



# Thriving in an uncertain environment

**The pharmaceutical  
industry refocuses**

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**Everything about the pharmaceutical industry is changing.** Payment models, operating models, and business models are being disrupted. Regulatory structures are being remodeled. Customer preferences and changing demographics are shifting demand. Industry convergence, mergers, and acquisitions are altering the value chain and creating new opportunities. New competitors and research ventures are driving up the competitive pressure. And changes to the current administration coupled with geopolitical shifts are providing another level of uncertainty.

In fact, it is becoming increasingly clear that today's pharmaceutical companies will find it challenging to survive in tomorrow's healthcare environment. Transformation is now an imperative.

At KPMG, we work across the healthcare continuum and understand the challenges and opportunities that are being created in today's rapidly changing healthcare environment. We think we know what it will take to successfully transform into tomorrow's leader. Let us show you how.





# Beyond convergence: The search for value

**As pressure mounts to contain (and reduce) the cost of healthcare, pharmaceutical companies are challenged to prove their value against higher expectations. Value is assessed by the patient, the provider, and the payer—and they don't all use the same measures. Pharmaceutical companies must determine if a cure is worth a higher cost versus managing a chronic condition. As healthcare continues to transform, so must the pharmaceutical industry in order to deliver both the scientific breakthroughs patients need and the innovation in their operating model to make sure their treatments get to the people who need them.**

We believe that this *search for value* will drive pharmaceutical, medical device, and diagnostics companies, as well as providers and health plans, to tap into new technologies, develop new business models, and create new partnerships that will ultimately underpin the next wave of transformation.

Industry convergence is clearly occurring. The big question for forward-looking organizations is how they plan to tap into these innovative trends to create value and sustain competitive advantage in the new environment, now, and for years to come.

## **Key questions for pharmaceutical organizations:**

- 1** What is our company's role in the transforming world of healthcare? How do we deliver value to patients and create value for our shareholders?
- 2** How do we need to change our current business model in order to thrive in the future? What new competencies do we need, and do we build, buy, or partner to get them?
- 3** Are we leveraging new sources of insight and analytics? How do we optimize our operations and prove the value of our therapies?
- 4** Where do we fit in the continuum of care? How do we work with providers and payers to deliver the best outcomes for patients?
- 5** Are we adequately evaluating the risks and opportunities in the changing global political economy? What decisions can we make now to position us for the future?
- 6** How do we best leverage new technologies in our business? How do we protect ourselves and our customers from cyber threats?

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# KPMG advantage

**We are one of the leading professional service firms in the pharmaceutical sector, providing a wide range of audit, tax, and advisory services to help our clients grow their business, enhance their performance, and control their risks.**

Our professionals understand your business, your challenges, and the changing environment that you operate in. We combine this insight with our recognized track record in corporate transactions and restructuring, commercial model transformation, and regulatory compliance and risk management to deliver practical solutions to the issues facing today's pharmaceutical companies.

Our independence and objectivity means that we are focused on making the best choices for our clients, not ourselves or our business partners. And our multidisciplinary approach helps ensure that we always take a 360-degree view of our clients' challenges to help them understand the broader context of their business decisions.

With a global network that spans all major markets and includes more than 4,000 professionals dedicated to healthcare and life sciences, our global life sciences clients know they can tap into global insights and foreign capabilities that match their business footprint.

Our commitment to the sector is clear. We have invested in developing a highly-experienced global practice with a strong approach to knowledge-sharing, led by professionals with decades of hands-on experience in the pharmaceutical sector. And we are continuing to make capital investments into researching and deploying new technologies to support our clients.

Most important in a rapidly changing world, our forward-thinking professionals—many with direct industry experience at Fortune 1000 pharmaceutical companies—focus on the horizon as well as the here and now, anchoring our experience in today's realities while helping pharmaceutical organizations anticipate and prepare for tomorrow's possibilities.

And that is why our clients consistently choose KPMG.



## KPMG by the numbers

– KPMG is one of the largest providers of professional services to healthcare and life sciences organizations globally

– More than 4,000 global healthcare and life sciences professionals, including:

4,000

• 2,800 U.S.-based partners and professionals

2,800



– We serve 100 percent and audit 24 percent of the top 25 global pharmaceutical and biopharma companies. We also work with:



• 100 percent of the top 10 U.S. medical device companies

• 9 of the top 10 health insurers

• Half of top 200 healthcare provider systems

• Half of the academic medical centers

– KPMG International’s network of independent member firms operates in more than 150 countries globally

## What others are saying about us

– Our success as an HCLS leader has been recognized by industry analysts and media influencers.

