



The future of the life
sciences industries:
Transformation amid
rising risk



Foreword



Charles Darwin once said, “It is not necessarily the strongest that survive or the most intelligent but the one most responsive to change.” The same can be said of businesses confronted with new market realities—and the life sciences industry is no different. There are numerous factors necessitating a new way of doing things. The traditional sales base for pharmaceutical companies is rapidly shrinking due to loss of patent protection and competition from generics. The costs of innovation and R&D have skyrocketed. Governments and insurers are wavering over the reimbursement of new products. Reputational risk, an increased emphasis on transparency from regulators, and the impact of non-governmental organizations are also presenting considerable pressures. Transformation is fast becoming an imperative—especially given today’s volatile economic outlook.

But are life sciences companies prepared to transform themselves—and if so, how? In seeking to answer these questions, the Deloitte Touche Tohmatsu (DTT) Life Sciences and Health Care (LSHC) Industry Group, in collaboration with the Economist Intelligence Unit (EIU), conducted a research program in which 360 senior life sciences industry executives were surveyed and leaders of the business and regulatory communities, and academia were interviewed. The resultant white paper, *The future of the life sciences industries: Transformation amid rising risk*, reveals a potential sea change in the life sciences business model, with many companies looking to move from a high-risk, high-margin business to one with managed risks and more conservative margins. This shift will likely involve transformation throughout an entire company—from its sales and marketing approaches, to its cultivation of talent, to its relationship with regulators.

Yet action from within companies may not be enough. This report also seeks solutions from a wide range of sources, pointing to greater collaboration among industry stakeholders as well as gleaning insights from outside the life sciences industry. Because you can’t meet the challenges of tomorrow with yesterday’s tools—and expect to survive.

Robert Go
DTT Life Sciences and Health Care Industry Group Leader

Preface

The future of the life sciences industries:

Transformation amid rising risk is a Deloitte Touche Tohmatsu (DTT) white paper developed in collaboration with the Economist Intelligence Unit (EIU). The findings and views expressed in this report are drawn from a global survey and individual interviews conducted with industry leaders.

During 2008, DTT and EIU professionals conducted a global online survey of 360 senior executives in the life sciences industries. The survey asked executives to predict the level of change their companies will undergo in the future to address growing risk, and what areas would face the highest growth in risk. The survey also examined how companies will increase proficiency and deal with rising risks in these areas, as well as how they would manage internal and external risk. Concurrently, we conducted individual interviews with board level executives in the life sciences and healthcare industries.

Our thanks are due to all survey respondents and industry interviewees for their time and insights. The EIU bears sole responsibility for this report, which was written by Alexandra Wyke, in collaboration with John Rhodes, DTT Global Life Sciences Sector Leader; and Robert Go, DTT Life Sciences and Health Care Industry Leader.



Executive summary

The life sciences industries are in a vulnerable state. For nearly a decade, they have struggled against low productivity in research and development (R&D), expiry of patents, price competition from generic producers, a rising cost base, an ongoing talent shortage, diminishing corporate reputations, and, in some cases, plummeting stock prices. However, life sciences companies have continued to fight these trends in hopes of being rewarded with a stream of products that will change the face of healthcare, allow people to lead healthier lives, and provide the industry with its just financial rewards.

Those aspirations have been the dream. But in 2008, the reality for life sciences companies was radical cutbacks to shore up profit margins—a short-term strategy at best. To survive in the long term, companies are realizing that they must do more than depend on future returns from new products; they must tackle current problems and address risk in a new way. In other words, life sciences companies are waking up to market realities. Similar to strategies adopted by the commodity industries, life sciences companies are adjusting their business models to take a more “intelligent” approach to risk. And in many cases, this will represent significant transformation for these companies.

The plight of the life sciences industries is nothing new. Other industries have gone through similar metamorphoses, where companies have transformed to remain high-value-added innovators and avoid becoming lower-margin suppliers. Other industries have experienced the trauma of commoditization. What makes life sciences’ situation particularly challenging, however, is that the disruption is caused by technology allowing less-costly replication in the form of generic drugs. “Most creative industries have encountered challenges when facing disruptive technologies,” says John Rhodes, DTT Life Sciences Sector Leader. “In the case of life sciences, these companies will survive and prosper by addressing new customer needs, whether economic, health, or both. Companies have to be willing to move away in some cases from past things that made them great to the new realities of delivering innovative medicines and devices within the economic realities of today’s markets.”



Introduction

The life sciences industries may have reached a low point in mid-2008, when pharmaceutical companies witnessed a significant decline in the growth of the previously robust U.S.-based market. IMS Health calculates that U.S. sales for pharmaceuticals grew by 2 percent in the year ending June 2008, the worst performance posted since 1962.¹ Meanwhile, branded blockbusters are coming off-patent and the traditional sales base is rapidly declining due to generic competition. A 2007 Frost & Sullivan report states that the generic share of the U.S. drug prescription market is set to rise to 78 percent by 2013, from 57 percent in 2006.²

Who took the survey?

Of the 360 executives responding to the survey, 40 percent came from North America, 24 percent from Western Europe, 22 percent from Asia-Pacific, 7 percent from Eastern Europe, and 7 percent from the rest of the world. Participants represented different industries within the life sciences sector, including healthcare services (23 percent), pharmaceutical research and development (22 percent), biotechnology (11 percent), pharmaceutical manufacturing (11 percent), medical devices (9 percent), and contract research (6 percent). Thirty-eight percent of respondents' organizations had annual revenue greater than US\$500 million and 38 percent had revenues less than US\$100 million. Board members and chief executive officers (CEOs) comprised 19 percent of respondents. Chief financial officers (CFOs), chief technology officers (CTOs), and other C-level executives made up 12 percent of the panel. Senior vice-presidents, vice-presidents, directors, heads of business units and departments, and managers made up the remainder of the respondent panel.

Meanwhile, despite companies' efforts to curtail expenditures, the cost of innovation continues to escalate. The substantial cost of R&D has a further impact on payers, such as governments and insurers. Faced with an aging population and soaring healthcare costs, payers continue to debate the value of paying higher prices for new products where effective treatments already exist. In countries like Germany, healthcare costs are passed on to the consumer in the form of higher insurance fees, so the public is also resisting higher prices for medicines. The medical device sector has seen an increase in R&D output, but, like the pharmaceutical sector, still faces serious obstacles in getting products reimbursed. Similarly,

biologics products are in danger of being dismissed by reimbursement authorities because of their cost.

And the costs are significant. The latest figures from Tufts Center for the Study of Drug Development (Tufts CSDD) indicate that the average capitalized cost to bring one pharmaceutical product to market grew from US\$802 million in 2003 to US\$1.3 billion in 2007.³ And then there are the climbing hidden, non-financial expenditures. Life sciences companies are increasingly concerned about companies' reputational risk, the emphasis placed by regulators on companies' transparency in their relationships with doctors and patients, and the growing influence of non-governmental organizations on health policy-making.

These combined stresses have forced leading life sciences organizations to make significant cost cuts in an attempt to shore up profit margins. During the financial period for 2007, Pfizer reduced its workforce by more than 11,000 people. In its 2007 annual report, GlaxoSmithKline (GSK) reported that due to the adverse effects of generic sales on its lead product, Avandia, the company will work with governments to reduce total healthcare costs and lower its expenditures in order to operate more efficiently.⁴ These are just two examples.

With pressure on pricing and increased demand for investment, life sciences companies are now forced to review and change strategies in order to survive. How they plan to do this is the focus of this report, which draws on a 2008 survey of 360 senior life sciences industry executives conducted by the EIU in collaboration with the DTT LSHC Industry Group, as well as interviews with business leaders, regulators, and academics. This report identifies a significant shift in the way these companies are moving forward, especially in today's increasingly volatile and depressed global economy. Life sciences companies are taking a hard look at their business model and seeing the need to transform from a high-risk, high-margin business to one with managed risks and potentially variable margins. This transformation is in process—and how effectively it is achieved—could very well make or break a company.

Recognizing the need for transformational change

Across the spectrum of life sciences companies, executives appear committed to changing their future. To understand their perspectives, life sciences executives were surveyed about the changes that must occur for their companies to address future risks and how they will make these changes to key areas. One quarter of respondents believe that their entire companies will have to change to face future risks, and more than three-quarters recognize that their companies will have to undergo a major transformation, at least in some parts of the organization.

The need for change is consistent across the industry's major sectors and markets. In the case of pharmaceutical R&D companies, 30 percent of executives say their companies will have to change completely to face future risk. And 82 percent of executives from biotechnology companies say that their companies need to endure major transformations to address future risk. This need to address risk is more important than ever given the current economic downturn. In Western Europe, where markets have experienced slow growth since 2001, 31 percent of executives call for a complete makeover of their companies. In the United States, nearly one in five of the executives who responded to the survey predicts that their organizations will have to undergo a wholesale transformation to address future risk.

To what degree will your organization's activities have to change in order to address future risks?
(% respondents by sector)

Type of business	Percent of executives who state that the whole organization would have to change to face future risk	Percent of executives who state that parts of their organization will have to change to face future risk	Total percent of executives who state that all or parts of their organization will have to change to face future risk
Total respondents	24	52	76
Pharmaceutical wholesale/retail	33	56	89
Pharmaceutical R&D	30	53	83
Pharmaceutical manufacturing	27	59	86
Contract research organizations	27	50	77
Healthcare services	21	50	71
Distribution	18	24	42
Biotechnology	15	67	82
Medical devices	24	55	79

To underscore the urgency of transformation, it is the largest companies that appear most concerned about their future prospects. Over 40 percent of executives from companies with revenues of at least US\$15 billion say that their companies need across-the-board reorganization to overcome the risks they face. This is a true indication that times have changed. In the past, these large companies would have argued that their size would protect them against the vagaries of the market and the boom/bust cycles of innovation. But now they are realizing that there is a need for major change to address risk—if they are going to survive.

To what degree will your organization’s activities have to change in order to address future risks?
 (% respondents by company size)

Sector defined in terms of US\$ revenue	Percent of executives who state that the whole organization would have to change to face future risk	Percent of executives who state that parts of their organization will have to change to face future risk	Total percent of executives who state that all or parts of their organization will have to change to face future risk
Total respondents	24	52	76
More than 15 billion	41	48	89
5–15 billion	25	58	83
2–5 billion	25	50	75
500 million–2 billion	27	56	83
100–500 million	22	64	86
<100 million	18	53	71

Where to make changes and what changes to make

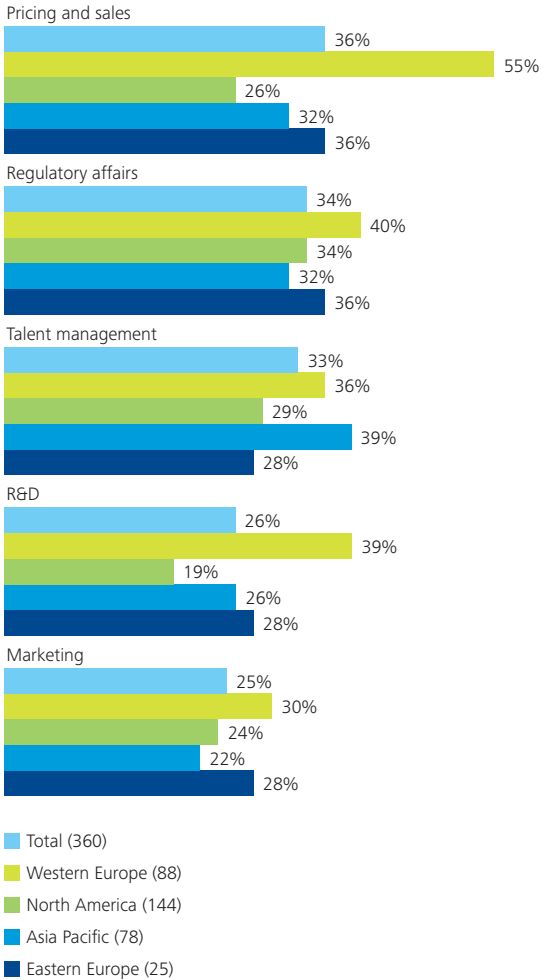
While executives recognize the need for transformation in their companies, the key to execution will be to identify where and what kind of change. Forty percent of survey respondents believe that one of the biggest barriers to effective risk management between now and 2015 is identifying and assessing emerging risks. When asked where they believe risk will rise most sharply in the next 10 years, executives identified the areas of pricing and sales; marketing; regulatory affairs; talent management; and R&D.

