2016 Risk in review: Going the distance Pharmaceuticals and life sciences industry analysis

Pharma and life sciences: Moving fast—but are they built to last?



Each year, PwC's Risk Assurance practice surveys senior executives, board members, and risk professionals worldwide to gain insights on current risk management practices and perspectives.

For our fifth annual Risk in review study, we received nearly 1,700 survey responses across 23 industry segments and conducted one-on-one interviews with executives from select Fortune 100 companies to help bring our findings to life.

Our survey showed that respondents in the pharmaceuticals and life sciences sector—representing a mix of biotech, medical devices, and pharmaceutical companies—are the most likely of all sectors surveyed to expect significant growth (i.e. of more than 5%) in both profit margins and revenues in the next two years. These companies have pursued a number of aggressive changes to their businesses to drive growth, such as identifying new products, making acquisitions, creating joint ventures, entering into partnerships, developing new marketing channels to reach end consumers, and moving into markets that have huge regulatory issues.

But even as these businesses translate their appetites into rapid real-world growth, our study findings suggest that their risk management programs may not be keeping pace, thereby imperiling their long-term success.

In the pages that follow, we detail the five top study findings relevant to pharmaceutical and life sciences companies.



The important connection between risk resiliency and risk agility

For many years, risk management has focused on protecting the brand and keeping the company out of trouble. "But if you're doing it right, risk management is about playing not only defense but offense as well: it's about value protection as well as value enablement," says Brian Schwartz, PwC Principal and Risk Management and Compliance Solutions Leader. This year's Risk in review study highlights the importance of that balance.



Risk resiliency: The ability to withstand business disruption by relying on solid processes, controls, and risk management tools and techniques, including a well-defined corporate culture and a powerful brand.

Risk agility: The ability to alter and adapt risk management infrastructure to respond quickly to changing markets, customer preferences, or market dynamics.

Source: PwC's *Risk in review 2016: Going the distance*, pwc.com/riskinreview.

Performers and movers: Building the risk agility/risk resiliency matrix

In our survey, we asked companies questions about their risk agility and risk resiliency capabilities, processes, and corporate characteristics. We then scored their answers on a 0-100 scale to create a risk resilience/agility matrix. Respondents across industries fell into four quadrants.

Overall, respondents in the pharma and life sciences sector fell squarely into the bottom-right quadrant of our matrix, scoring higher on risk agility than most sectors but lower on risk resiliency. These sector's respondents are composed primarily of midsize biotech companies, medical device manufacturers, and pharmaceutical developers. Sixty percent of respondents in this sector have annual revenues of \$1 billion to \$20 billion.

This paper further explores responses by pharma and life sciences companies.



Top finding #1: Pharma and life sciences companies are expanding their offerings and aggressively pursuing acquisitions to boost growth

Pharma and life sciences companies are amongst the most likely of all sectors surveyed to expect significant growth (i.e. more than 5%) in both profit margins and revenues during the next two years. To realize those expectations, they are emphasizing strategic acquisitions as well as development of new products. In fact, the sector saw a record for total closed deal values in 2015: \$402.9 billion, compared with just \$169.3 billion in 2014.



40% of total respondents



of pharma and life sciences respondents have increased their product offerings in the past 18 months versus 72% of total respondents



of pharma and life sciences companies have made strategic acquisitions in the past 18 months versus **49%** of total respondents

In the past two years, given the focus on acquisitions in the sector, companies' risk profiles have often shifted quickly. To be successful and not hinder growth, the integration of operations, products, and organizations demands a different lens on risk management. Is your organization effectively leveraging risk management through this rapid change, and has it answered the following questions?

- How can better risk management help clear the path for more-effective and successful mergers and acquisitions?
- Is your company's chief risk officer or equivalent involved in integrating business processes and models of newly acquired firms?
- The rapid pace of mergers and acquisitions will have to taper off sometime. What steps will your company take to expand its product pipeline, and how involved is risk management in that strategy?
- Has your organization considered a specialized focus, and has risk management been involved in those conversations?

Top finding #2: High risk agility is key in the pursuit of new opportunities

Risk agility means not only being able to get ahead of some risks before they become roadblocks but also having the skills to turn risks into opportunities. Pharma and life sciences companies outperform most sectors in their risk-agility scores. They are more likely than respondents overall to say they can identify and rapidly pursue opportunities ahead of their competitors and can change business processes and organizational structure to meet changing market needs.



of pharma and life sciences executives say they identify opportunities ahead of their competitors versus **45%** of total respondents



of pharma and life sciences respondents say they can change business processes and organizational structure to meet new market need versus 41% of total respondents



of pharma and life sciences executives say they are good at rapidly pursuing growth opportunities versus **41%** of total respondents

53.9

Pharma and life sciences' risk agility score (out of 100) is among the **highest** of all industry subsectors surveyed versus an average 50.14 score for total respondents

New entrants are forcing companies to either become more agile and to take chances, or risk being outpaced or even leapfrogged. "Agility is something that needs to be continually improved upon to create momentum," says Craig Cleaver, PwC's US Pharmaceuticals and Life Sciences Risk Assurance Leader. To do that, pharma and life sciences companies should answer the following questions.

