

The Risk Intelligent life sciences company



Preface

This publication is part of Deloitte’s series on Risk Intelligence — a risk management philosophy that focuses not solely on risk avoidance and mitigation, but also on risk-taking as a means to value creation. The concepts and viewpoints presented here build upon and complement other publications in the series that span roles, industries, and business issues. To access all the white papers in the Risk Intelligence series, visit: www.deloitte.com/risk.

Open communication is a key characteristic of the Risk Intelligent Enterprise™. We encourage you to share this white paper with your colleagues — executives, board members, and key managers at your company. The issues outlined herein will serve as useful points to consider and discuss in the continuing effort to increase your company’s Risk Intelligence.

As used in this document, Deloitte means Deloitte & Touche LLP, a subsidiary of Deloitte LLP. Please see www.deloitte.com/us/about for a detailed description of the legal structure of Deloitte LLP and its subsidiaries. Certain services may not be available to attest clients under the rules and regulations of public accounting.

When today's life sciences executives were pursuing their MDs, MBAs, and PhDs, they probably had little inkling that their future job would resemble that of an oil wildcatter as much as a business executive. An odd comparison, to be sure, yet the similarities are striking: Both the energy extraction and life sciences industries employ highly skilled individuals. Both take great monetary risks in pursuit of uncertain rewards. Each industry grapples with heavy upfront investment and long lead times in their revenue cycles. Each faces the ever-present threat that they will drill a "dry hole." And each holds the enticing prospect of discovering a "gusher" that makes it all worthwhile.

The risks can be immense in both industries, but they are willingly taken, because the rewards can be similarly vast, not solely in monetary terms, but also in human terms: in delivering new oil reserves to an energy-hungry world, or in introducing innovative pharmaceutical, biotechnology, and medical products to improve health and save lives.

Risk, multiplied

Risk permeates every aspect of the life sciences industry (pharmaceuticals, biotechnology, and medical devices). Discovering and developing products entails high risks, given the required investment in time, money, and expertise. Along with life-saving benefits, the industry's products themselves can pose risks to users, as recent lawsuits remind us. The regulatory environment, which arose because of the industry's risks, adds another layer of business and financial exposure, as do issues of efficacy, pricing, and availability.

In addition to these inherent risks, complexity (and thus additional risk) arises in the form of pressures from consumers, payers, physicians, and markets. Life sciences companies respond to these pressures and risks by taking steps that:

- Feed product development pipelines with the help of alliances, joint ventures, in-licensing, and other strategies that can provide access to needed products or technology, or can increase speed to market, but may also reduce control

- Meet production requirements through outsourcing, contract manufacturing, and alliances, which heighten concerns about quality, security, privacy, and control
- Work against lengthening development times amid the expiration of patents and intense competition for new intellectual property rights
- Address increasing demand for lower-priced products from consumers, physicians, politicians, and regulators, as well as a desire for higher returns from investors
- Deal with a rising call from consumers for safer or risk-free breakthrough therapies
- Cope with heightened media scrutiny and escalating litigation, which broaden potential legal and financial exposure.

Yet underlying all this uncertainty is an unassailable fact: Life sciences companies must take risks to remain competitive and to thrive.

Our recommended response to such challenges is for life sciences companies to develop "Risk Intelligence." What is Risk Intelligence? And how can a life sciences company attain it? This paper will answer those questions.¹

Steps to Risk Intelligence

The fundamental steps toward creating a Risk Intelligent Enterprise™:

1. Establish a framework, policy, and process for managing risks.
2. Identify key risks and plans to address them.
3. Define your tolerance for risk in specific areas.
4. Decide who has the responsibility and authority to take specific risks.
5. Determine your capability to manage risk on an integrated, sustainable basis.

¹ This publication is part of Deloitte's series on Risk Intelligence — a risk management philosophy that focuses not solely on risk avoidance and mitigation, but also on risk-taking as a means to value creation. The concepts and viewpoints presented here build upon and complement other publications in the series that span roles, industries, and business issues. To access all the white papers in the Risk Intelligence series, visit: www.deloitte.com/risk.