Pricing, sales, and marketing

Thirty-six percent of executives identified pricing and sales as a key concern when asked which areas are likely to see the sharpest rise in strategic risk between now and 2015. More than half of the respondents based in Western Europe agreed. Additionally, 25 percent felt that marketing would also be an area of sharply increasing risk.

As cost-conscious customers attempt to keep expenditures to a minimum in today's tight economy, companies are under even more pressure to consider new models around pricing, sales, and marketing. In Europe, reimbursement authorities of national health systems have taken measures to evaluate and reimburse new products at higher price levels only where they show increased efficacy over existing products in the market. And it would seem that few of the products that cross the desks of regulators are considered innovative enough to command the higher prices. This can effectively bring down the prices of new products compared with those of older ones. "The demand for healthcare services is rising with aging populations, and healthcare systems are under pressure to pay for the extra demands on their services," says Arthur Higgins, chairman of the board of management of Bayer HealthCare and president of the European Federation of Pharmaceutical Industries and Associations (EFPIA). "But even now, governments are struggling to meet that demand. In the future there is a risk that government focus will increasingly be on costs and not on the value of medicines and their contribution to health."

For each of the following functions within your organization, how do you feel the risk level will change between now and 2015? (% who say there will be a sharp rise in risk)



Likewise, U.S. healthcare payers in the private sector and federally- and state-run healthcare systems are embracing European-style reimbursement systems to keep costs down, according to Kenneth Kaitin, professor of medicine at the Boston-based Tufts School of Medicine and director of the Tufts Center for the Study of Drug Development. Legislation is already being considered to undertake federal research into the comparative effectiveness of new versus existing products. Life sciences companies may be required to demonstrate that products are not only cost-effective in the confined setting of a clinical trial, but also when used in real-world clinical situations.⁵ There may also be additional pressures with the new political dynamic in the United States.

Biotechnology companies also face difficulties in obtaining reimbursement for their products, according to Aisling Burnand, Chief Executive of the UK BioIndustry Association (BIA) and Chair of the EuropaBio's National Associations Council. European governments are usually unwilling to pay for products that provide benefits to small sections of the population, or merely improve quality of life (rather than extend it). Yet these latter types of products are the primary focus of biotech. According to Kaitin, this approach represents a tremendous clash of competing interests. For example, patients may seek pain relief in the last two months of their life, but supplying pain medication is not cost-effective to healthcare systems. "We live in an environment where drugs are not free and there is a finite budget, so where do you draw the line?" Kaitin asks. "This form of rationing may seem distasteful, but governments also have a fiscal duty to the public they need to meet."

And with sales and marketing investments—the industry's single biggest expenditure—offering diminishing returns, internal pressures are also strong. "Pharmaceutical companies got used to seeing their stock double every five years," says Bayer's Higgins. "Now that this trend is no longer happening, there is a need to step back and look at the business model. For instance, you have to ask whether it still makes sense to support massive field forces in primary care when reimbursement decisions are being made by governments in Europe and managed care in the USA." Industry executives (41 percent) believe that between now and 2015, sales forces will become more versed in economic issues and adept at selling the economic virtues of products to patients, physicians, and payers. Executives also foresee adopting sales strategies that have been successful in other industries, including value-added services that use technology to drive relationships and partnering with customers and end users/consumers. In fact, more than one-third of survey respondents believe that developing relationships with end-users, payers, and regulatory groups—as well as with clinician networks, academics, and patients—will be key in increasing proficiency and addressing risk in the sales and marketing functions. This strategic change is already under way at some companies.

Outsourcing marketing is another way to mitigate risk, a strategy that has been successful for Bayer, as well as in other industries. In 2004, Higgins outsourced the marketing of Bayer's pharmaceutical primary care products in the United States, reducing the size of its German and American workforce. Since then, he has used strong fiscal discipline to increase profitability among the groups under his supervision. This transformation is more than just a matter of cost-reduction exercises.

Is the emphasis on cost, not effect?

In January 2006, Exubera, a product that enabled diabetics to take their insulin through inhalation rather than as an injection, was approved for use by the U.S. FDA. Yet by October 2007, Pfizer, which manufactured the drug, announced that it would take a US\$2.8 billion loss and abandon the drug.⁶ One of the reasons Exubera failed to take off was because healthcare payers refused to reimburse the high prices charged for the product — US\$300 to US\$600 dollars a year per person and more than twice the cost of the injectable version.

WellPoint, the United States' largest health benefits company, with 35 million members across the country, was a key player in the debate over the adoption of Exubera. According to Brian Sweet, Chief Clinical Pharmacy Officer at WellPoint, his company, like others, has its own in-house methodology for evaluating the outcomes and cost-effectiveness of medicines. Ideally, WellPoint wants treatments that make people more healthy and productive for employers, its primary customers.

According to Sweet, the fact that Exubera was a unique delivery device was not the issue. The main focus was if the product helped patients' compliance with treatment by improving their quality of life. "The value was not there," he says, "as the inhaler was large and inconvenient for patients and there were no data available to demonstrate that Exubera would increase compliance."

Regulatory affairs

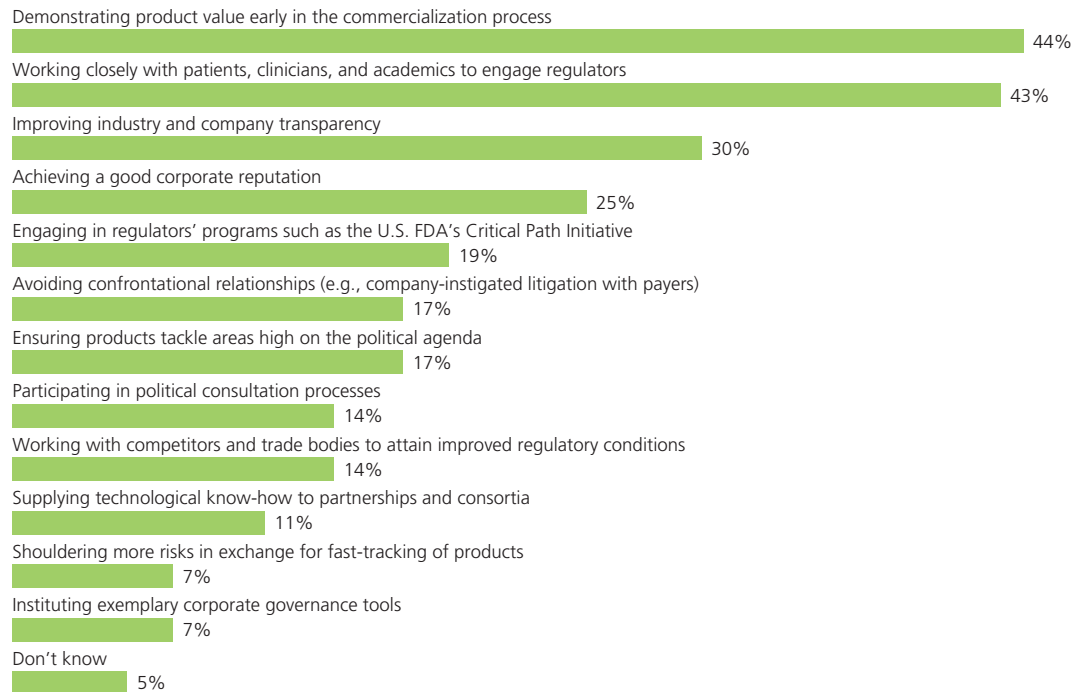
Regulatory affairs, where tougher sanctions regarding patient safety continue to increase the costs of innovation, is another area where risk is expected to rise sharply, according to 34 percent of life sciences executives. Even though life sciences is one of the most regulated industries, drug and medical device regulatory agencies continue to institute stricter guidelines to ensure that products are safe and cost-effective. This results in a longer and costlier product approval process and, in turn, requires drug companies to invest greater amounts to earn a potential return and recoup the cost of development.

The current trend of tightening regulatory restrictions is not unprecedented. In 2004, it was found that life-threatening side-effects were associated with the widely used anti-arthritis drug Vioxx, which was withdrawn and its market position forever changed. At the time, the U.S. Food and Drug Administration (FDA) was lambasted for being too lax. Since then, the FDA has adopted more rigorous procedures to monitor drug safety. In another example, six healthy volunteers participating in a clinical trial fell dangerously ill and came close to death in a London hospital in March 2006. The incident led to sweeping revisions for conducting clinical trials, not only in the United Kingdom but also across Europe.

These regrettable events have prompted regulators to view new medicines differently, in part because of the challenges associated with assessing products of advanced technology as compared with traditional pharmaceutical drugs. BIA’s Burnand, for one, worries that this may affect the growth prospects of the biotechnology sector she represents. Given the novelty of scientific approaches within biotechnology—protein rather than chemical products, cell and tissue engineering, genetic engineering of stem cells—emerging products, which are considerably more complex than small molecule medicines, are likely to get a critical reception from risk-averse regulators.

As regulatory approval and pricing hurdles become more difficult to overcome, cultivating better relationships with regulators and reimbursement authorities is paramount. More than 40 percent of respondents believe that demonstrating product value early in the commercialization process—as well as working closely with patients, clinicians, and academics—is the best way to engage regulators.

Which strategies do you think are most likely to help cultivate good relationships with regulators and reimbursement authorities and speed up approval procedures?



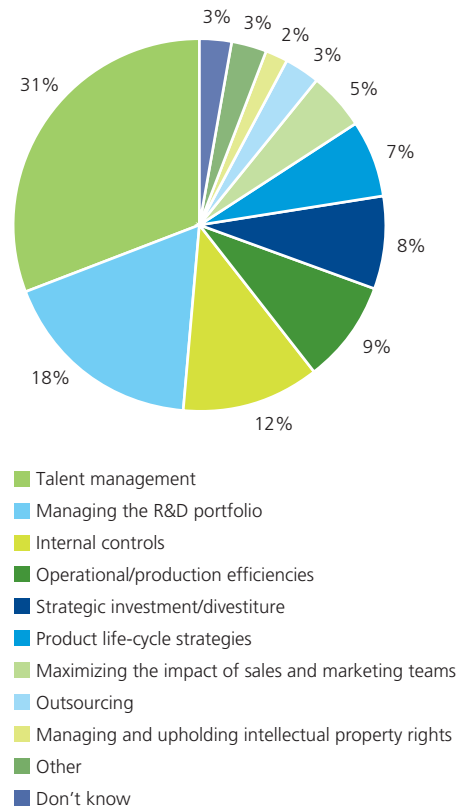
Talent management

Finding and retaining technical resources for R&D efforts has always been a core issue for the life sciences industries, and has escalated in the last decade as companies look beyond the blockbuster model. Over the past ten years, the high number of mergers and acquisitions in the industry and the heightened concern about its future stability have also strained the once strong ties between employees and companies. Due to the changing business models, overall employee turnover has reached record highs at life sciences companies. Paired with the increasing costs of R&D and manufacturing, this turnover is squeezing margins even further.

