

Pursuing Risk Intelligence in a
rapidly changing industry
Addressing operational risks faced
by pharmaceutical companies

Preface

This publication is the 21st whitepaper in Deloitte's series on Risk Intelligence. The concepts and viewpoints it presents build upon those in the first whitepaper in the series, *The Risk Intelligent Enterprise™: ERM Done Right*, as well as subsequent titles. The series includes publications that focus on roles (The Risk Intelligent CIO, The Risk Intelligent Board, etc.); industries (The Risk Intelligent Technology Company, The Risk Intelligent Energy Company, etc.); and issues (The Risk Intelligent Approach to Corporate Responsibility, Risk Intelligence in a Downturn, etc.). You may access all the whitepapers in the series free of charge at www.deloitte.com/us/RiskIntelligence.

Unfettered communication is a key characteristic of the Risk Intelligent Enterprise. We encourage you to share this whitepaper with colleagues — executives, board members, and key managers at your company. The issues outlined herein will serve as the starting point for the crucial dialogue on raising your company's Risk Intelligence.



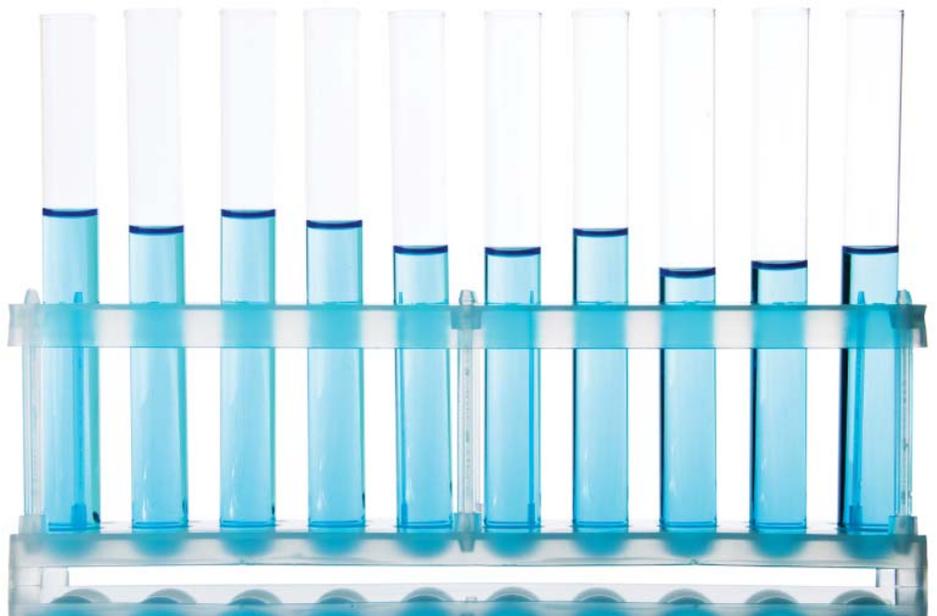
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Introduction

As the pharmaceutical industry continues to face significant change and challenge, the implications for enterprise risks in the sector have broadened and deepened. In addition to significant strategic risks associated with business planning and senior-level decision making, pharmaceutical companies also face increased regulations and related compliance risks, as well as heightened financial threats — and opportunities — driven by disruptive change. But we believe the operations sphere may be the area of the most significant threats and opportunities for pharma companies today. This paper focuses on operational risks, describing substantive issues that might arise in managing pharmaceutical operations in light of industry change, including effective integration of risk considerations in addressing a list of important trends that we believe best summarize the issues many pharmaceutical decision makers will be facing in the risk management arena for the foreseeable future:

- Product/service and geographic diversification
- Consolidation
- Increased regulation
- Commercial model changes
- R&D model changes

In the following pages, we offer some recommendations for linking operational plans, strategies, and activities with your risk management program — all focused on preparing you and your management team to help seize the right opportunities and help mitigate the risks that can be associated with facing change and capitalizing on opportunity.