Risk Intelligence defined

Risk Intelligence takes risk management to a higher level to create a new view of and approach to risk. (See sidebar, "Steps to Risk Intelligence.") Essentially, a Risk Intelligent approach:

- Recognizes and manages the full spectrum of risks the organization faces
- Minimizes "siloed" behavior that can obscure an integrated view of risk
- Allocates proportionally more resources to the most strategic and pertinent risks
- Considers effective risk management to be an organization-wide responsibility and competency
- Anticipates and prepares integrated responses to risks
- Manages risk with a view toward maximizing the upside of strategic decisions while minimizing the downside
- Acknowledges the need to take intelligent risks to create value.

Especially important is the final point: A Risk Intelligent approach values the ability to anticipate and respond to market opportunities as highly as it does readiness for potential disruptions. This goes beyond viewing risk as "bad outcomes to be avoided." Rather it defines risk as *the potential for loss or the diminished opportunity for gain caused by factors that can adversely affect the achievement of a company's objectives*. A Risk Intelligent approach protects existing assets **and** enhances growth opportunities. It focuses on avoiding negative outcomes **and** on achieving positive outcomes.

A Risk Intelligent approach values the ability to anticipate and respond to market opportunities as highly as it does readiness for potential disruptions.

Rising risks and rewards in life sciences

Among other nuances, a Risk Intelligent approach distinguishes between unrewarded risk and rewarded risk. Taking on an unrewarded risk, as the name implies, provides no premium. For instance, a risk that could compromise the integrity of financial reports or reduce regulatory compliance presents only downside potential. In contrast, assuming a rewarded risk can create value: The risks assumed in allocating capital and other resources to drug discovery and development can yield new products, expanded markets, and successful businesses.

During every day of business and within almost every activity, pharmaceutical, biotechnology, and medical device companies deal with unrewarded and rewarded risk. The complexity and convergence of these risks provides ample opportunity for these life sciences companies to benefit from a Risk Intelligent approach. Of course, far more risks exist than can be described in this paper. However, a representative sampling of unrewarded and rewarded risks is included below.

Unrewarded risks can result from actions either internal or external, including the following:

- Compliance with the dictates and guidelines of the Food & Drug Administration, Department of Health and Human Services/Office of Inspector General, Securities and Exchange Commission, Department of Justice, European Medicines Agency, Japanese Ministry of Health, and numerous other regulatory agencies
- Accelerating global regulatory activity regarding consumer privacy and the inappropriate exposure of consumer information
- Issues of product safety that go beyond regulatory (sometimes only discovered when the product has reached market)
- Security breaches and IT system failures
- Inadvertent exposure of intellectual capital
- Cost and availability concerns.

Examples of rewarded risks in the life sciences include the following:

- Products that prove to be more effective than anticipated: This is seen in Phase III trials, or even as the result of post-marketing studies, and it leads to gaining unanticipated market share upon launch, sometimes resulting in demand outstripping supply.
- Competitors' products fail or develop safety issues: Same result as above.
- Products are approved earlier than expected or in more markets (U.S. and global): While this happens infrequently, it does occur, particularly where there are active consumer advocacy groups and pressure for early review.
- Production yield improves; or the manufacturing process improves potency or significantly lowers production costs.

Biotech manufacturing processes are especially unpredictable; however, the experience curve generally points to improving yields.

- Additional indications are discovered during pre-approval or post-approval clinical activities: For this to be legitimate, additional clinical trials need to be run, but this has become common recently with biotechnology drugs. (There are also downside risks associated with this if these trials have not yet been run, and there is word-of-mouth demand. This results in unrewarded regulatory risks associated with allegations of off-label promotion.)

How can you best consider and manage these risks? By evolving toward Risk Intelligence.

Life events in life sciences

In our experience, companies that excel at managing risks to existing assets and to future growth will outperform those that do not. The risks in life sciences arise around definable initiatives and occurrences that we call "life events" for the company.

We have identified the following life events that a pharma, biotech, or medical device company will likely face, albeit in different ways and with different potential outcomes:

Search & Development™

Engaging in activities, solely or in partnership, ranging from compound identification to in-licensing to formation of alliances for development or promotion.

In addition to traditional R&D, Search & Development encompasses the tasks of locating potentially successful compounds and reliable partners, conducting sound due diligence, managing multiple collaborations and commitments, and monitoring decisions and operations of partners.

Product commitment

Developing a product from Phase IIa to Phase IIb clinical trial and gauging product efficacy, protecting markets, controlling costs, dealing with competitors, and practicing pharmacovigilance.