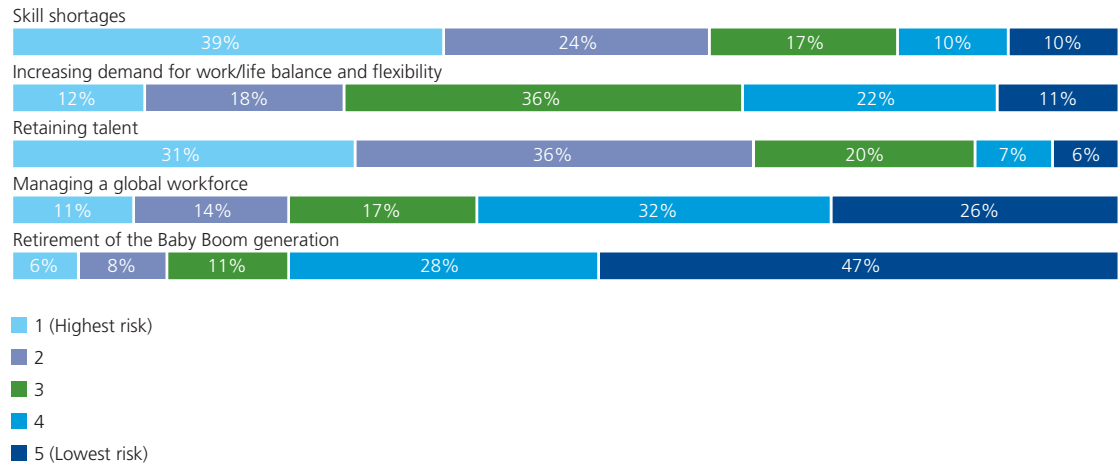
In the future, the success of life sciences companies will continue to rest, in good part, on the ability to attract and retain talent. In fact, talent management was identified by more than 70 percent of respondents as an area where risk would rise moderately (38 percent) or sharply (33 percent). And when asked to identify the top strategy or activity that would be most helpful in mitigating companies' exposure to internal risks, 31 percent of respondents indicated that talent management was critical. The equivalent figure for contract research organizations (CROs)—among the most competitive sectors within the life sciences industries—is 41 percent.

Executives perceive that talent management-related risks between now and 2015 will be greatest in the areas of skill shortages and talent retention, much as they are today. In the current environment, it is not unusual for the most talented individuals to search for the company offering the greatest short-term rewards, or where the company is implementing a transformational strategy.

Which one of the following strategies or activities is most helpful in mitigating your organization's exposure to internal business risk?



Please rank the following talent management-related issues in order of risk to your organization between now and 2015, where 1 = Highest risk and 5 = Lowest risk.



As life sciences companies' margins shrink and companies continue to feel pressure, firms will depend more and more on talented employees to help the organization succeed. And as the industry transforms, the need for talent will expand well beyond the R&D functions to a far more diversified set of skills, such as regulatory and government relations, leading in a changing environment, and working with third parties across the enterprise. It is interesting to note that managing a global workforce is not perceived as high risk for life sciences companies, which should help their long-term survival.

R&D

Today, R&D is at the root of the life sciences industries' need for transformational change. Twenty-six percent of executives surveyed—39 percent in Western Europe—say that risks associated with R&D are set to rise sharply through the next decade. In the United States alone, the number of new molecular entities (NMEs) approved by the U.S. FDA slumped to a 25-year low in 2007, and the numbers approved in 2008, according to Tufts' Kaitin, represent only a marginal improvement.⁷

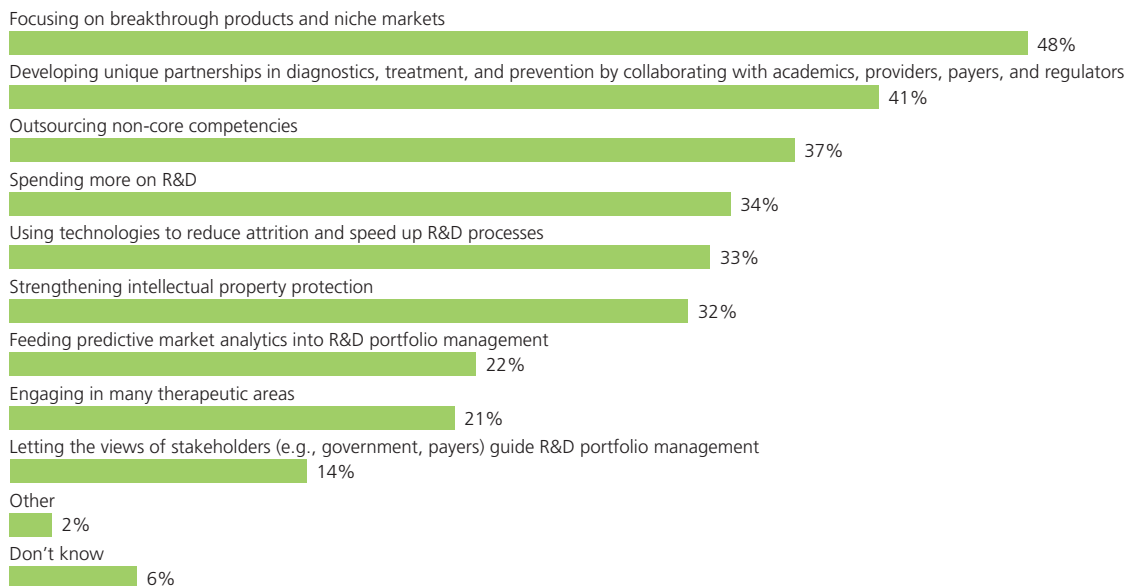
"There is a general consensus, looking at the pipeline, that the number of new product approvals each year will remain the same for a while," adds Thomas Lönngren, Executive Director of The European Medicines Agency (EMA), which regulates the approval of most new medicines destined for distribution in the 27 EU member states. "Those in the drug discovery business have picked all the low hanging fruit. Now they have to reach out for the fruit at the top of the tree, but the ladder isn't always quite high enough."

Managing the R&D portfolio is key in mitigating exposure to internal company risks, according to 18 percent of respondents. Historically, R&D strategies have largely depended on generous funding for scientists, in the hope of securing a few products capable of producing enormous amounts of revenue. However, this formula is no longer as effective. “There is no real evidence that increasing R&D budgets results in a concomitant increase in R&D output,” says Higgins. “You have to focus on efficiency of R&D operations.” Higgins believes that companies must change their approach from a success-based model, to one that minimizes failure—in other words, risk mitigation. Interestingly, some companies do not anticipate changes to their approach to R&D, according to the survey results. More than one-third of survey respondents indicate that they will mitigate risks attached to R&D by simply spending more money. Nevertheless, Kaitin believes that as high-risk, high-reward opportunities become less attractive to companies, life sciences firms will have to explore less risky R&D strategies. But which ones?

In an interview with *The Economist* in August 2008, Andrew Witty, CEO at GSK, said that a key component of his future strategy is ending the current obsession with blockbusters, which he likened to “finding a needle in a haystack.” In effect, Witty suggested that it would be better to develop many products that may not command high prices or high levels of profitability individually, but taken together, can still produce a healthy profit margin and reduce the development risk.⁸

According to BIA’s Burnand, there is an inverse correlation between the ability to innovate and company size. Pharmaceutical companies that have been successful in the discovery of multi-billion-dollar drugs have accepted that the blockbuster era is over. Large corporate structures have destroyed the entrepreneurial environment needed for life sciences innovation, as well as the ability to make decisions quickly about proceeding with candidate drugs. To prevent the departure of talent, suggests Burnand, some of the largest pharmaceutical companies, such as GSK, have started experimenting with in-house

Which of the following risk mitigation strategies does your organization use—or plan to use—in R&D?



infrastructure to create a more entrepreneurial environment and strengthen R&D. They might follow the lead of companies like 3M, which allows employees to use up to 15 percent of their time to pursue independent projects.

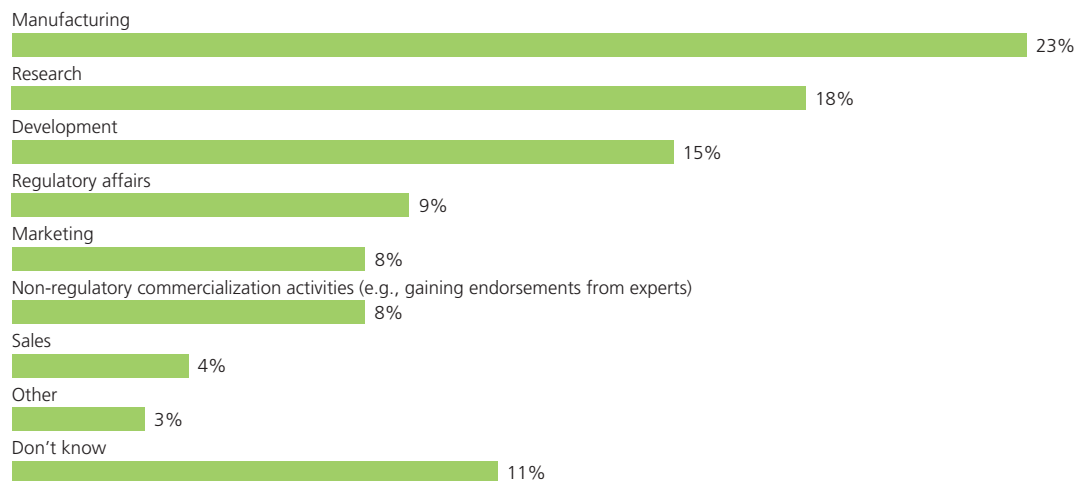
Another way of diminishing the possibility of failure is to spread the risk. Although surveyed executives may still be drawn to the big-spend, blockbuster model for R&D, 41 percent also see value in forming collaborations with academics, providers, payers, and even regulators, to share not only R&D's risk but also its innovative approaches. Sharing ideas and collaborating on R&D is nothing new—even in life sciences. But there is now a strategic recognition that such collaborations yield a new level of interaction and cooperation and leverage complementary talents.

Sharing risk in the form of outsourcing is not foreign to life sciences companies, either. Many companies have outsourced various operations, particularly the

manufacturing process. However, they have been reluctant to let go of clinical development and research, a core part of their business. Not only is R&D at the center of life sciences companies, but achieving results depends on ensuring high quality and securing sound intellectual property rights. These objectives can be difficult to achieve if R&D is conducted outside the company. However, it is a process that successful companies will have to master: one-third of survey respondents believe that outsourcing R&D can significantly reduce their organization's risk profile.

In addition to typical outsourcing agreements, Kaitin predicts that "the pharmaceutical industry will probably turn out to be like the entertainment industry, where the large players, like Paramount, MGM, and Universal, act as holding companies, supported by a plethora of other smaller companies." The August 2008 deal between the pharmaceutical giant Eli Lilly and Covance, a contract research organization, is a case in point. (See box, "Who are the future drug hunters?")

In which one of the following business areas do you believe outsourcing will reduce your organization's risk profile most significantly over the next decade?

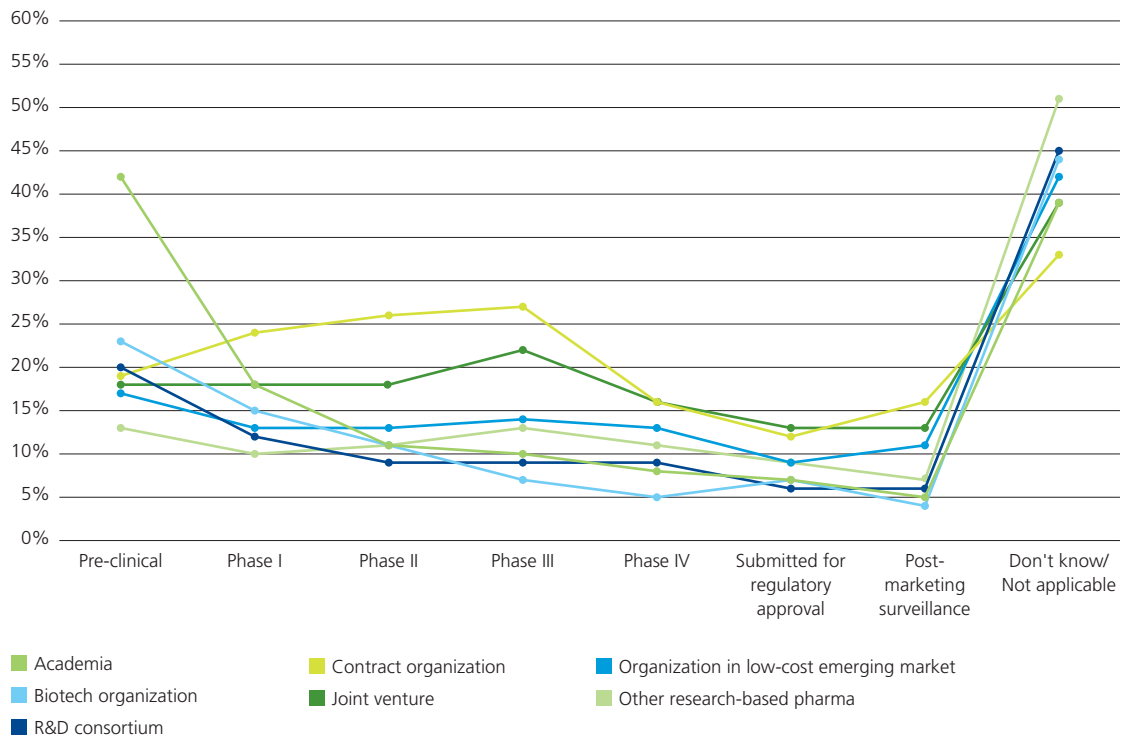


Who are the future drug hunters?