– Black Book, a healthcare-centric research company, recently awarded KPMG’s healthcare practice with the following awards:

• #1 Ranking for Value-Based Strategy Consulting, 2016

• Highest Client Satisfaction in Healthcare Management Consulting, 2016

• #1 Ranking for Healthcare Operations Transformation Consulting, 2016

– Forrester and Gartner have rated KPMG a “Leader” in Data & Analytics.

– *The Forrester Wave: Insights Service Providers, Q1 2017, from Forrester Research.* “KPMG’s broad ecosystem is the gold standard among insights service providers.” And added that KPMG is at “the forefront of innovation.”

– KPMG was named an ALM leader in:

• Human Capital Risk Management Consulting; Human Resources Consulting Research Series, August 2016

• Finance Excellence Consulting; Strategy & Operations Consulting Research Series, September 2016

KPMG has also been ranked as a High Performer in the HfS Blueprint Report: Intelligent Automation 2016. The firm was also named Best in Risk Management Advisory at the CFO Innovation Awards 2016.

## Commitment to serving our communities as well as our clients:

• No. 12 ranking on the 2017 Fortune’s 100 Best Companies to Work For

• Top 50 ranking for Diversity; DiversityInc.

• In Top 10 of *Working Mother* “100 Best Companies”

• Best for Vets Employers, Military Times

• Best Places to Work for LGBT Equality

• Board representation on the Healthcare Businesswoman’s Association (HBA)

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# Key market drivers for the pharmaceutical industry

**We have a long track record of helping pharmaceutical companies create and implement practical solutions to their most complex challenges. Based on our experience in the sector, we believe there are five major trends that are altering the business environment for the pharmaceutical industry.**

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## **Digitization to automation**

The widespread digitization of the healthcare sector has led to significant investments in core health IT, mobile, and data management. Now organizations are taking the next step, adding cognitive computing and leveraging robotics process automation (RPA) to help eliminate manual errors, reduce labor costs, improve consistency in decision making, and tighten compliance. From drug development and manufacturing to sales force management and compliance, automation will both drive and enable transformation in the pharmaceutical sector.

## **Regulatory compliance innovation**

Over the past decade, regulatory change, growing compliance requirements and tax system adjustments have been both a catalyst and a barrier to transformation in the pharmaceutical industry. Today, however, many organizations are starting to rethink their complex regulatory and compliance architecture to find opportunities for simplification, efficiency, and competitive advantage. As technology starts to play a greater role, many are finding significant improvements in both cost and compliance while also uncovering new opportunities to drive growth.

## **Consumer commercialization**

Consumers are more empowered than ever and are demanding information in new ways. Health plans are demanding a shift from treatment to prevention. At the same time, the time healthcare professionals are spending with sales reps is diminishing. This is driving significant change in not only the way pharmaceutical companies *detail* and market their products; it is also driving a massive transformation in the relationship between patients, healthcare professionals, and pharmaceutical companies. Organizations will need to work harder to understand their customers in order to win in the new environment.

## **Cybersecurity prioritization**

With the black-market value of electronic health records continuing to rise, healthcare organizations are now on the frontline of the criminal cybersecurity threat. Customers, regulators, and patients demand that information remain secure, not only within the four walls of the organization, but across the entire value chain. As technology and digital start to play a greater role in the pharmaceutical life cycle, greater emphasis is being placed on prevention strategies, controls, remediation, and attestation reporting through frameworks such as SOC2 and HITRUST.

## **Analytics integration**

Data and analytics (D&A) underpins and informs much of the transformation now underway across the sector. By expanding their use of data, analytics, and technology, pharmaceutical companies are identifying opportunities to make significant improvements in decision making (particularly related to patient care and new product development), back-office operations, regulatory compliance reporting, and drug discovery and development. Improving data management, developing new analytics capabilities, and enhancing trust in D&A will be key to driving value in the new environment.

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# Key perspectives for the pharmaceutical industry

**At KPMG, we don't just work with the world's leading pharmaceutical organizations, we help them innovate for tomorrow. No matter what business challenge your organization is facing, KPMG has the capabilities, experience, and insight to help you solve them.**

## **Business model optimization**

As digital labor and Robotics Process Automation (RPA) begin to play a greater role across the pharmaceutical value chain and organizations start to search for value from their integration investments, our professionals help organizations find the right target operating model to achieve their long-term cost objectives and then work with them to operationalize it.