Committing to a product means ensuring product safety and efficacy while properly assessing and protecting markets and working well with FDA, OIG, and other agencies.

Scale manufacturing capability

Developing production capacity or outsourcing production while ensuring good manufacturing practices, quality control, and security.

Scaling manufacturing capability entails building new productive capacity or using external production resources. If the latter, the company must choose a joint venture or alliance partner or a contract manufacturer, then craft a sound agreement.

(continued on page 7)

A case of commercialization

To show a Risk Intelligent approach in action in a life sciences context, we turn to a hypothetical case of the risks associated with a key activity within a life event — commercialization. This case study is representative and illustrative, but by no means is it intended to be comprehensive. That is, each life event (see sidebar, “Life Events in the Life Sciences”) has a multitude of activities and each of those encompasses numerous risks.

TCC: The Case Company

The Case Company (TCC) discovers, develops, manufactures, and markets high-value/high-margin biotechnology products. TCC has placed a huge bet — in the form of substantial capital and significant resources — on a product that’s expected to gain market share and acceptance quickly, due to its high degree of efficacy in a subset of patients exhibiting a measurable genetic trait. The product is made from a protein-based active ingredient that appears to be easily tolerated with negligible side effects. If all goes as planned, this product will become the flagship therapeutic in its class and TCC’s leading product.

However, the manufacturing process for the product is new and still being refined; thus, production costs are difficult to predict with accuracy. This product is currently in large-scale global Phase III trials being conducted by the company with the assistance of third parties.

Among the key initiatives necessary to prepare TCC for the product launch are the following:

- Gaining regulatory approval for the product, manufacturing facility, and supporting activities (including those of suppliers and contract manufacturers)
- Obtaining fair reimbursement from government and private buyers
- Refining and scaling the manufacturing process to handle market quantities and filling the supply chain to meet demand
- Preparing the marketing plan and the sales force
- Gaining adoption of the product in the market to achieve peak sales as quickly as possible.

In order to depict a Risk Intelligent approach based upon this hypothetical case, we will home in on just one initiative: preparing the marketing plan and the sales force to launch the product. Here, as with almost all the initiatives, a number of risks converge and demand the attention of multiple functions within the organization.

Life events in life sciences (cont.)

Commercialization

Undertaking post-FDA-approval tasks involving reimbursement, sales and marketing, distribution, patient and customer service, and post-market surveillance.

This encompasses positioning, branding, launching, and labeling the product, and ensuring inclusion in the Medicare/Medicaid formulary.

Merger, acquisition, and divestiture

Deciding to merge with or acquire, or be acquired by, another company and performing due diligence amid increasing competition and consolidation — and properly executing spin-offs and divestitures.

Key tasks in this life event are identifying market needs and opportunities, developing ways to scan and source potential partners, and structuring deals with performance and risk management incentives for each partner.

Unexpected occurrences

Responding in a timely, optimal manner to adverse or positive events in development, production, or commercialization by means of a predetermined but flexible response capability.

Unexpected occurrences can undermine or enhance the achievement of objectives. The key tasks are to anticipate losses that could occur even if the situation that could trigger the loss cannot be defined, and to anticipate occurrences that could accelerate development or growth.

TCC: Sales force issues and risks

Specific risks that converge in this area include those arising from a need to ensure that:

- Labels and marketing materials include only FDA-approved statements
- Proper training programs for the sales organization are in place, including those addressing issues around safety, quality, and adverse events
- Salespeople sell only for approved indications and engage in no off-label promotion
- Salespeople offer or provide no illegal inducements or services in exchange for sales
- Third-party sales channels, such as independent sales reps or distributors, conform to FDA-approved materials and messages
- Financial forecasts reflect the on-the-ground realities and constraints that marketing and sales people face in building demand and securing sales
- Revenue recognition methods are appropriate and include reasonable reserves for returns
- Appropriate information technology systems have been established to support the sales and marketing initiative
- Manufacturing capabilities can be scaled to accommodate an upsurge in sales activity
- Communication channels and procedures allow and facilitate interaction between commercial operations, sales, and other key groups, including regulatory, compliance, and legal.