The move to outsource R&D typically declines as products get closer to market and gain monetary value. In the early stages of R&D, academics are more popular partners. In the later stages of development (for example, phase III) contract research organizations (CROs), collaborators, and organizations based in emerging markets are preferred because of cost-benefit opportunities. Also, in emerging markets, patients can be recruited more quickly. If large clinical studies are conducted faster, then costs come down.

In some cases, these trends are being challenged. In August 2008, Eli Lilly announced it would horizontally integrate its early drug development campus in Greenfield, Indiana, with the U.S.-based CRO company, Covance. Covance agreed to pay Eli Lilly US\$50 million for use of its R&D facilities and staff. In return, Covance agreed to provide Eli Lilly with a broad range of drug development services over the next 10 years.⁹ Kenneth Kaitin, professor of medicine at the Boston-based Tufts School of Medicine and director of the Tufts Center for the Study of Drug Development, comments, "Eli Lilly is saying that large pharmaceutical companies do not have to be a one-stop shop for R&D; instead, they can have a portfolio of capabilities."

Which types of outsourcing does your organization use—or plan to use—for each phase of R&D?



While the immediate motives for R&D outsourcing appear to be reducing costs, according to survey respondents, as well as increasing capacity and speeding up processes, there will ultimately be another benefit: the exchange of new ideas. It is not difficult to imagine that R&D in the future will involve a variety of players, each contributing their unique capabilities toward the generation of a single product. This more collaborative approach finds resonance among surveyed executives: 44 percent say that, over the next decade, most discovery and early-stage research will be conducted outside large life sciences companies. This sentiment holds true in the largest companies—with 52 percent of executives from companies with revenues of US\$ 15 billion agreeing—as well as across sectors. Fifty-eight percent of respondents from pharmaceutical R&D firms and 67 percent from biotechnology companies also agree.



Bringing in the outside world

The recognition that there needs to be transformational change within the life sciences industry is a critical step in sustaining companies and driving success in the future. However, companies would do well to look outside their own corporate sphere for ideas on the way forward. There is much to be gained by bringing various stakeholders to the table—and even from seeking insight from outside the industry itself.

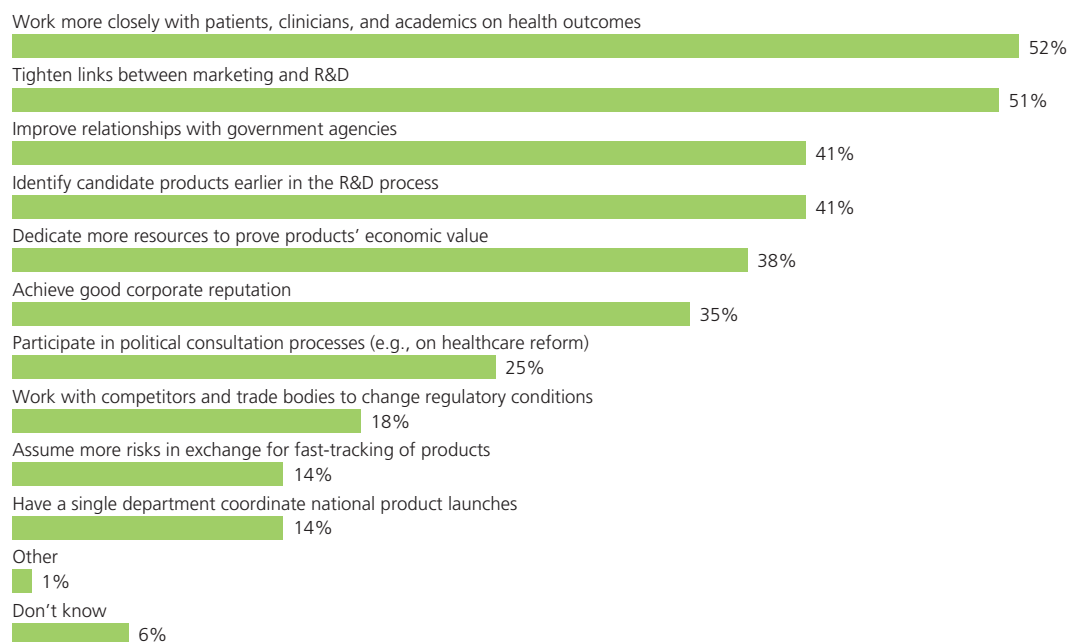
Stakeholders and science

Since its inception in the 1950s, the pharmaceutical industry has conducted research, developed medicines, and marketed products without significant intellectual input from the people that influence sales: agencies that assess whether products should be made available for sale (regulators), customers (payers), or the ultimate users (patients). Few other industries could survive without at least consulting the end consumer. In order to meet the needs of the market, life sciences companies know they need

their marketers, who are the critical link to these key stakeholders, to collaborate with their scientists—an approach supported by just over half (51 percent) of the executives surveyed. “Given the pressures on companies to prove the economic as well as the therapeutic value of their products,” says Kaitin, “it is likely that R&D divisions will have to work even more closely with sales and marketing, perhaps even in the preclinical stages, to ensure that the product is optimally positioned to be competitive once it hits the marketplace.”

As products become more expensive and more complicated in terms of delivery and patient compliance, such as biologics, coordination early on will be increasingly important. Additionally, this early focus will aid the reimbursement process from governments and other third parties; companies will have to be able to provide products at a cost affordable to payer organizations.

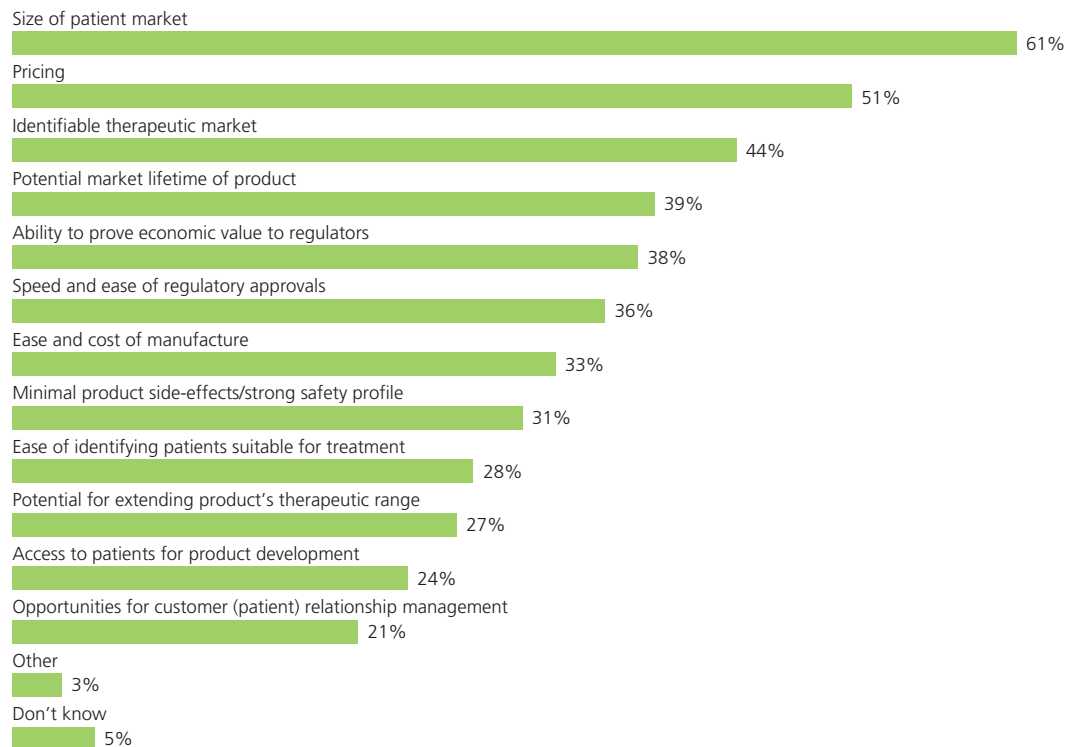
Which of the following strategies or actions will your organization use to make its commercialization processes more efficient?



The influence of third-party stakeholders may also be felt as companies decide what drugs are picked for commercialization. In the past, the decision-making process for selecting a candidate drug in R&D for commercialization was straightforward—companies simply focused on diseases that affected large populations. But recently, some companies' products have failed financially, because payers refuse to pay the high prices required for a return on R&D investments. Although the size of a patient market remains an important factor in deciding whether to proceed with commercialization, executives agree that many other elements may influence the decision by 2015: a country's pricing structures (51 percent); ability to prove economic value (38 percent); speed and ease of approvals (36 percent); and a strong safety profile (31 percent).

Life sciences companies also need to create strategies to improve the success of product commercialization. Fifty-two percent of life sciences executives say they should work more closely with patients, clinicians, and academics to help ensure that the final product is accepted by the market. And about one quarter highlight the importance of engaging patients to prove product worth. Brian Sweet, Chief Clinical Pharmacy Officer at WellPoint, adds that life sciences companies will need not only to make the economic case for their products, but demonstrate patient satisfaction as well as health outcome and quality of life improvements. "Healthcare must be meaningful to patients," he says. "Pharmaceutical and biotechnology firms will need to collect that data earlier in drug development to ensure better and broader access to markets."

By 2015, what factors are likely to influence your organization's decisions to commercialize a product?



In the future, getting a product from the laboratory bench into mainstream healthcare systems will be an increasingly complex affair. To minimize the chances of failure, life sciences companies will need to reach out to new constituents; networking and partnering with patients, clinicians, regulators, and academics will be critical. Yet, this will not be without challenges. For example, due to the highly regulated nature of their business, life sciences companies are legally and ethically restricted from partnering too closely with regulators. Forging these relationships to generate mutual benefit, while potentially beneficial, is a controversial step, and would have to occur within the bounds of current regulation and policies.

As a regulator, Lönngrén rejects the idea of partnerships with life sciences companies, believing in a clear line between industry players and those who monitor them. He does acknowledge, however, that agencies like EMEA can play a part in enabling life sciences companies to be more innovative. Lönngrén would like EMEA to support companies in the dissemination of their research that may never be released publicly, but could benefit the industry. “Today, EMEA will provide general scientific advice about structuring and designing clinical trials to improve the chances of product approval,” he says. “And it is already clear that those that take advice appear more successful in getting approval compared to those who do not.”

But despite Lönngrén’s reservations, some ambitious partnerships between life sciences companies, government agencies, and regulators are beginning to emerge. One example is the Innovative Medicines Initiative (IMI), which was launched in early 2008 as a €2 billion public-private partnership to encourage academics and small enterprises to find new ways of conducting R&D and innovating products. Half of the funds are provided by the European Commission, while partner companies contribute by sharing research laboratories or donating the time of scientists.

According to Higgins, since research financed by IMI occurs very early in the process—before rewards can give one participant a competitive advantage over another—results from the collaboration can be shared. The initiative is a breakthrough as pharmaceutical companies typically compete fiercely with one another. Yet companies have accepted that the challenge to develop new roadmaps for innovation is too big to solve alone. IMI, says Higgins, is an example of the significant shift now taking place in industry thinking.

Managing risk: learning from other industries

During the 1980s and 1990s, life sciences companies were rewarded for taking risks and innovating, receiving patent protection that enabled them to recoup their investments. But with companies now developing fewer truly new products and encountering more and more difficulty in gaining returns on investment for their leading products, senior executives may need to look beyond their own industry for ideas.