## **Tax and regulatory compliance**

From developing and improving tax and regulatory strategies through to the optimization of compliance, our professionals provide integrated advice across the full life cycle of tax, risk, and regulatory issues, including compliance and monitoring of new regulations; working closely with regulators and tax authorities to understand future direction; improving operating models of the tax and regulatory affairs functions; and conducting third-party assessments.

## **Commercial model transformation**

The traditional sales channels are blurring, and patients are taking an increasingly active role in their treatment decisions. We help pharmaceutical companies understand the drivers of customer engagement in today's marketplace and create innovative strategies to help inform patient decisions while improving overall safety and compliance.

## **Information protection and cybersecurity**

We recognize that strong cybersecurity is a business enabler. We help organizations improve their cyber defenses in a way that goes beyond regulatory requirements to help pharmaceutical organizations build trust with their customers and confidence in their systems. From cyber defense and recovery to creating and implementing a strong cyber strategy, KPMG professionals understand how to derive value from a strong cyber defense.

## **Disruptive technologies and advanced analytics**

Data is an organization's most valuable asset. But it also takes the right technologies, capabilities, and analytics to turn that data into innovative strategies that drive business performance, patient safety, and growth. Our experienced data professionals understand the value of data and know what it takes to help organizations move from data to insights and from insights to value.





# How we've helped



## Transforming the commercial model

The performance of the U.S. business of a top five global pharmaceutical manufacturer varied significantly across its local markets, with some significantly underpenetrated relative to top performing markets. KPMG worked with the company to identify the issues causing the under-penetration and developed a three-phased approach to success. In phase 1, KPMG assessed the changing dynamics in each market to determine how patient care was evolving. In phase 2, KPMG identified customer needs by conducting research on top-priority customers, assessing their receptivity to different levels of service/support, and analyzing customer responses to alternative value propositions. In phase 3, KPMG developed go-to-market plans, realigning commercial resources in the local markets to ensure focus on the highest potential customers and alignment of capabilities with customer needs. In the 18 months since the project was completed, performance has risen significantly, matching those of the highest-penetrated markets.



## Rethinking the compliance strategy

When a multinational life sciences manufacturer that boasts hundreds of compliance offices and a sterling reputation for compliance excellence wanted to reassess its strategy, they called KPMG. While the organization was content with their progress, key stakeholders were concerned that recent changes to their operating models and regulatory requirements had changed the need to address risks within their compliance program. Our review found that the organization faced unanticipated risks related to anti-bribery and corruption, privacy, government pricing, off-label usage, and cybersecurity. International operations and growth efforts were not being properly managed. Monitoring was not optimized and resources were being wasted. KPMG helped the organization achieve an improved view of their most critical risks. Based on KPMG's review, the organization shifted their resources to tasks that delivered the highest value to the organization and pushed accountability for compliance monitoring back down to the business. As a result, they have improved value, enhanced efficiencies, and reduced complexity for themselves and their organization.





### Operations and margin improvement

Following a long period of steady growth, our client faced slowing top-line growth for one of its largest brands along with lingering integration issues resulting from several previous acquisitions. Although committed to growth through innovation, the economic environment and growing competitive intensity had placed pressure on margins and constrained our client's ability to invest as its support costs had been increasing at three times the pace of revenue growth. Our client needed to rapidly chart a course towards a sustainable operating model and improved profitability. KPMG was engaged to help provide cost transparency and develop a strategic plan for senior leaders to confidently move towards a leaner, more agile global support model leading to a multiyear transformation. We resolved challenges that were limiting cost competitiveness, cost transparency, and support for the core business needs while identifying potential EBITDA value opportunities.



### Creating a world-class supply chain

When a U.S.-based global healthcare services company purchased a *carved-out* division from a larger multinational, they knew they needed to work quickly to integrate operations if they hoped to secure maximum value from the deal. The U.S.-based company already boasted a robust domestic supply chain. But its existing international manufacturing, warehousing, and distribution operations were limited. The acquisition was an opportunity to firmly establish new adjacent and international capabilities. Working with a team from KPMG, the buyer quickly evaluated and documented the key capabilities of the target company. Critical aspects of the supply chain were assessed—including the new Target Operating Model, the sourcing strategy, product flows, financial transaction flows, and regulatory and quality controls. By conducting careful planning prior to integration, the buyer achieved an issue-free operational Day 1 with no disruption to demand, inventory management, or customer shipments. And they had successfully stood up and integrated commercial and supply chain operations in over 50 jurisdictions.