Operational risks increasingly impacted by industry dynamics

Risk has always been an important and inherent part of doing business in the pharmaceutical industry, but the volume and complexity of change required to survive and thrive in this sector have greatly intensified the implications of risk. Strategic risks, for example, are commonly front-and-center in rethinking a company's business model, products, customers, and markets. Financial risks are becoming more acute with changes in a company's revenue stream and cost models. Compliance risks, which are an ever-present threat in pharma, are exacerbated by the challenge of keeping up with new legislation, evolving interpretations of existing regulations, and increased enforcement.

But a fourth category of risk — operational risk — has arguably been impacted the most. Here are just a few of the significant changes in the pharmaceutical industry that are impacting operational risks:

- Scarcity of new blockbuster drugs and increased focus on diversification into related product areas, such as medical devices, biotechnology, and consumer/generics
- Increased emphasis on global expansion, specifically into the high-growth, emerging markets of Asia and Latin America
- Increased M&A activity aimed at improving the product pipeline, realizing synergies, and achieving critical mass
- The shift toward outsourcing key functions across the product lifecycle, including research and development, clinical trials, manufacturing, and sales and marketing

In considering these four tough challenges for pharmaceutical supply chains — from R&D to manufacturing and distribution of a company's core products and services — it's no surprise that industry executives are focusing on the growing urgency to effectively identify and address operational risks. In fact, when the implications of the changes described above are synthesized, it could be that the operations area is where pharmaceutical companies face their greatest levels of risk.

This paper focuses on operational risks, describing what we believe to be the most significant threats that might arise in managing pharma operations in light of industry change, including effective integration of risk considerations in addressing planning and decision making. Specifically, we have identified a list of trends that we believe best summarize and consolidate operational activities embodied in the key areas of disruptive change outlined above — and which we believe most pharma decision makers will be facing as risk management issues for the foreseeable future:

1. Product/service and geographic diversification
2. Consolidation
3. Increased regulation
4. Commercial model changes
5. R&D model changes

How closely linked are the plans, strategies, and activities of your operations with your risk management program?
How prepared are you and your management team to seize the right new opportunities and mitigate the risks that can be associated with capitalizing on opportunity?

Applying Risk Intelligent principles to managing operational risks

While many ERM practices may have worked well in the past in dealing with industry issues, the level and pace of change today—and the increased uncertainty that underlines global business activity—demands a more strategic approach to managing risk in order to position companies to survive and thrive in today’s marketplace.

Reactive risk management certainly is an important component of the equation for pharma companies, but it is only part of the answer. Complexity and turbulence call for heightened judgment and enhanced decision-making support systems that often aren’t available with conventional approaches. We believe that the ability to respond to the issues and trends cited earlier, and to do so knowledgeably and confidently, is directly linked to the practice of “Risk Intelligent” enterprise management.

Risk intelligence treats risk management as an integral part of proactively managing your company’s strategy and operations and recognizes that risk and value cannot be separated or siloed — that calculated risk-taking is necessary to survive and thrive. Generally, unrewarded risks deliver little or no *upside* business value in return for incurring them. Rewarded risks, on the other hand, must be taken in order to drive enterprise value. Pharmaceutical companies in particular must innovate and drive value creation in order to stay competitive and succeed, and Risk Intelligence is a framework for helping management make choices that are consistent with the organization’s risk appetite and tolerance and permit just the “right” amount of risk to achieve value creation.