It is not a new phenomenon for an industry to transition from a high-risk, high-margin approach to a risk-balancing strategy. When chemicals, textiles, semi-conductors, and entertainment industries found themselves in danger of extinction, they stayed alive by adopting new models for product development and manufacturing. Some sought control over all in-house activities, while others developed networks and partnerships to ensure their survival. And, as stated above, they also nurtured new relationships with outside stakeholders to obtain greater assurances of commercial success when products were launched.

These kinds of strategies enabled companies to keep going in an atmosphere where high margins were no longer a given. Although few life sciences companies may term their situation as commoditization, they are facing some of the same issues, and would do well to learn from others’ successes and failures.

But the task before life sciences companies is even more daunting as they work within tightly controlled markets distinct from their ultimate customers. Moreover, while markets would welcome growth, governments and commercial payers of healthcare prefer strict control and regulation. Other industries do not face the regulation that is central to the life sciences industry, and are able to work in free markets. Products can be priced as high as the market will bear.

When asked about the commoditization of life sciences industries and how it might compare with other sectors, Higgins points out that the reality for life sciences will be more challenging. Particularly in the current climate, governments and other payers who control the market have a laser focus on minimizing costs, often reimbursing based on generics pricing. While other industries may provide guidance, life sciences companies need to find ways to apply their lessons within the unique confines of their sector.



Conclusion

Life sciences companies are now realizing that their business models must change. The increasing cost of innovation and the growing hurdles to gain adequate compensation for brand leading products have made businesses far more risk-averse. Executives agree that new alternatives must be considered to bridge the gap in their innovation pipelines.

Yet the full implications of these shifts in the life sciences industries have yet to be wholly understood. If the transformations that occurred in such industries as textiles, chemicals, semiconductor, and entertainment are any indication, life sciences companies may be facing the prospect of strategic transformation as an ultimatum rather than an option.

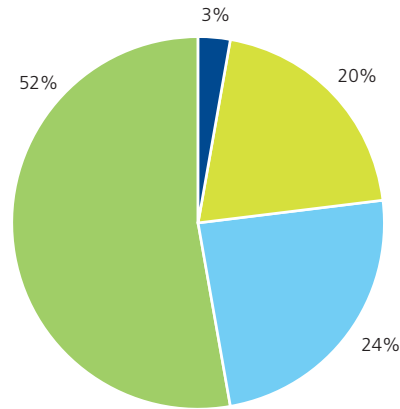
And while this transformation may prove uniquely challenging in the heavily regulated world of life sciences, companies, regulators, and payers must work together to find new approaches that work for everyone. "This is a real crisis. There is a need to know how we are going to tackle the treatment of Alzheimer's, hypertension, or cancer," warns Higgins. "The research pharmaceutical industry can play a key role, but there have to be the right incentives to justify the costs and risks involved."



Appendix

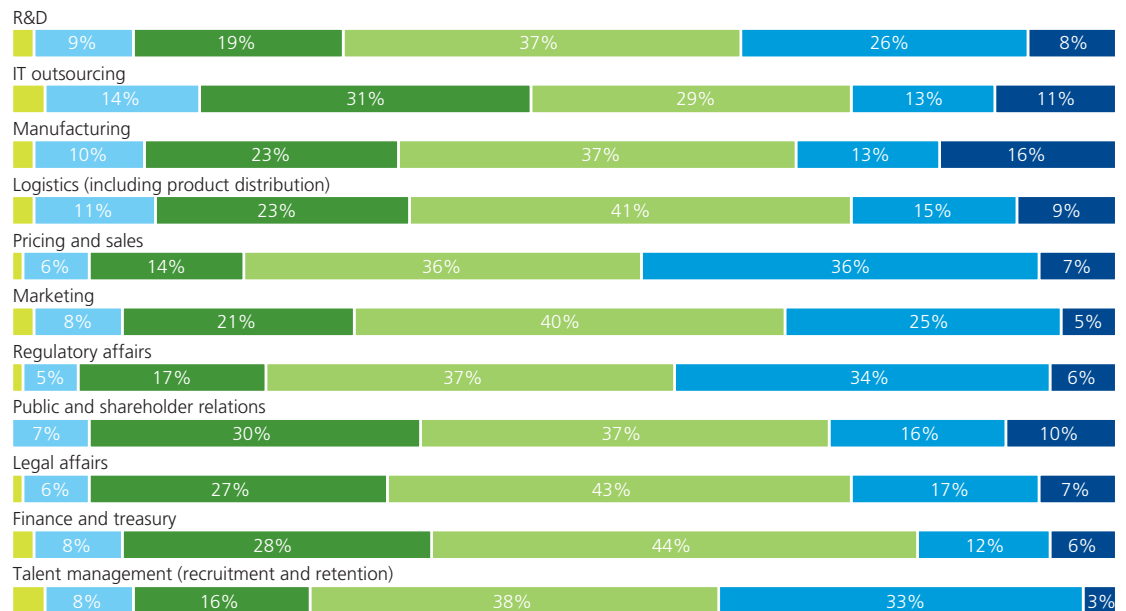
Survey results: 2008 online survey of 360 senior life sciences industry executives, conducted by the EIU in collaboration with the DTT LSHC Industry Group.

To what degree will your organization's activities have to change in order to address future risks?



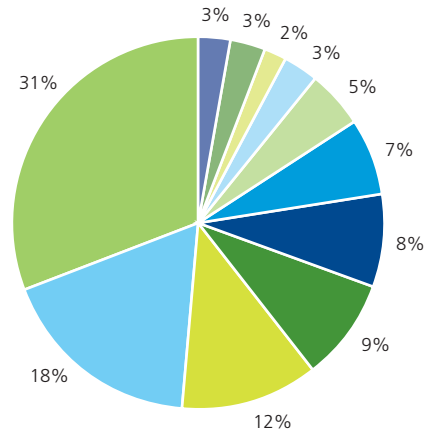
- Major changes in some parts of the organization are needed
- Major changes across the whole organization are needed
- Some minor change is needed
- No change is needed

For each of the following functions within your organization, how do you feel the risk level will change between now and 2015?



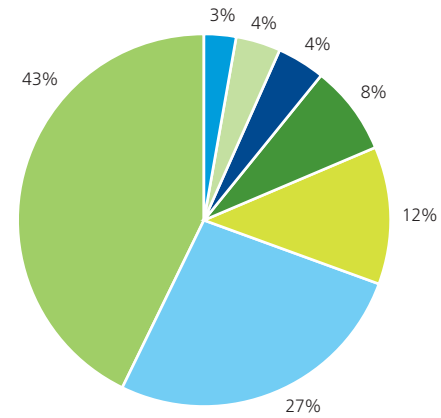
- Sharp drop in risk (less than or equal to 3%)
- Moderate drop in risk
- No change
- Moderate rise in risk
- Sharp rise in risk
- Don't know/Not applicable

Which one of the following strategies or activities is most helpful in mitigating your organization's exposure to internal business risk?



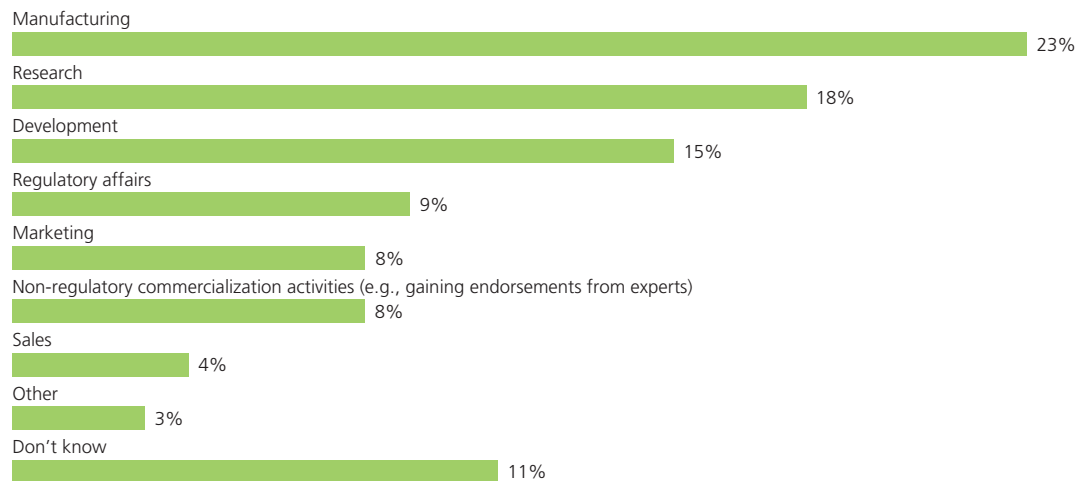
- Talent management
- Managing the R&D portfolio
- Internal controls
- Operational/production efficiencies
- Strategic investment/divestiture
- Product life-cycle strategies
- Maximizing the impact of sales and marketing teams
- Outsourcing
- Managing and upholding intellectual property rights
- Other
- Don't know

Which one of the following strategies or activities is most helpful in mitigating your organization's exposure to external business risk?

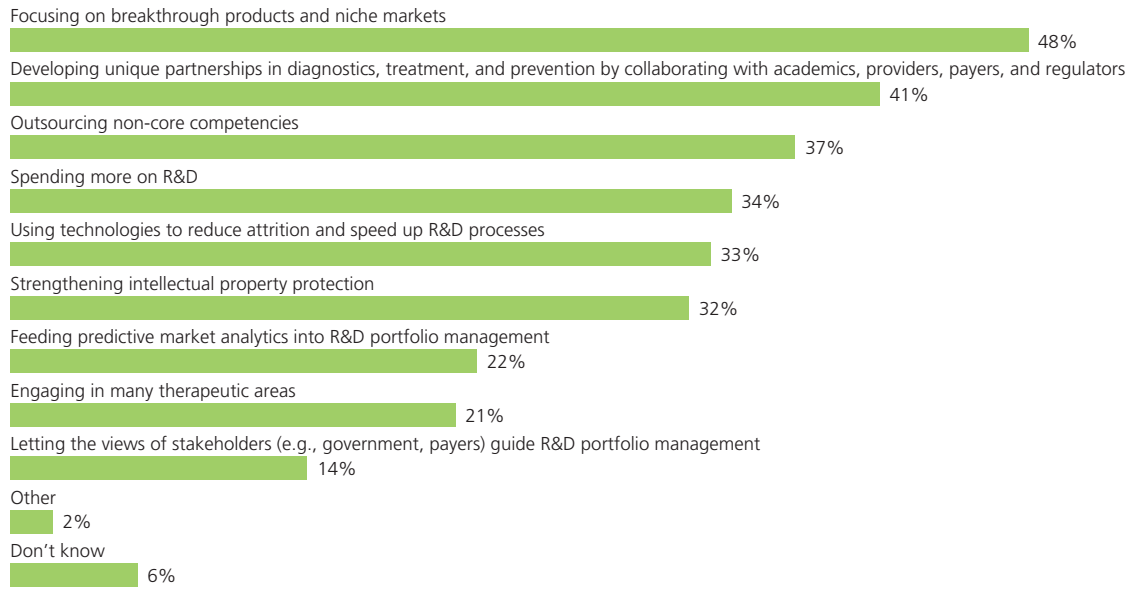


- Understanding the demands of end users, such as patients or regulators
- Improving communications with research collaborators, investors, regulators or patients
- Developing better mechanisms for choosing business partners
- Getting more involved in policy decisions about intellectual property
- Instituting crisis and pandemic management plans
- Don't know
- Other

