key technologies, and provide critical M&A support.

- Quality and regulatory operating model transformation
- Quality and regulatory digital transformation (i.e. Sparta Trackwise Digital and RimSys implementation)
- GxP, supplier quality and manufacturing audits and remediation
- Computer system validation
- FDA observations and warning letter remediation support
- M&A due diligence and support

**Visit our website
to learn more**

Contact us

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