For these reasons, we believe pharma operations can benefit from the application of the basic Risk Intelligent principles:

- Understand that both value and risk are key to enterprise management
- Understand that risk management must be “operationalized” into the core ways of protecting existing assets and of creating future value
- Assume that turbulence is inevitable, and emphasize prevention and preparedness to improve both resilience and agility
- Be vigilant in identifying and effectively managing a broad range of opportunities and risks across the enterprise
- Acknowledge the need for specialization by business function, as well as the need to harmonize, synchronize, and rationalize risk management and controls
- Consider interactions among multiple risks, rather than focusing on a single risk or event, and the impacts that could result from multiple threats
- Create a common language of terms and metrics for value and risk, and promote a culture where people account for value and risk in every key decision and activity
- Encourage informed risk taking for reward and value creation, rather than focusing only on pure risk avoidance

Identifying risk and opportunity in operations central to success

We have detailed below a number of areas of operational risk in which we believe pharmaceutical companies would benefit from understanding where both risk and opportunity lie, especially as they relate to the five key trends impacting the industry. As many considerations involve tax and risk management implications, a few thoughts on each of those are highlighted separately, as applicable.

Trend #1: Product/service and geographic diversification

Product safety and quality: New ways and places of manufacturing

Product safety and quality have always been central to the success of pharmaceutical companies, and issues associated with them are coming under increasing scrutiny as companies explore new product development, supply chain improvements, and cost containment. Product adulteration and quality issues, in particular, are receiving increasing attention in the marketplace, as pharmaceutical companies struggle with understanding and tackling how to expand and manage their quality systems outside the four walls of their companies. The inability to manufacture products due to a shutdown puts supply at risk and leaves patients in need of treatment with very few choices, usually limited to selection of a comparable product on the market or doing without. In other cases, once the product has been recalled, companies may struggle to recover their market share.

For many companies, the risks are becoming more complex to manage, as more companies contract with vendors and outsource manufacturing to contract manufacturing organizations (CMOs) in emerging markets that may have less stringent quality and safety standards than in North America and Europe. The basic risk is that a vendor or contract manufacturer may not adhere to the outsourcing company's quality standards, both with respect to manufacturing processes and active pharmaceutical ingredient (API) or material sourcing.

To guard against intentional or inadvertent lapses in quality, it is important to enforce and revisit manufacturing specifications and to develop strong policies and procedures around where and how product components are sourced. The organization needs to consider the risks of the CMOs as a key element of its overall risk profile. There may be some interdependency among the CMOs that increase the overall risk to the organization. That in and of itself is not a reason to avoid a CMO relationship (e.g., the increased value may offset the potential risk), but it does suggest the need for monitoring that risk and putting controls in place to mitigate potential risk.



Trend #2: Consolidation

Supply chain complexity

Thanks in part to continuing industry consolidation, today's pharmaceutical companies have extremely complex supply chains in which third parties often play a prominent role. The more complex the supply chain, the greater the risk that a supplier will fail to deliver as expected, and the more important it becomes to manage the risk of supply-chain breakdowns.

Moreover, as the ripple effects of a shrinking global economy spread through the supply chains of pharmaceutical companies, the potential for cascading business failures threatens to disrupt product development and delivery. Today, given the tenuous nature of the global economy, companies are experiencing an increased risk of having critical or sole-source suppliers fail financially. Although pharmaceutical companies are doing more to apply new and better tools to monitor the financial performance of public companies, many are unable to gather similar information for private suppliers. Limited or no direct access to accurate, timely financial and other performance data for private companies makes monitoring their viability difficult.

Multi-faceted partner relationships dominate the marketplace. Worldwide drug supply chains include a complex network of manufacturers, wholesalers, secondary distributors, and retailers, all with independent risk mitigation issues. Increasing this complexity are varying chargeback and rebate practices where various participants, including hospitals, dispensing physicians, clinics, elder care facilities, pharmacies, retail chains, and the government, receive a wide range of discounts.

The area of the supply chain is an excellent example of how critical it is for risk management to be fully integrated with other functions and the business units. Those responsible for execution of supply chain operations must have an understanding of both the value of the chain to the organization and the risks inherent in supply chain operations.

Creating a culture where people focus on risk in their daily activities and understand the risk/value decisions they make is critical. Educating those that are making the key decisions on the principles of Risk Intelligence and providing them with a common language and set of tools to measure and monitor risk will help embed risk in the overall supply chain operations.