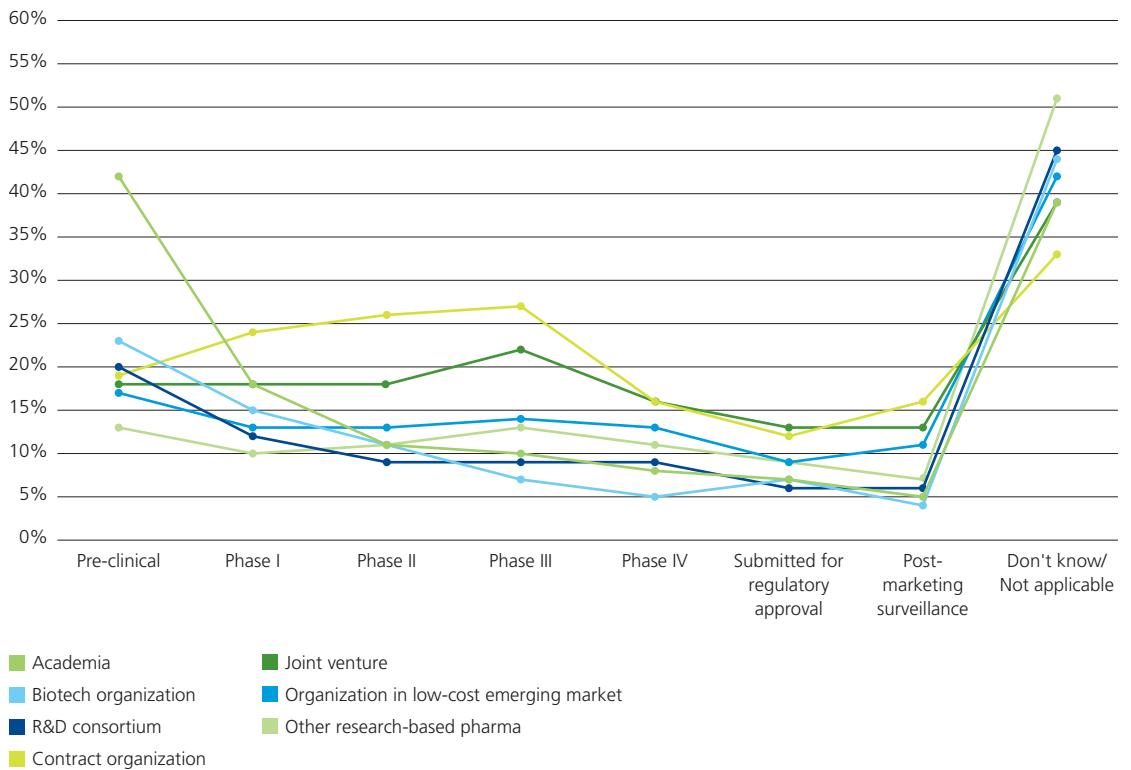
In which one of the following business areas do you believe outsourcing will reduce your organization's risk profile most significantly over the next decade?



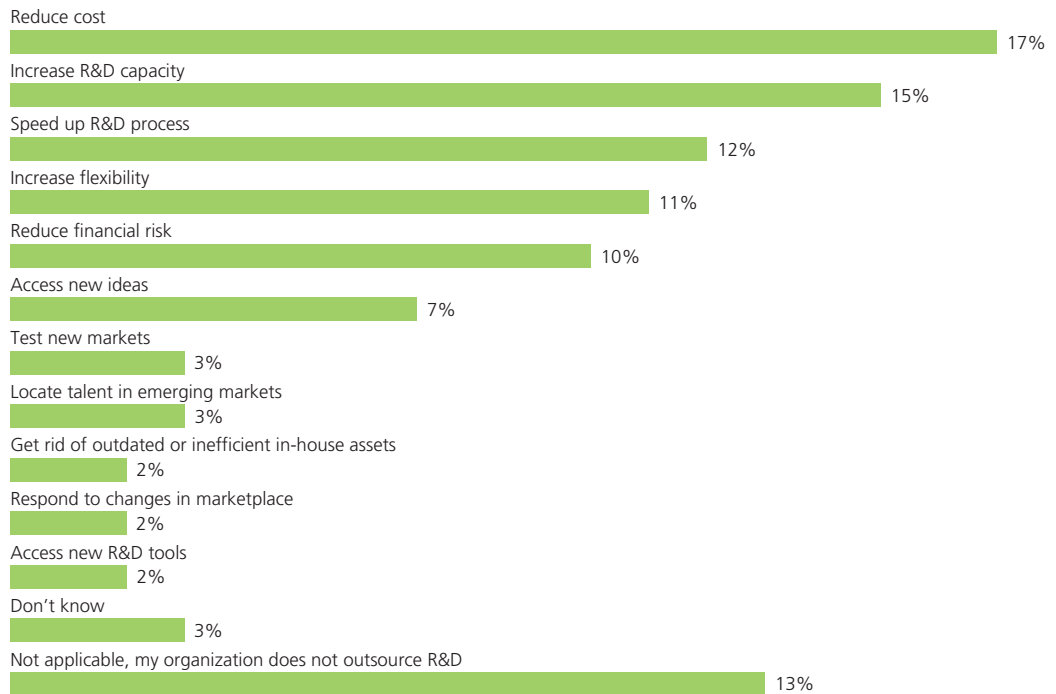
Which of the following risk mitigation strategies does your organization use—or plan to use—in R&D?



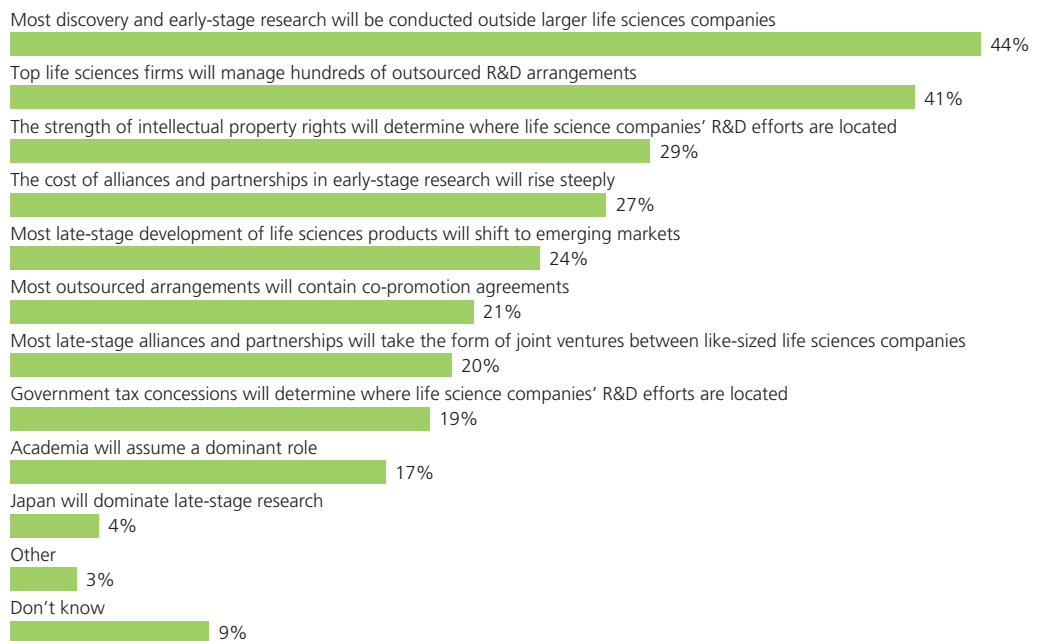
Which types of outsourcing does your organization use—or plan to use—for each phase of R&D?



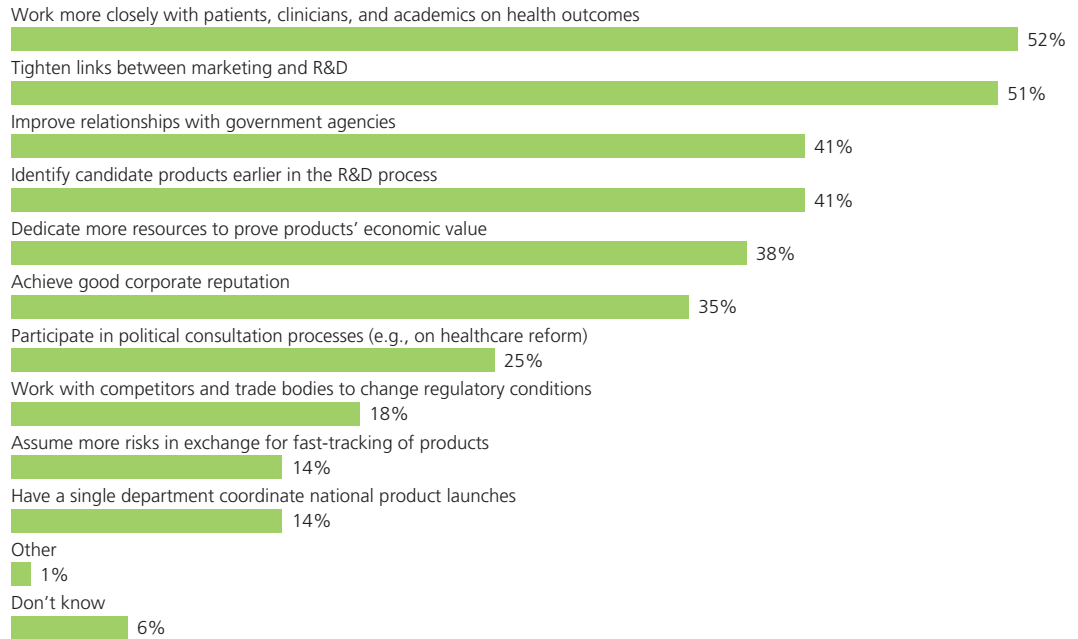
What is the main reason your organization outsources research and/or development?



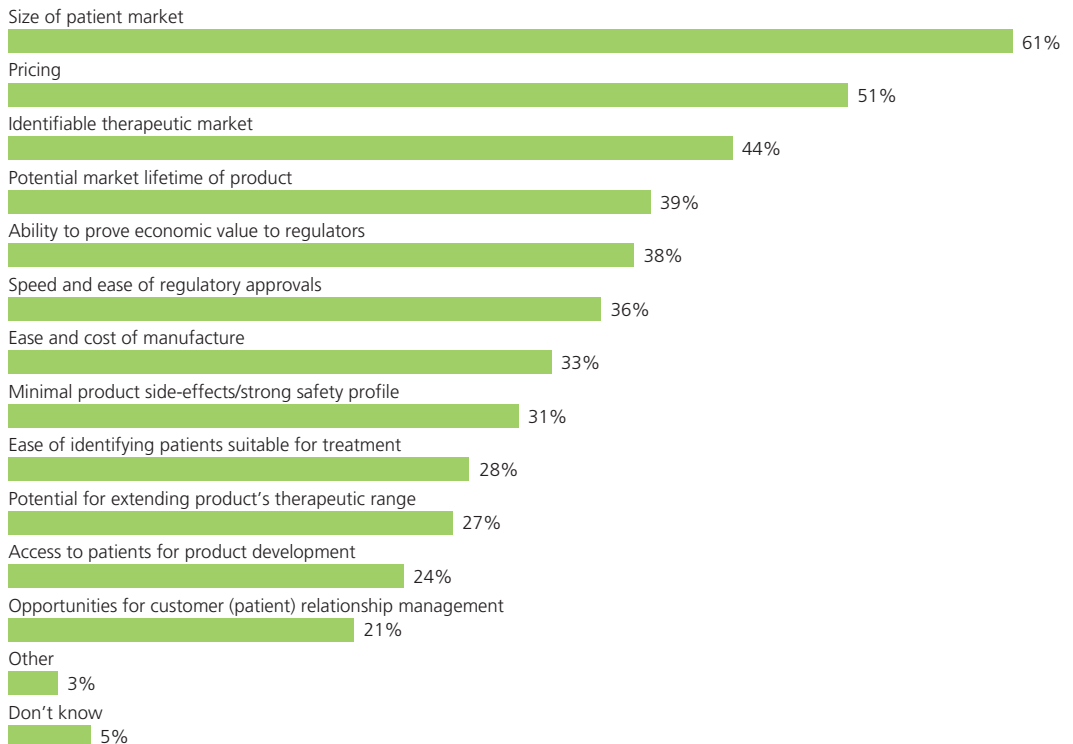
How do you think outsourcing will transform R&D in your industry over the next 10 years?



