Turning risk into opportunity

Managing risk for life sciences organizations: KPMG can help

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Finding a way to move forward in a regulatory landscape with more questions than answers.

Negotiating the complicated interplay between pricing and corporate reputation.

Responding to payer mandates to forecast future outcomes.

Accepting that valuable new digital technologies also introduce potential cyber-attack vectors.

Addressing the fact that expansion to a global playing field brings new regulatory, cultural, legal, political, tax, and logistical challenges.

And, across it all, balancing the need for third-party support that helps your organization thrive amid the reality of a whole other set of risks.

This is your world. As a life sciences organization, you must transform to meet market realities and innovate for the future. But, at the same time, you have to manage associated risks. What if you could view risk management not as a burden, but as an accelerator of opportunity?

KPMG

Turning risk into opportunity

In our view, managing risk in life sciences should evolve from protecting value to creating it. Organizations that follow this model are still able to protect their businesses, but gain the freedom to innovate, expand across jurisdictions, get strategic insights out of patient data, share intellectual property with strategic partners, and bring new products to market with less apprehension.

KPMG has a well-established heritage helping the world's leading life sciences organizations manage risk. As our clients have evolved, so has KPMG. Together with our clients, we are able to stay several steps ahead of regulatory change, industry disruption, third-party compliance issues, and the ever-expanding threat of cyber-crime.

Our risk practice includes not only some of the world's leading risk experts, but strategy professionals, pricing specialists, information technology leaders, and the unparalleled Center for Regulatory Healthcare Insight. Our ability to recommend both long-term risk management strategies and immediate responses is informed by our world-class data & analytics practice, including proprietary reference data sets and superior analytics tools.

As life sciences organizations are faced with a dramatically changing industry, they are increasingly turning to KPMG to blend risk and compliance principles with more strategic efforts to achieve innovation, growth and competitive advantage.

Get the most out of your efforts

With KPMG's counsel, life sciences organizations are able to pursue innovation while addressing risk across regulatory, technology, financial and operational functions.

Regulatory

- **Ensure that future-directed business model,** information technology and operational decisions are not at odds with anticipated regulatory changes.
- **Mitigate reputational, brand and monetary risks** associated with misreading government pricing policies, or outsourcing pricing programs through a managed services approach.
- **Get ahead of regulatory compliance requirements** by stratifying and analyzing potential actions according to likelihood, pace and degree of impact.
- **Stay within patient data protection guidelines** mandated by HIPAA and the upcoming General Data Protection Regulation (GDPR) being introduced in Europe.
- **Foster strategic two-way communication** and mutually beneficial relationships with governmental regulatory bodies.
- **Ensure that product quality and patient safety** are suitably protected to mitigate the risk of regulatory action.

Technology

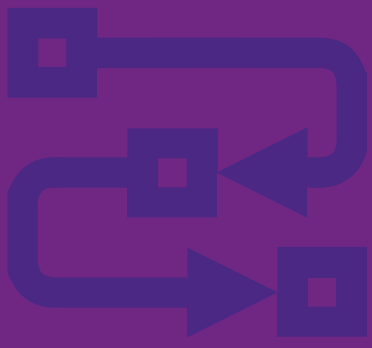
- **Pursue technology innovations** that facilitate patient education, medication compliance, and appropriate sharing of intellectual property, while minimizing the potential for cyber-attacks.
- **Increase likelihood of medical device and wearable adoption** by integrating cyber-security safeguards during the earliest phases of product design.
- **Better protect organizational systems and intellectual property** from cyber-attack by creating a culture of cyber security that blends technology protections, sound policies and staff education.

Financial

- **Prioritize market access strategies** by separating likely regulatory actions from hype.
- **Ensure products receive favorable formulary placement** by addressing pricing issues during the research and development stage.
- **Enter into mergers, acquisitions, and partnerships** with full understanding of the potential for inherent risks and liabilities.
- **Approach cost takeout efforts aggressively**, as cost pressures can negatively impact internal control and compliance funding.
- **Take a proactive stance against fraud, waste and abuse** stemming from off-label product use, false claims, and counterfeit drugs.

Operational

- **Institute third-party governance and due diligence programs** to reduce financial and operational risks from suppliers, partners, agents, and customers.
- **Evaluate risks associated with third-parties** in the supply chain by introducing advanced techniques, such as serialization.
- **Customize clinical trial strategies** to minimize geography-specific risks and regulatory compliance issues.
- **Utilize internal audit as a change agent** to address risk challenges, evaluate risk management programs, and influence employee behavior and organizational culture.



KPMG's advisors

Recent additions to the risk consulting practice at the KPMG U.S. firm include:

Regina Cavaliere, JD, is a principal in KPMG's Compliance Risk Management practice with a focus on forensics. She has experience building and enhancing comprehensive ethics, compliance and quality programs specifically for life sciences companies.

Prior to joining KPMG in 2015, Regina was Vice President and Chief Compliance Officer for the US affiliates of a Japanese pharmaceutical/medical device company. She led the ethics, quality & compliance group, overseeing a comprehensive ethics and compliance program. Her experience there encompassed healthcare law compliance, internal investigations, auditing and monitoring, training, privacy and information security, transparency, policies and procedures, document control, contact call centers, manufacturing quality, and clinical trial/GCP quality.