- · Are you reviewing your company's growth and business models in response to new industry entrants?
- Does your company have a well-defined process for identifying opportunities and pursuing them quickly in addition to factoring in how to manage key risks along the journey?
- Is your company's acquisition process streamlined and highly agile? Can you set the process in motion quickly to take advantage of new opportunities?
- Do you have a playbook of integration risks and integration considerations? Does it get updated regularly based on learnings from prior integrations?
- For smaller companies, how agile is your company's IT infrastructure? Could it easily integrate or leverage the IT system of a merger partner?
- For partnerships, do you have a risk management strategy for change-in-control situations?

Top finding #3: Improving risk resiliency creates a stronger foundation for enduring success

In contrast to their risk agility strengths, pharma and life sciences companies lag other sectors on metrics that indicate strong risk resiliency, including having solid business continuity strategies, documenting risk management processes, and ensuring their risk management approaches evolve over time. Our research shows that although agility is essential for generating shorter-term growth, companies must invest in risk resiliency to sustain that growth over the longer term—an important caveat for this high-growth industry.



53.12

Pharma and life sciences' risk resiliency score (out of 100) is among the **lowest** of all industry subsectors surveyed versus an average 57.91 score for total respondents

As players in a highly regulated industry, pharmaceutical and life science companies have an opportunity to become more resilient. Companies in this sector should answer the following questions.

- When you acquire and integrate companies, do you carefully assess the risk resiliency of the acquired businesses and ensure it aligns with that of your own company?
- Do you regularly review and update your company's risk management practices to address both immediate and emerging risks? Is your risk management program integrated into the company's existing strategic planning processes and aligned to its business strategy?
- Have you reviewed your supply chain and created a strategy to see to supply chain continuity? to deal with major patient safety situations? to manage cybersecurity incidents? to handle third-party-relationship disruptions (consider chief risk officer or chief marketing officer relationships)?

Top finding #4: Adopting advanced risk management tools and techniques boosts both risk resiliency and risk agility

Our study found that pharma and life sciences companies are notably less likely than are overall respondents to use many of today's advanced risk management tools. They also lag in documenting their risk management processes.

By building agile and flexible risk management frameworks to identify, monitor, and mitigate risks, pharma and life sciences companies can boost both their risk agility and their risk resiliency. Key tools and techniques to focus on include identifying key risk indicators (KRIs), aggregating risk against the company's overall risk appetite, undertaking reputation assessments, and developing scenario-planning capabilities.



"Many companies see risk management as an inhibitor of growth, as they often layer on regulatory controls instead of finding common practices that cut across regulations to leverage once and operationalize, " says PwC's Cleaver. "It's important to put risk management tools in place to build resiliency and establish a foundation for growth." Pharma and life sciences companies should answer the following questions.

- Have you quantified how much risk you're willing to take on to pursue growth, and have stakeholders been engaged in the decision-making process?
- Does your company have a process in place to identify changing regulations and adapt thoughtfully rather than reacting late, which can be costly?
- · How can your company leverage risk management to differentiate itself in a highly regulated environment?
- Do you have an understanding of the risk management tools needed to build agility and resiliency as the business grows?

Top finding #5: Pharma and life sciences companies should focus on better alignment between risk and business operations

Pharma and life sciences respondents are far less likely than are respondents overall to say their companies have strong alignment between business strategy, risk management, and business continuity management. They are also less likely to say their risk management function is aligned with strategic planning, operations, or finance.

Aligning risk management with a company's strategic objectives is more than a check-the-box exercise; it requires an active mind-set and frequent communication. Executives in the pharma and life sciences sector have an opportunity to significantly improve their efforts in this area.



Too often, risk management sits outside the circle of leadership and strategy. Alignment is important, and the following questions should be answered.

- What does alignment mean at your company? How does the senior executive team achieve it?
- Does risk management have a seat at the table when it comes to assessing risks related to strategy, acquisitions, or other key decisions?
- In what areas of the business is the connection with risk management strongest—and weakest? How do you apply the alignment techniques that work well in your organization?

Summary: Leveraging risk management for enduring growth

The fast-moving pharma and life sciences industry is facing significant upheaval and competition in a heavily regulated environment. Genomics and big data are changing the landscape for drug discovery, and companies are facing widespread pressure to lower drug prices.

To get the greatest benefits from their risk management programs, pharma and life sciences companies need to realize that agility without resiliency raises longer-term risks around business sustainability. Our analysis shows that although pharma and life sciences companies are clearly among the most risk agile, agility alone doesn't always yield long-term business success. Building an effective, risk-resilient organization and a deeply ingrained culture of risk management across the company can be challenging, but it is necessary.

Pharma and life sciences companies can pursue a number of activities to strengthen their risk management programs. They can:

- Incorporate advanced risk management tools and techniques into their analysis when considering strategic acquisitions and pursuing other avenues toward business growth.
- Strengthen alignment between risk management and business functions as a whole, including operations—especially when it comes to the C-suite and management.
- Ensure that risk management and compliance programs are aligned with the company's business units and are involved in developing products and service offerings.
- Reassess the risk management framework on a regular and ongoing basis to ensure it remains relevant as new risks and opportunities emerge and as the external environment for pharma changes.

To learn more about Risk in review: Going the distance, please visit pwc.com/riskinreview.

At the site, you may download the full report, benchmark your risk profile, and view other, related information.

For comments or questions on business risks the pharma and life sciences sector faces, please contact:

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