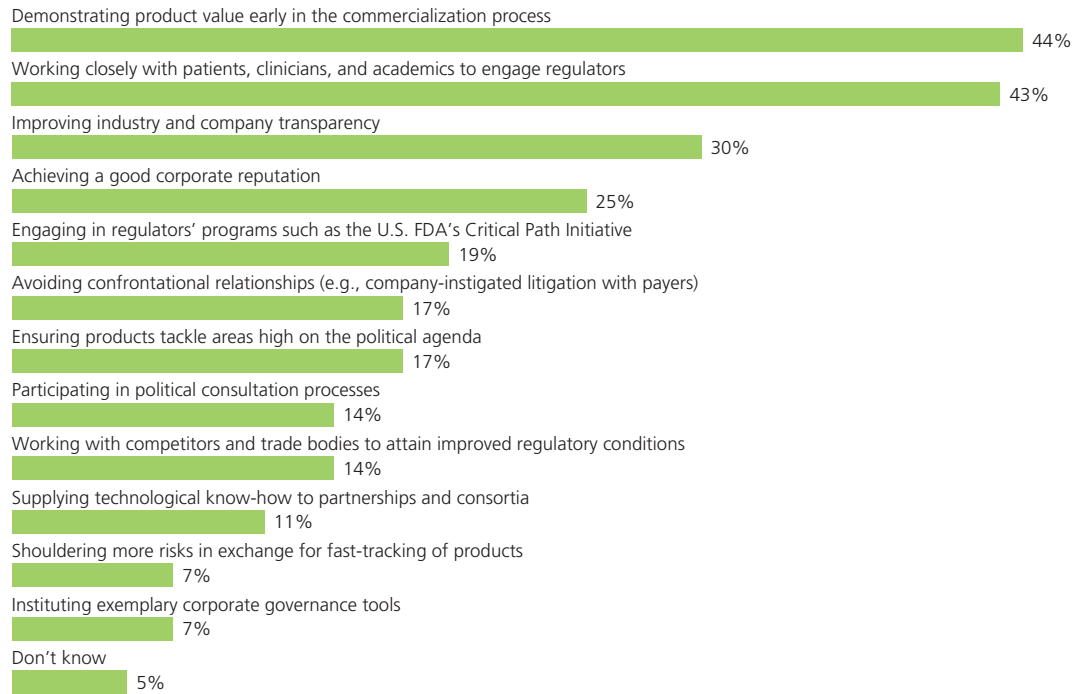
Which of the following strategies or actions will your organization use to make its commercialization processes more efficient?



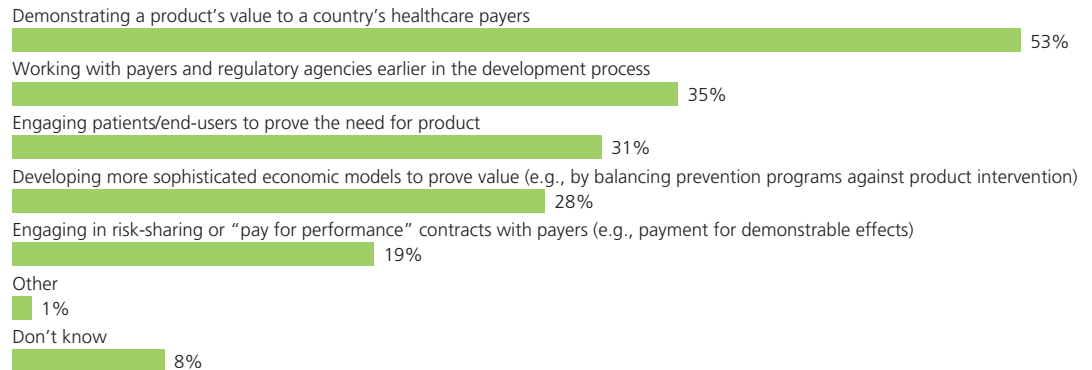
By 2015, what factors are likely to influence your organization's decisions to commercialize a product?



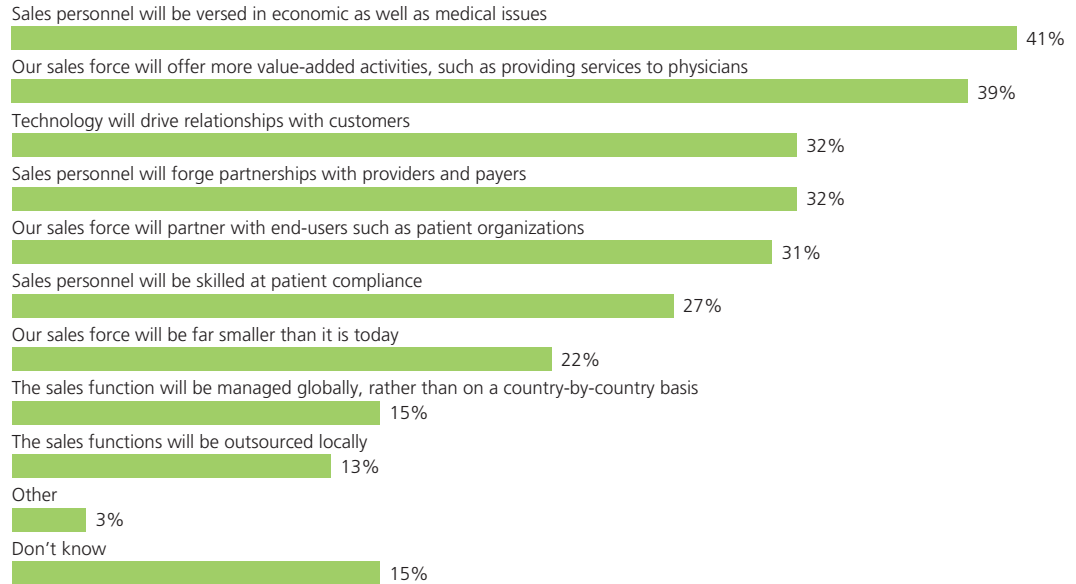
Which strategies do you think are most likely to help cultivate good relationships with regulators and reimbursement authorities and speed up approval procedures?



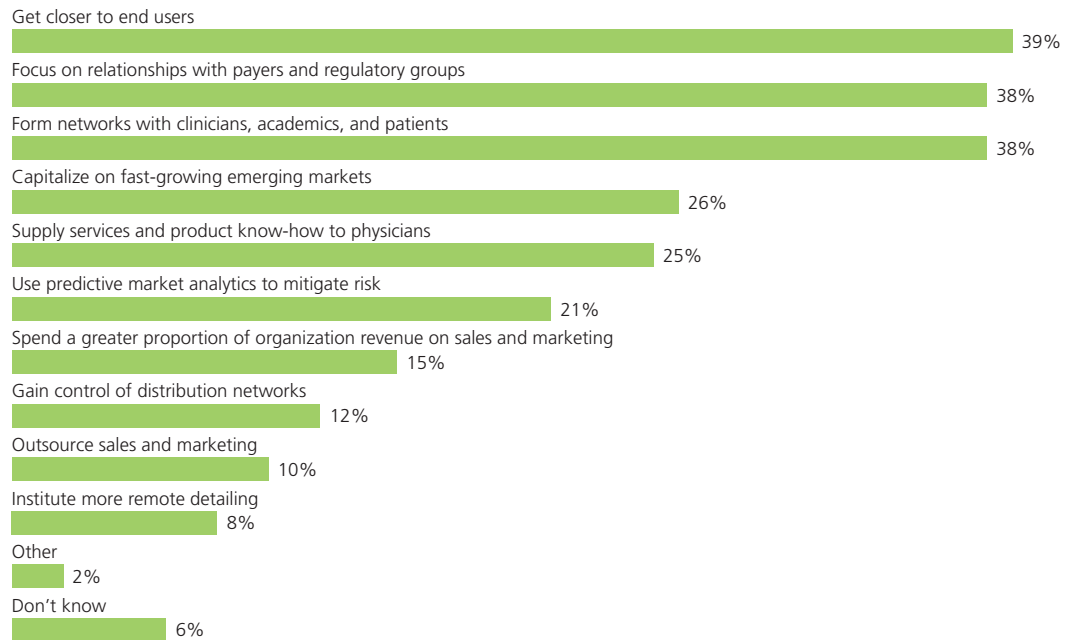
What strategies do you think are most likely to help prove a product's intrinsic worth to regulators?



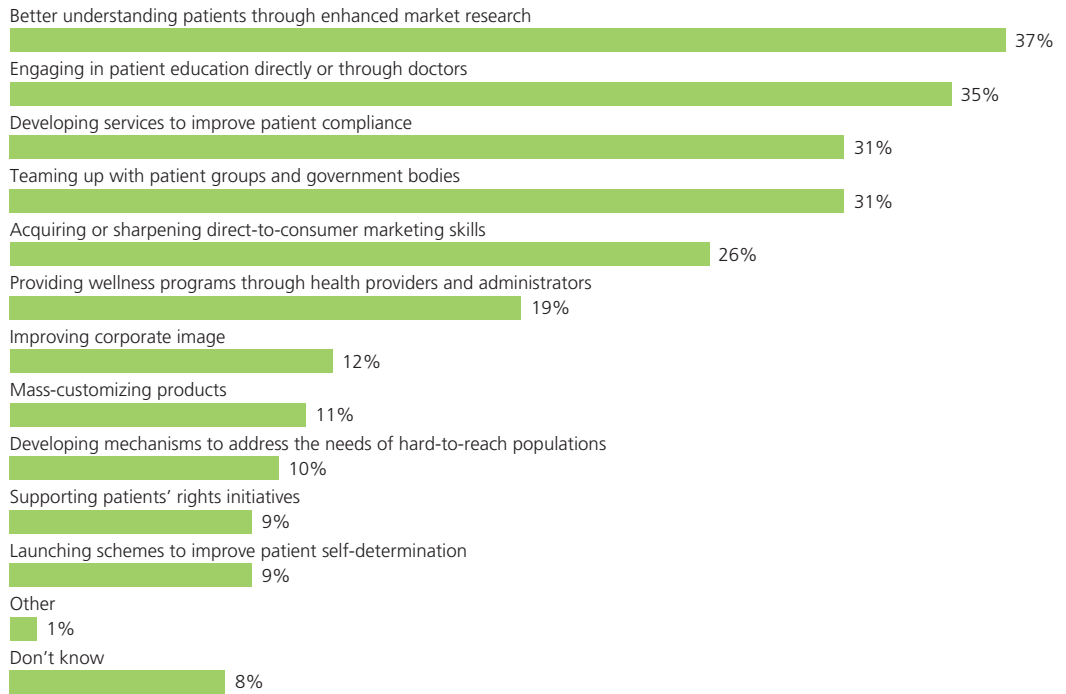
How will the design of your organization's sales force be changed between now and 2015 to mitigate industry risk?



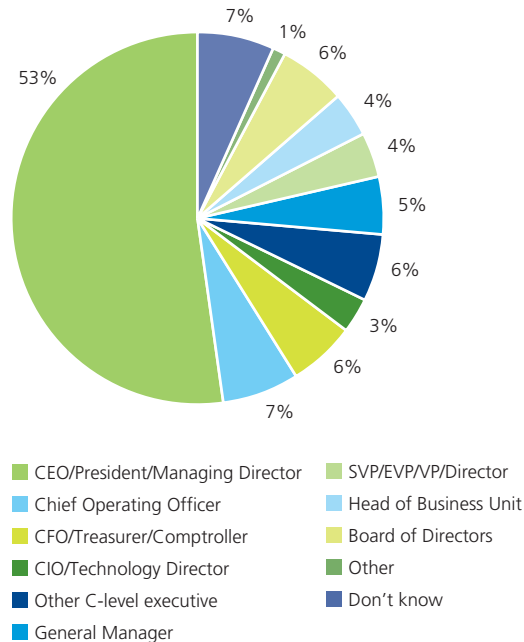
What do you think will be the main steps that your organization will take to increase proficiency and reduce the risks facing sales and marketing between now and 2015?