Jennifer Shimek is a principal in KPMG's Advisory Services practice, where she specializes in regulatory enforcement and compliance in the life sciences and healthcare industries. Her clients include providers, payers, home health organizations, hospices, labs, DME, and medical device companies. Jennifer offers a unique blend of core industry, business strategy, and compliance skills. She has conducted complex payment analyses, compliance assessments, Independent Review Organization (IRO) services, investigations, and complex coding/billing analyses.

Jennifer's perspective was shaped during her tenure as the Chief Operating Officer for a large orthopedic specialty physician group practice, which included sub-specialties, pain management, pharmacy, physical therapy, and an ambulatory surgery center.

David Remick is a partner in KPMG's Healthcare Advisory Practice, specializing in cyber security and successful information technology-related change at global organizations. David leverages his knowledge of accounting, audit, technology, and risk management to help organizations realize their IT, internal controls, data governance, cyber-security, information protection, and privacy-related objectives.

Rick Zimmerer, CPA, is a Principal and co-leads KPMG's Life Sciences Regulatory Enforcement & Compliance Practice, as well as leads the Government Pricing and Contracts Practice. He has over 25 years of experience assisting clients in navigating business challenges and opportunities that arise from complex contractual relationships, expansive government regulation and significant litigation.

Matt McFillin, CPA, CFF, is a Partner in the KPMG Forensic practice. He provides investigative and dispute services for attorneys and corporate management on a variety of matters involving financial statement fraud investigations; foreign corrupt practices act ("FCPA") issues, government contracts and business disputes. Matt has been involved in a number of matters which required him to present to and assist the Securities Exchange Commission ("SEC"), U.S. Postal Inspectors and the United States Attorney's Office. His experiences also include providing auditing and consulting services to Fortune 1000 companies.

Kelli J. Brooks is a Principal in the Forensic practice and provides companies and their law firms with litigation and investigation consulting services, including electronic discovery strategies and discovery management services. Kelli has a wealth of experience in the areas of litigation, investigations and discovery management, which includes the entire lifecycle of evidence identification, preservation, collection, processing, hosting, managed review and production. Prior to joining KPMG, she was a partner in a San Diego and Los Angeles based law firm for ten years where she worked in the firm's Litigation Practice Group and focused on corporate litigation.

Chris Cobourn is a Managing Director in KPMG's Life Sciences Regulatory Enforcement & Compliance Practice focusing on Government Contracts & Pricing Practice, and leads KPMG's Managed Service Operations (MSO), providing outsourced Commercial and Government Operations support for the Pharmaceutical and Biotech industries. He has nearly 20 years of experience assisting organizations with their Government Programs (GP) Compliance and Operations, including GP audit and assessment, methodology development, GP recalculations, and investigation support. He has provided expert testimony in litigation and his support for manufacturers involves interactions and negotiations with, the OIG, DOJ, CMS, VA, SEC, NAMFU.

Angela Rodin is a principal in KPMG's Washington, DC Risk Advisory Forensic Practice. She has responsibility for developing and maintaining comprehensive ethics and compliance programs, and providing assurance to the Board and Audit Committee on key risks, auditing & monitoring outcomes, and internal investigations.

Angela has 17 years of experience in the pharmaceutical industry having served as Compliance Officer for global support functions, VP, Head of Global Investigations and Business Monitoring, Head of Global Internal Audit, and Head of Information Technology Audit.

Related thought leadership

The ethical incentive program – Don't let aggressive growth targets drive questionable sales tactics

As the financial sector reels from government investigations into incentive programs, life sciences companies are asking whether they could also miss critical risks related to their incentive programs. Find out the tough questions life sciences boards should be asking about their programs.

Pharma Outlook 2030: From evolution to revolution

Pharmaceutical companies that manage to embrace the most appropriate archetypes, and master disruption, have the greatest chance to deliver real value to patients and be successful in the new, disrupted world.

Value-based Pricing in Pharmaceuticals: Hype or Hope?

Value-based pricing (VBP) is receiving increased scrutiny from the public and government. KPMG outlines the challenges facing VBP implementation, notably the need to define and measure outcomes, and overcome any regulatory and legal barriers.

Medical Device Cyber Trends: Cybersecurity in the medical device industry

This brief highlights how understanding technical requirements impacting the medical device industry is only part of the equation. Additionally, medical devices manufacturers must detect signals of change and capitalize on disruptors before their products become obsolete.

The real risk in life sciences – Neglecting to evolve compliance programs

Over the past decade, compliance programs at life sciences companies have grown in scope and complexity. Now, executives and boards of directors are questioning whether these larger programs are effectively reducing their risks, or have they become too onerous to deliver real business value?

Personalized care requires personal data – GDPR in Life Sciences Reference Card

Healthcare & Life Sciences Global life sciences organizations are working hard to meet the May 2018 compliance deadline for the European Union's General Data Protection Regulation (GDPR). To help organizations begin to refine their approach to GDPR compliance, this reference card outlines the primary areas on which life sciences organizations should focus.

Awards and acknowledgments

CFO Innovation crowned KPMG as Best in Risk Management Advisory at the CFO Innovation Awards 2016.

ALM recognized KPMG as a "Vanguard Leader" in Supply Chain Risk Consulting and Cybersecurity.

Cyber Risk Integration and Stakeholder Management named KPMG as "Best in Class" for Governance & Control.

M&A Today named KPMG as US Anti-Money Laundering (AML) Firm of the Year in 2016.

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