For TCC, at least six functional areas of expertise are required to address these marketing and sales-related risks, including:

- *FDA regulatory*, to provide assistance on labeling, promotional materials, and sales messages
- *Health care fraud* and abuse compliance, to provide input on appropriate sales methods
- *Office of privacy or privacy officer*, to help resolve any issues around collecting, using, or disclosing personally identifiable information, and to ensure that any data collection conforms to U.S. and global guidelines

ERM in theory and practice

Current enterprise risk management (ERM) efforts provide a coherent, comprehensive approach to managing risk — in theory. In practice, ERM often lacks the concrete steps and actions necessary to realize the anticipated benefits. Implementing ERM typically requires a level of alignment across multiple activities that most organizations have not achieved. Implementation often takes the form of top-down mandates that may or may not suit the needs of each business unit. Naturally, when needs aren't addressed, mandates fail. ERM also poses concrete costs to an organization in exchange for largely conceptual payoffs. Finally, in practice, ERM tends to focus on risks to existing assets, paying insufficient heed to the potential benefits of risk-taking for reward. Risk Intelligence embodies "ERM done right" in that it delivers the benefits of ERM in a practical, step-by-step, evolutionary way that integrates and aligns the business units' goals of growth with risk management functions.

- *Security*, to help make certain that sales people and channel partners do not jeopardize the security of intellectual property or drug supplies
- *Finance*, to ensure that revenue forecasts are realistic given market realities and sales challenges
- *Legal*, to draft and approve any sales and distribution agreements, oversee foreign sales activities, particularly in light of the Foreign Corrupt Practices Act, and assist with any other legal opinions or transactions regarding the launch.

It is the presence of these risks and the need for related expertise that necessitates a Risk Intelligent approach.

TCC: Narrow vistas

The risks are myriad even in this example of one initiative — preparing a marketing plan and prepping the sales force for a product launch — and so are the specialists needed to address them. Ironically, this in itself can increase the risks that TCC faces. The depth and breadth of specialized knowledge the company must possess in order to deal with the number and complexity of unrewarded risks may work against having an integrated view of the totality of the risks, both rewarded and unrewarded, involved in the product launch.

Focused expertise, while necessary, prompts each expert to view an activity as if through an endoscope, whether that specialist deals with regulatory, compliance, privacy, security, or another concern. A Risk Intelligent approach bundles those endoscopic views of an activity — and, ideally, of all activities — into a wide-angle view of the risks that TCC faces.

Narrow views of risk occur because most companies have created functions to address the risks of specific activities, or have tasked various existing functions with addressing risk. Thus, a patchwork of regulatory, compliance, privacy, security, and other specialists arise as risks occur in these areas. As regulatory priorities surface and change — Sarbanes-Oxley being the most recent major example — a company's internal emphasis changes. This diffuses risk management in most life sciences companies, providing the full picture to almost no one. (We say "almost no one" in deference to a small subset of chief risk officers and legal departments at the most risk-savvy companies, who may have a full-spectrum view of risk.)

Most life sciences executives would admit that this is not the way they would have designed their risk management functions had they created them from scratch. Many would also note that enterprise risk management has proven more useful in theory than in practice. (See sidebar, "ERM in Theory and Practice.") Unfortunately, there's no feasible way for a large, established company to design its risk management function from the ground up. But with a Risk Intelligent approach, a company can, by means of pilot programs and an evolutionary approach, lay the groundwork for an integrated system of risk assessment and management. A Risk Intelligent approach bridges the silos and coordinates the expert views and

recommendations by harmonizing, synchronizing, and rationalizing the various approaches to risk management. The process leads to a convergence over time in support of an increasingly integrated risk management strategy.

TCC: Risk Intelligence and sales force deployment

On the path to becoming Risk Intelligent, a company like TCC may take the following steps when preparing its marketing plan and sales force for a product launch:

1. Establish an overall framework, policy, and process for assessing and managing risk.

Many life sciences companies are still establishing these frameworks, policies, and processes. Some have adopted risk assessment and management methods, but usually not in ways that foster an integrated view of risk.

For example, as our hypothetical case depicts, TCC had many different risk specialists weighing in: FDA, healthcare fraud and abuse, privacy, security, finance, and legal. The sheer number of specialists involved would normally preclude an integrated view of risk, unless strong mechanisms were established to ensure that such a view emerges at some level of management.