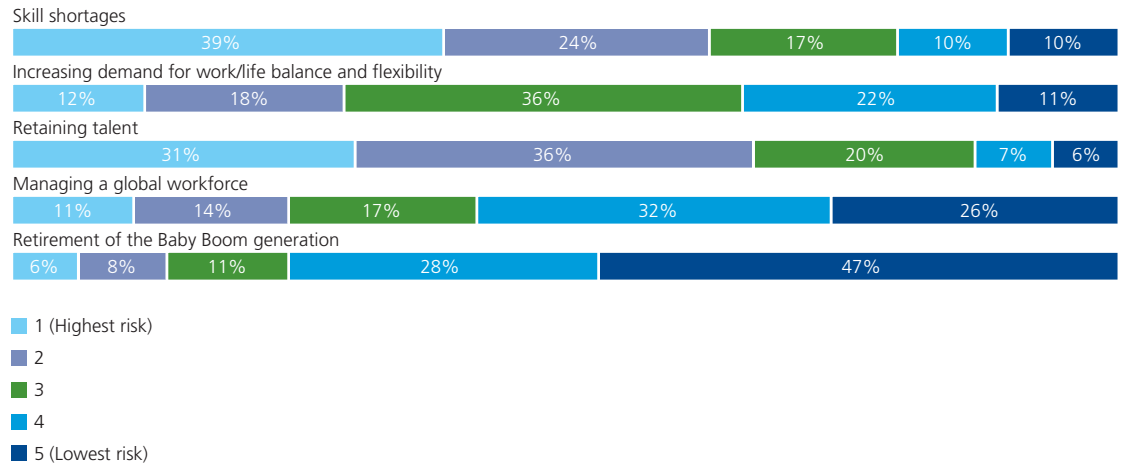
What strategies are your organization most likely to adopt between now and 2015 to get closer to the patient?



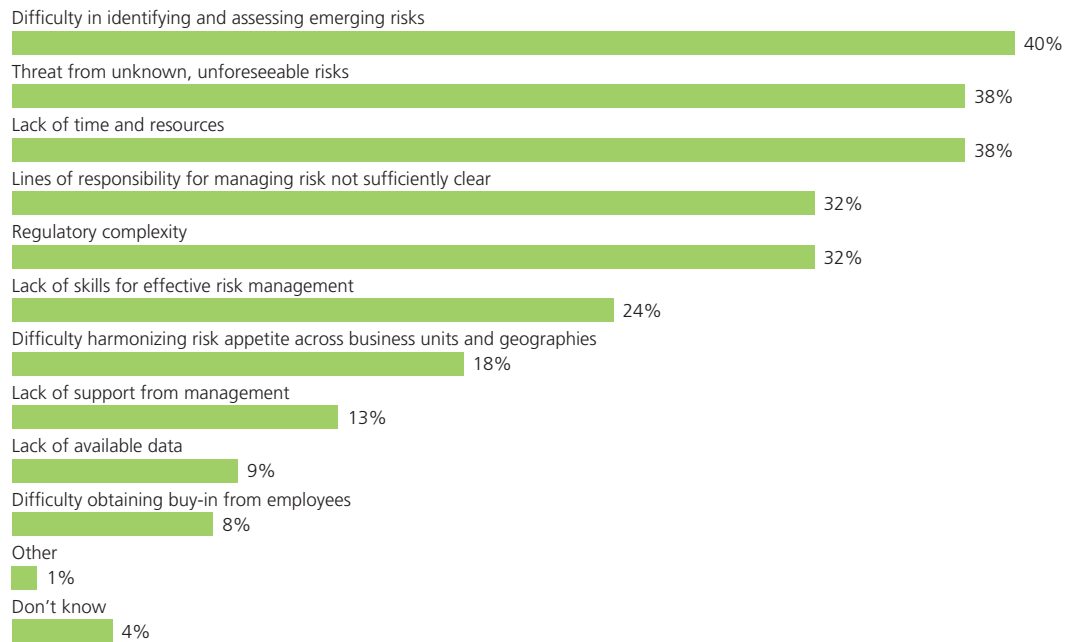
Within your organization, what is the most senior level of executive responsible for looking at systemic or enterprise risk and anticipating how it will change between now and 2015?



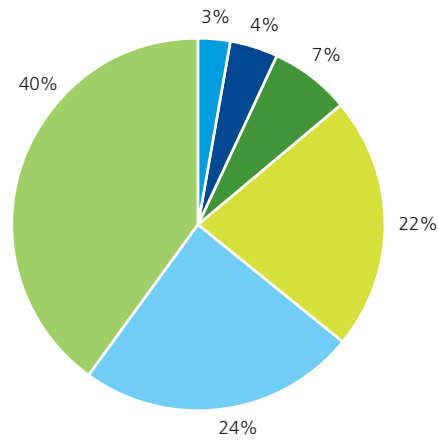
Please rank the following talent management-related issues in order of risk to your organization between now and 2015, where 1 = Highest risk and 5 = Lowest risk.



What do you see as the greatest barriers to the effective risk management in your organization between now and 2015? (Respondent selected up to three.)

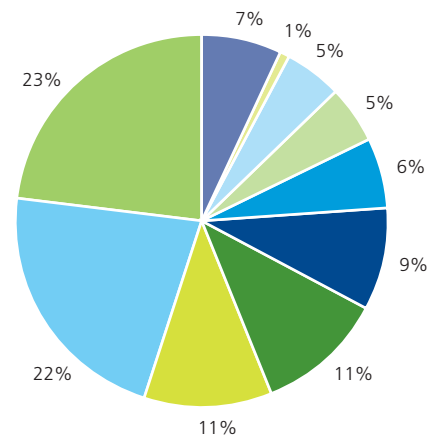


In which region are you personally located?



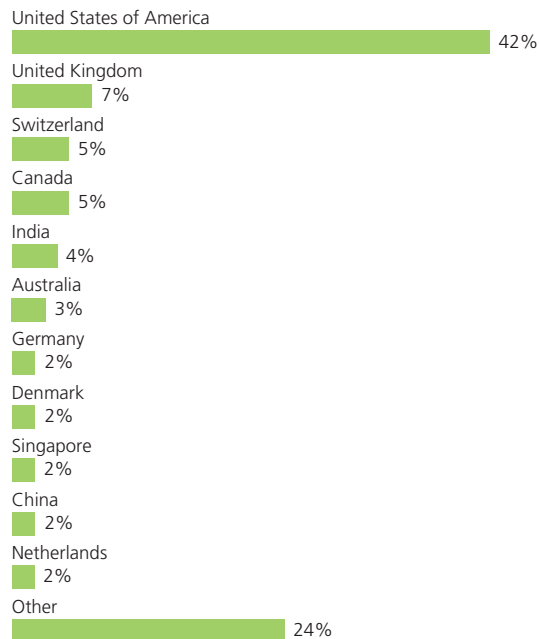
- North America
- Western Europe
- Asia-Pacific
- Eastern Europe
- Latin America
- Middle East and Africa

What is your primary industry sector?

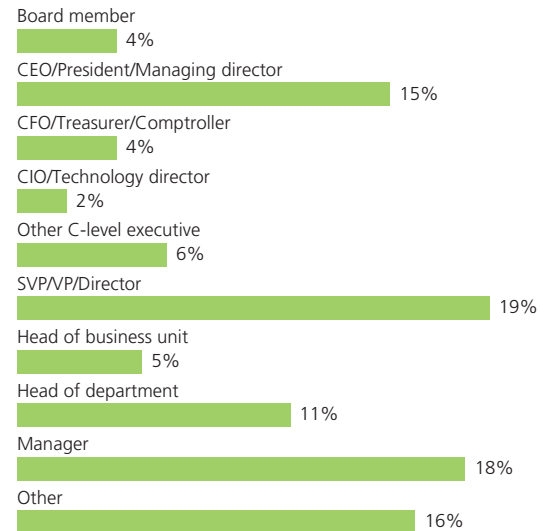


- Healthcare services
- Pharmaceuticals R&D
- Biotechnology
- Pharmaceuticals manufacturing
- Medical devices
- Contract research
- Pharmaceuticals wholesale/retail
- Distribution
- Health insurance
- Other

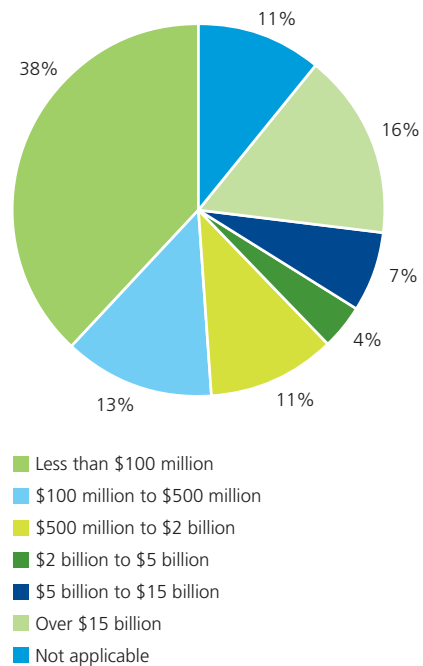
In which country is your company headquartered?



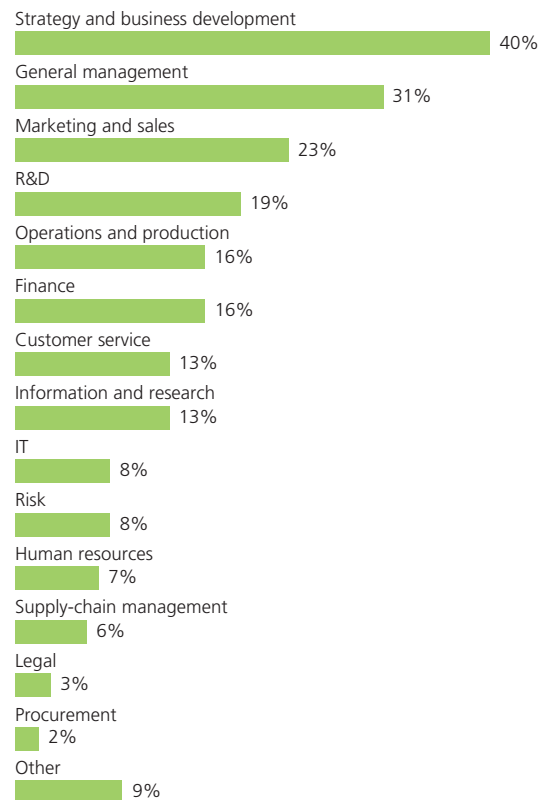
What is your title?



What are your company's annual global revenues in U.S. dollars?



What are your main functional roles? (Respondent selected up to three.)



Endnotes

¹ *Retail Drug Monitor*, IMS Health, June 2008, http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Retail_Drug_Monitor_June_2008.pdf.

² *US Generic Pharmaceuticals Outlook*, Frost & Sullivan, April 30, 2007, <http://www.marketresearch.com/map/prod/1487625.html>.

³ "The Cost of Biopharmaceutical R&D: Is Biotech Different?" by J.A. DiMasi and H.G. Grabowski, *Managerial and Decision Economics*, 2007; 28:469-479. Note: US\$802mil is in 2001 dollars and US\$1.32bil is in 2005 dollars.

⁴ *Answering the Questions that Matter*, Annual Report, GSK, 2007, page 4.

⁵ H. R. 2184: To amend the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to expand comparative effectiveness research and to increase funding for such research to improve the value of healthcare.

⁶ Pfizer's Exubera Flop, *Business Week*, October 18, 2007, http://www.businessweek.com/technology/content/oct2007/tc20071018_028695.htm?chan=top+news_top+news+index_businessweek+exclusives

⁷ Personal Communication, Kenneth Kaitin, January 2009.

⁸ "Triple therapy," *The Economist*, August 14, 2008.

⁹ Covance and Lilly Enter Into a Strategic R&D Collaboration, Press Release, Covance, August 6, 2008.

Contacts

Life Sciences and Health Care (LSHC) Industry Group

The DTT LSHC Industry Group, made up of the LSHC specialists from DTT Member Firms, is comprised of more than 4,000 professionals in over 47 countries. Their understanding of the industry's challenges and their ability to quickly respond with integrated, comprehensive services put the DTT Member Firms in a unique position to help clients. The DTT LSHC Industry Group professionals work with their clients to help them shape the evolution of the industry. These professionals can help companies in their efforts to bring discoveries to life and improve the quality of care while they create and sustain long-term, bottom-line profitability. DTT Member Firms provide professional services to 80 percent of the life sciences and health care companies in the Fortune Global 500.

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