Tax implications

Companies must design and implement global transfer pricing policies for related party supply chain partners that address the rigorous requirements of major jurisdictions. Tax authorities may view a life sciences company as having higher transfer pricing compliance risks than other companies. Changes in tax regulations and more-rigorous regulatory enforcement can sometimes be viewed as challenging the fundamental arm's length principles contained in local tax law or cross border income tax treaties.

M&A-related process disruption

With respect to merger and acquisition-related consolidation, process disruption and ineffective process integration in the post-merger phase are important operational risks. For instance, two merging companies may each have a process that works well for each company as an independent entity — but neither may be effective for the combined, larger organization. Hence, it is important to determine whether wholesale adoption of one or the other company's process is in fact an effective approach.

There is also the risk of processes "falling through the cracks" at a merged company some time after an integration is complete. (This may happen, for instance, if each legacy company assumes that the other company's personnel are responsible for a process.) Roles and responsibilities should be clearly defined and responsible parties clearly informed of their duties in a timely manner. Effective communication during transaction integration is critical, as is the establishment of accountability for the outcome.

The potential for the loss of intellectual capital related to specific process know-how is also an issue. When organizations combine, resources and skills inevitably overlap, and decisions must be made to realign or downsize teams. A critical step before making decisions about resources is to conduct a process-knowledge inventory and continuity assessment that can identify specific resources that must be retained or positioned for knowledge transfer.

Tax implications

Tax efficiency is a component of enhancing the value of M&A activity and strategic alliances and should be factored into any operating model. Business is motivated to achieve the operating synergies promised by the transaction, and many of those business decisions need to consider the related tax impacts in order to manage the implications.

Failure to take tax into account could result in loss of potential tax saving opportunities. For example, upon completion of an acquisition, companies often “inherit” excess or inactive legal entities and/or entities that operate in the same jurisdictions as pre-acquisition companies. This commonly results in multiple legal entities within various tax jurisdictions, tax rate inefficiency, and unnecessary entity carrying costs. In order to simplify the legal entity structure, inputs from multiple business functions (e.g. IT, accounting, finance, legal, et al) are required.

Risk management

Most M&A transactions complicate the interaction between operations and risk management. This is especially true if one or both organizations have taken a less “formal” or less disciplined approach to applying key principles of Risk Intelligence. This may have worked pre-merger, but post-merger changes in operations, operating model, governance structure, etc., increase the need to build out a more integrated and formalized approach to how operational risks are identified, assessed, mitigated, and monitored.

Typically, there are separate workstreams during an M&A deal. One will address operational synergies, identifying any potential process improvements, harmonization, or other changes that will help with the ongoing operations post-merger. A second workstream will look at risk

management functions and how to provide risk oversight in the post-merger world. What might be missing is how the new organization impacts operational risks and how that might change the role of the risk management function and the risks of which operations people need to be aware in their daily activities. Even when an organization has strong alignment between risk and operations pre-merger, it may become hazy in the post-merger environment. There will likely be significant focus on regulatory compliance and value protection activities, but the value creation aspect of Risk Intelligence can fall by the wayside if not carefully managed.

A sampling of post-merger integration risks

Because consolidating processes and organizations is often complex, a company can face post-merger integration risks in any aspect of operations. Important risks include:

- A company’s focus on customers may suffer when realigning sales and marketing territories and accounts
- The interim organizational structure may become the norm, leading to ineffective or inefficient management and/or process execution
- Politics, tenure, and loyalty to individuals may create roles that do not support the organization’s vision, strategy, or operating model
- The skills of existing personnel in both legacy organizations may not be well suited to the desired culture of the larger organization
- Staffing or selection processes may become overbearing, with the risk of litigation driving the process rather than business need
- The company may lose high-performing and/or critical employees due to the uncertainty and turmoil of the post-merger period
- The Quality and Compliance group of one company may have concerns, deficiencies, and inherent risks that were not identified during the due diligence. Once the combination is complete, regulators view the organization as one company