2. Identify key risks and vulnerabilities and the plans to address them; assess existing and anticipated value; determine where risks could impact value.

Life sciences companies tend to view risk management, partly or wholly, in terms of regulatory compliance, and understandably so. However, once the company determines that its strategies, plans, and processes are compliant, adding a Risk Intelligent dimension improves the depth and breadth of risk assessment and management to address future growth issues as well as risks to existing assets.

For instance, a company like TCC, after learning that its product has cleared the regulatory hurdles of the Phase II and IIb trials, and after receiving early positive data on Phase III, may reduce its focus on the risk of the product's safety or side effects. However, successful clinical trials do not eliminate those risks. Life sciences companies need to consider ongoing risks, such as long term use of the product, and assess all potential risks in all areas of commercialization. Key groups, including the sales force, customer service representatives, and health care providers,

must be trained to provide product feedback to the company, beyond traditional adverse event reports, even if earlier clinical trials predict that the product is safe.

3. Establish risk tolerance; determine how much risk currently is being taken on; and decide whether to take on more or less.

Knowing how much risk you are willing to assume demands ways of measuring risk. By their nature, measures promote standardization and can be compared across life events and activities within them. Risks can be measured in terms of dollars (revenue, costs, and profits at stake), reputation (negative mentions in local, regional, national, or international media), regulatory agency action (warning letters, non-approval, and discontinuation orders), or specific occurrences (such as Sarbanes-Oxley deficiencies). Recall too the distinction between unrewarded and rewarded risks.

Once risks can be measured in standard and comparable ways, a company can judge the interaction of risks, and more effectively assess risks across the organization. Then, and only then, can executives make an explicit decision to assume, reduce, or increase an entity's exposure to a risk.

In commercializing a product, a company like TCC has already taken on large risks — those associated with committing to a drug or device and developing it to this point. Now, commercialization will justify or expose those risks, by either rewarding or penalizing the company in the marketplace. In that sense, those prior risks are now subsumed to the risks of commercialization, which poses its own risks. In other words, there's a lot riding on things like labeling, marketing messages, and the sales force engaging only in approved sales practices. Explicit decisions regarding the risks associated with commercialization clarifies what rides on them. For instance, if the company lobbies for watered down warnings or the sales force engages in practices that could appear to be non-compliant, the full implications of such activities should be understood in advance.

Similarly, the company must explicitly decide how large a sales force to deploy and how many of what type of other marketing and sales channels may be necessary, and when they'll be required, in the event that growth skyrockets.

To achieve extraordinary growth a company must plan for it. Planning for the upside in this way distinguishes a Risk Intelligent approach from mere risk management.

4. Decide who has responsibility and authority to accept risk on behalf of the company.

The chief risk officer and the legal department are not the true risk owners; rather, business unit executives should own the risk. In a Risk Intelligent enterprise, risk specialists properly act in advisory capacities. Neither the risk owners nor the risk specialists can operate alone. The risk owners need the expertise that resides in regulatory, compliance, privacy, and so on. And the risk specialists need the business perspective that only those on the business side can provide.

However, without an integrated view and standard measures of risk neither risk specialists nor business heads can make optimal decisions about risks, nor can they consider the risk posed to other areas and activities by their decisions. Explicit assessment of risk in the preceding step enables the company to assign responsibility and authority for risk reporting and mitigation to the appropriate managerial levels. For instance, if quantified risks are characterized as Level 1, 2, or 3, then responsibility and authority for addressing or reporting the risk can be prioritized and assigned to specific people with the appropriate levels of authority.

When such a system is not in place, it is extremely difficult to know who owns a risk, who decides which actions are needed to mitigate the risk, and who is responsible and accountable for addressing the risk. This can lead to a tug-of-war, for example, between compliance and sales and marketing, in which both want the product brought to market quickly, but compliance wants more sales training, while sales and marketing (ever mindful of their goals and time constraints) want less. Without documented ownership and a clear delineation of responsibility, accountability, and authority for risk management, the tension in that tug-of-war is directed toward discussions and activities that are inadvertently counterproductive; that is, they neither mitigate the downside compliance risks nor increase speed to market.