### Identifying cyber risk

KPMG worked with one of world's largest pharmaceutical companies to identify cyber risks faced by business units operating Operational Technology (OT). KPMG held over 30 key stakeholder interviews to assess the cybersecurity landscape of the manufacturing and laboratory environment. We conducted a series of operational technology Threat and Vulnerability Workshops to assess risks to the operational technology assets and developed a plan for treating risks. High-value assets critical to the business process were identified together with the impact of a compromise on the assets or process, threats generating a Heat Risk Map for Board reporting. Client business unit executives better understood their current security posture and could focus strategic improvements on the right areas to receive best value for their security investment. The report's detailed findings and technical instructions enabled improved security of day-to-day operations and technical configuration details.



### Assessing global regulatory technology

A major life sciences company defined a goal to unite all regulatory activities under a single global regulatory operating model supported by one global regulatory platform. KPMG assessed the current state of business through a series of stakeholder interviews and review of existing materials and process documents for 100+ systems and identified the technology capabilities required to support global regulatory business strategies and operational direction. As a result, KPMG developed an IT road map and execution plan, which lead to a new global regulation operations target operating model (TOM) for the business. This new regulatory model is currently in the process of implementation.

# On thought leadership

**We're not just business leaders, we're also thought leaders. KPMG professionals invest significant time understanding trends, comparing methodologies, and sharing best practices. Our people can frequently be found presenting at leading industry events and conferences and are often cited in both trade and mainstream media as experts in their field.**

We continually invest in thought leadership, Centers of Excellence, research, and knowledge-share forums to help clients stay informed of industry, technical, and regulatory challenges worldwide. Our industry white papers and research spans a wide range of topics that have direct relevance to pharmaceutical and biotechnology organizations.

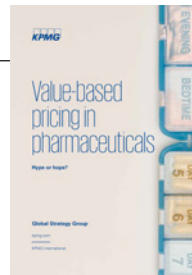
For particularly complex business challenges and industries, KPMG sponsors numerous industry-focused institutes that provide a wealth of relevant information. Visit our Healthcare and Life Sciences Institute to learn more at: <http://www.kpmg-institutes.com/institutes/healthcare-life-sciences-institute.html>



## **Pharma Outlook 2030**

KPMG looks at the future of the pharmaceutical industry and sees three company *archetypes* emerging —

1. Active pharmaceutical portfolio company,
  2. Virtual value chain orchestrator,
  3. Pharmaceutical niche specialist.
- Those 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?**

The industry is under the public and political microscope, with demands for an alternative to the traditional, sales-led approach to marketing. One payment model receiving increasing attention is value-based pricing (VBP). KPMG outlines the challenges facing VBP implementation, notably the need to define and measure outcomes, and overcome any regulatory and legal barriers. We discuss how to overcome these challenges and feature a case study.



### **The real risk in life sciences: Neglecting to evolve compliance programs**

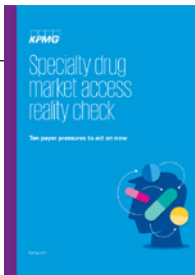
Over the past decade, compliance programs at

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?



### **Intelligent augmentation: Life sciences companies are a natural fit for digital labor, from robotics to cognitive**

Life sciences companies that aren't thinking about integrating advanced automation into their workforces probably should be. KPMG explores the growth and role of robotic process automation (RPA) to help organizations scale back-office IT, speed up clinical trials and drug releases, increasing accuracy in pharmacovigilance, and turbo-charging big data.



### **Specialty drug market access reality check: Ten payer pressures to act on now**

KPMG explores the debate about market access in the specialty drug area and provides insight into opposing views on this topic, as well as ten actions companies should consider if they see themselves falling into one of three categories: "Act Now," "Watch & Wait," or "Deprioritize."



### **Global business services in life sciences: A window to the future**

The report explains the orientation of end-to-end processes as part of global business services (GBS) that can enable a company to adopt new technologies more rapidly and benefit from them faster. The report also clearly lays out the five benefits, the ten dimensions, and five levels of maturity of GBS. KPMG's report provides a great starting point for any life sciences organization trying to achieve true success in the future or for those companies looking to overcome some stumbling blocks along the way.



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