Trend #3: Increased regulation

Compliance-related processes

As new regulations continue to be passed both in the U.S. and globally, the importance of appropriate processes to comply with regulations becomes more significant. It is vital for companies to understand the implications of applicable regulations on their operations, and to develop the capabilities to execute the processes necessary for compliance. For instance, in the U.S., compliance with Risk Evaluation and Mitigation Strategies (REMS) is required for products whose risks may outweigh their benefits. Close monitoring, education, and potential restricted distribution may be required. To comply with REMS, especially with restricted distribution, it is up to the manufacturers, not distributors, to develop a REMS program and to certify the eligibility of pharmacies, dispensers, and/or health care providers, as well as to communicate their eligibility status to distributors. Addressing compliance risks is table stakes. Controls and compliance processes should be “operationalized” into the daily activities and processes of the functions and business units that have compliance requirements and not viewed as a separate or sideline activity. Compliance roles should be clearly communicated and understood and compliance should be recognized as everyone’s responsibility.

Emerging markets

Local customs

When entering a new market, companies may find it challenging to align various aspects of their operations with the market’s local culture and business practices. Areas that may need to be tailored to fit local circumstances include sales practices, as buyers differ from market to market; marketing, to determine which products and delivery methods are most appealing to customers in each market; reimbursement, to accommodate local differences in payment practices; and pricing, to develop prices suitable for each market. It is also important to maintain an effective government affairs group for each market that can understand each jurisdiction’s requirements and regulations and maintain a workable relationship with government agencies.

Beyond Health Care Reform: The Many Faces of Regulatory Change

In the U.S., new regulations are being passed that affect the way in which pharmaceutical companies obtain approval for, market, and sell their products. The recently passed U.S. Patient Protection and Affordable Care Act is one obvious example of regulations that affect the pharmaceutical industry, but others also exist. For example, the 2007 U.S. Food & Drug Administration Amendments Act (FDAAA) has increased the emphasis on product safety and risk assessment. The FDAAA allows post-approval label changes to address unexpected safety issues and grants the FDA the authority to impose penalties against drug makers that fail to complete previously agreed-upon, post-marketing studies. The FDAAA also gives the FDA the authority to require manufacturers to develop a Risk Evaluation and Mitigation Strategy (REMS) to demonstrate that the benefits of a drug or biological product outweigh its risks.

Tax implications

Emerging markets present multi-faceted tax opportunities and challenges that should be analyzed along with development of a new market strategy. For instance, some markets may enable pharmaceutical companies to potentially reduce manufacturing and R&D expenses, but these opportunities need to be balanced with the need to adequately protect intellectual property.



Risk management

Entering emerging markets can be a risky endeavor. Operations that work for the organization in current locations today may not work in the new market. Knowing this, conventional approaches to risk management might dictate that the new market should be avoided. But Risk Intelligence acknowledges that these might be risks, or challenges, worth taking due to the long-term potential for producing rewards. It is critical that the underlying operational risks of expansion into emerging markets be represented as part of the overall decision making equation. While it is unlikely that the operational risks involved will change management's decision to pursue a valued opportunity, careful consideration of them provides executives with more complete information for making a reasoned risk- and value-related decision.

Sales force management

Pharmaceutical companies generally maintain a large sales force whose actions are coming under increasing regulatory scrutiny. Organizations that fail to properly implement and monitor activities associated with field sales operations can face several business and compliance risks, including violations of federal anti-kickback laws and product marketing statutes and industry standards; internal financial losses resulting from inadequate expense reporting and discretionary and marketing spending controls; and loss of reputation in industry and consumer communities.

The sales force in a life sciences company, an employee population that is distinguished by close customer access as well as high turnover, is making risk/value decisions on a daily basis. As such, it is critical that organizations build formal compliance activities into these employees' routines and reports, ensuring they have the tools, experience, and incentives to execute their roles and judgment effectively and in line with company policy and management expectation.