5. Determine capability to manage risk on an integrated and sustainable basis.

Given the nature of their products and regulatory environment, most life sciences companies employ risk specialists, although they often focus on risk avoidance rather than intelligent risk-taking for reward. Yet the risks, stakes, and required number of specialists argue for a Risk Intelligent approach. Separate “silos” of expertise spawn an atomized view of risk that can foster an unbalanced or reactive approach to risk management. As noted in the sidebar (“ERM in Theory and Practice”), ERM is a step forward, but its adoption must be more evolutionary than episodic. Risk Intelligent enterprises build risk considerations into decision-making and operations in a sustainable way rather than as a project. A Risk Intelligent approach seeks objectives similar to those of ERM and employs similar elements, but at a more practical level, a level that can be cost effectively implemented and managed.

Lacking an integrated approach to and standardized framework for risk management, including those associated with preparing the sales force for the launch, companies tend to view each risk in an isolated manner. This creates a host of problems, including a limited focus on safety risks that remain after FDA approval, unresolved labeling issues, and a conflict between compliance and sales over the training content and timeline.

Also, the financial, compliance, regulatory, privacy, security, and legal specialists tend to raise risk issues and make recommendations in their areas of expertise, without any real clarity over who owns the risk and has final decision-making authority. A better approach codifies roles and responsibilities, enabling these specialists to describe the floor, ceiling, or range of acceptable risk; empowering senior management to define the company’s tolerance for risk based on its capacity to manage such risks; and leaving the business decision to the appropriate level of operating management. This encourages the operating managers to consider risk management part of their job; allocates responsibility for risk assessment, management, and reporting to risk owners; and leaves more upside possibilities within the purview of operating managers.

Evolving toward Risk Intelligence

A company typically evolves into a Risk Intelligent Enterprise™ rather than achieving it in the short run by means of mandates. Mandates tend not to work because they position risk management as another add-on activity or initiative for the business units to embrace, endure, or avoid.

How does a company evolve toward Risk Intelligence? Here are several guidelines:

- Bridge the “silos” by setting up processes and systems in which risk experts and operating managers communicate in ways that measure the frequency, formality, and results of their interactions.
- Mandate that business units aggregate the unrewarded and rewarded risks they face and develop a risk portfolio based on likelihood, measurable impact (dollars, reputation, etc.), and vulnerability to the risks.
- Assess and adjust preparedness by accepting tolerable levels of risk or mitigating the risk more or less aggressively, as needed.
- Rationalize, synchronize, and harmonize the approach toward risk management by using measurement, review, and reporting processes and procedures, and by deploying controls that address multiple risks.
- Imbed Risk Intelligence within the culture and the initiatives that permeate the company. One example may be found in a “Six Sigma” company, where the practice is widespread and infused into the daily life of the organization. In this environment, people apply Six Sigma’s DMAIC approach (define, measure, analyze, improve, control) to many aspects of the operation. The same would hold true for a Risk Intelligence-embracing organization, where people understand and apply the Risk Intelligent concepts in a similar “institutionalized” manner.

Becoming Risk Intelligent requires people and systems to change the way they handle risk. In most respects, supporting technologies are still in development, but the human factor remains the highest hurdle. Once executives and risk management professionals in life sciences see the value of changing their thinking, behavior, and approach toward risk, the benefits soon become apparent. Those benefits include improved ability to detect, prioritize, and mitigate risk; standardized risk management principles and language; reduced risk management costs; improved flexibility to respond to positive as well as negative events; and confidence of the board and other stakeholders that the full range of risks is understood and managed.

In sum, to truly excel, life sciences companies must consider risk in new ways and address it aggressively. The need for compliance remains paramount, but organizations can enhance their prospects by adopting the principles of Risk Intelligence to manage risk-taking for reward as proactively as they manage risks to existing assets.

In doing so, life science executives can, like their brethren in the energy industries, increase their chances of striking a gusher.

This publication contains general information only and Deloitte is not, by means of this publication, rendering accounting, business, financial, investment, legal, tax, or other professional advice or services. This publication is not a substitute for such professional advice or services, nor should it be used as a basis for any decision or action that may affect your business. Before making any decision or taking any action that may affect your business, you should consult a qualified professional advisor.

Deloitte shall not be responsible for any loss sustained by any person who relies on this publication.

Copyright © 2013 Deloitte Development LLC, All rights reserved
Member of Deloitte Touche Tohmatsu Limited