Trend #4: Commercial model changes

Management of unfamiliar business models

As pharmaceutical companies diversify into new businesses or segments — for example, into generics or consumer drugs — they should be mindful that these new businesses may require a significantly different operating model than most pharmaceuticals are accustomed to. For instance, a company whose core business is in branded drugs — where historically high gross margins may have made inventory costs less of a concern — may need to develop new inventory management capabilities if it decides to enter the consumer drug market, where high volumes and low margins make it critical to manage inventory costs. Or as another example, a pharmaceutical company acquiring a business in biologics should be aware that biologics require very precise storage conditions (e.g., cold chain) requiring a fundamentally different approach than for most pharmacological compounds. They should also note that fewer suppliers exist for biologics than for drugs, which means that the company will have a more limited choice of backup suppliers.

Lacking the operational know-how to manage an unfamiliar business can raise risks ranging from delays in market entry, to failure to comply with applicable regulations, to increased costs. It is important for companies to find managers and executives with the appropriate skill sets and knowledge to run each type of business effectively, with a thorough understanding of the unique demands of each business' operating model. One way to do this might be to run each type of business as its own separate subsidiary, complete with its own executive team. This can not only improve the fit between the leadership team and the business, but also allow the performance of each type of business to be measured and reported independently of each other.

Talent alignment with new models

For pharmaceutical companies, the shift in focus from basic research to product development can raise talent-related risks with respect to hiring, talent development, and overall corporate culture. The skills important in a research-driven organization — those needed to discover new drugs and obtain FDA approval — are different from the skills needed to effectively develop and commercialize products, which require an understanding of finance, markets, and sales. Misaligned hiring and development practices may occur when a company operating primarily in the development space maintains talent management practices more suitable to a basic research organization.

Tax implications

Talent management presents significant tax-related considerations. A globally mobile work force, for example, and development of creative methods of compensation to counter competitors, both carry potential tax implications and consequences that should be analyzed before being implemented.

Risk management

The area of talent risk is one of the best examples of how operations — in this case human resource (HR) operations — needs to focus not just on risk avoidance, but also on adding value. Typically, a discussion of risk and HR operations, mainly brings to mind compliance issues around a laundry list of regulations handed down by DEA, DOL, IRS, ERISA, FMLA, etc. However, having an effective recruiting and retention program that aligns with company business and talent objectives has great potential for adding significant value to the organization.

“Lower Profile” Areas of Model Changes

Pharmaceutical companies have historically focused their sales and marketing efforts heavily on physicians, but now are exploring new methods of commercialization as their interactions with physicians come under increasing regulatory scrutiny. Direct-to-consumer marketing has become more prevalent, including the use of social networking to reach consumers. In addition, pharmaceutical companies are stepping up their efforts to influence health care payors, since payors’ decisions on which drugs are covered under which plans can have a huge impact on potential sales volume.

Increasing pressure to bolster the new product pipeline to compensate for patent expirations and rising R&D costs are also driving manufacturers to re-think their R&D model. The goal is to increase profits by reducing costs while also accelerating product development. This process is leading many companies to enter into complex arrangements, such as alliances and joint ventures, with biotechnology and other types of pharmaceutical companies — even competitors in some instances. In these relationships, large pharmaceutical companies often rely on outside parties for basic research, retaining the “development” phase of the product lifecycle in-house.

Trend #5: R&D model changes

“Blockbuster” drug issues

There are very good reasons why many of the world’s largest pharma companies have been committed to production of “blockbuster” drugs since the 1990s. According to an October 2010 report issued by URCH Publishing, a provider of pharmaceutical industry business information, it is estimated that the top 100 blockbuster drugs generated sales of approximately \$285 billion in 2009, while the top 125 drugs classified as non-blockbusters generated only about \$1 billion. Recently, however, the pace of blockbuster drug sales has slowed dramatically as many of these drugs go off-patent, or, in the case of a few, as the drugs have been removed from the market due to complications or lawsuits.

There also are multiple, complex reasons for the decline of the “blockbuster” drug model as a growth strategy for large pharma companies. The loss of patent exclusivity is certainly one, but others, such as the rise of drugs for more “targeted” populations is another significant cause of the shift in R&D strategy. Specifically, the most promising drugs in the industry pipeline today are designed for much smaller populations of patients who have less common medical problems. Smaller, biotech companies are leading the way in production of the more targeted drugs. Moreover, over time, the impact of comparative effectiveness likely will have a dramatic influence on drug portfolios.

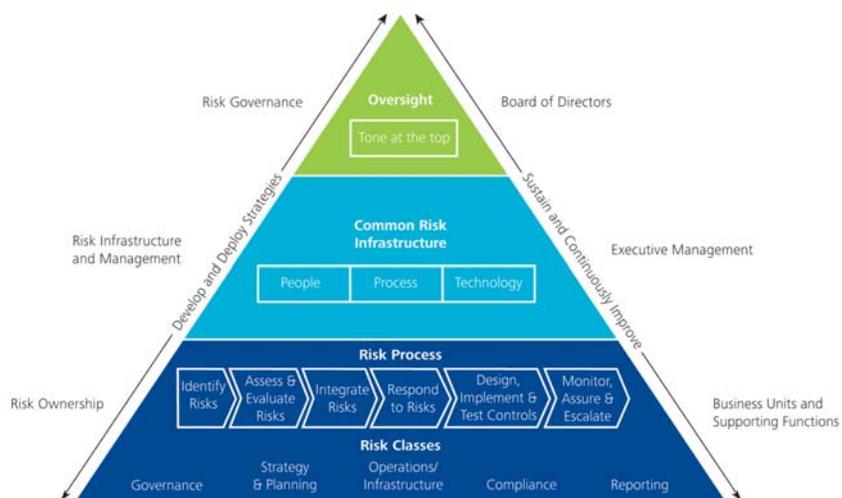
Tax implications

In order to effectively utilize tax incentives and other tax reduction opportunities, analysis of the R&D tax provisions in each prospective location is required. This includes planning for the tax-aligned business ownership of intellectual property so that return on the R&D investment is enhanced.

Risk management

As pharmaceutical companies look to identify new, innovative R&D approaches, they face a plethora of potential risks — from the cost of restructuring their R&D organizations and processes to accommodate new treatment trends to securing proprietary information and competing with smaller, more nimble rivals.

The Risk Intelligent Enterprise™ framework



How it Works

The concepts of Risk Intelligence can help guide pharmaceutical companies in their efforts to more effectively manage operational risk. At the apex of the organization, strong risk governance can help leaders identify which risks they wish to take in the pursuit of value, and which they wish to avoid or reduce. In the middle, a strong risk management infrastructure can help companies gather and communicate risk information, develop processes for managing and mitigating risks, and build risk management responsibilities into appropriate positions throughout the enterprise. And at the bottom, risk owners in the functions and business units can execute risk management processes, as well as stay alert for new risks that might arise. Effective coordination among all three levels of the organization is important in order to keep all parties “on the same page” as to how risks are to be addressed.

Toward a Risk Intelligent approach

Pharmaceutical companies face a two-fold challenge with respect to operational risk. First, they need to identify and understand the specific operational risks they face, and, second, they must also create a fundamental, practical approach for evaluating these risks, implement strategies to address them, and gather detailed information about risks that can guide the strategic decisions that enterprise leaders must make every day.

As the pharmaceutical industry evolves and changes, so too will the nature of the risks these companies face. The operational risks discussed here are those that we believe should be at the forefront of pharmaceutical leaders' minds — but they represent only a sampling of the total universe of possible operational risks. A Risk Intelligent approach to understanding and addressing risks can help keep companies attuned to what risks are most important, what risks may be emerging, and what can be done to both manage risks and capitalize on them in an increasingly complex and challenging environment.



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