



PHARMACEUTICALS

Pressure Points

Risk Management in the Pharmaceuticals Industry

ADVISORY

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Introduction



“If we do not take change by the hand it will surely take us by the throat.”

Winston Churchill

The link between risk and reward has never been more important than it is now in the pharmaceuticals industry as it grapples with the challenges of delivering profitable, new solutions for better healthcare in the global marketplace. Never before has effective management of business risk been so critical to achieving positive results and to enhancing corporate reputation. At the same time, the industry has witnessed a series of extreme events that have exerted pressure on shareholder value and proven costly to resolve. History has shown that although significant risks are often known in some parts of a company, those risks may not have come to the attention of the right people at the right time.

These companies, which have focused so much on innovation in science, are now looking for progressive ways to manage and mitigate their business risk not only to gain competitive advantage but, in some cases, to survive. They are sensing that their current approaches to risk may no longer be sufficient to support their rapidly changing business models.

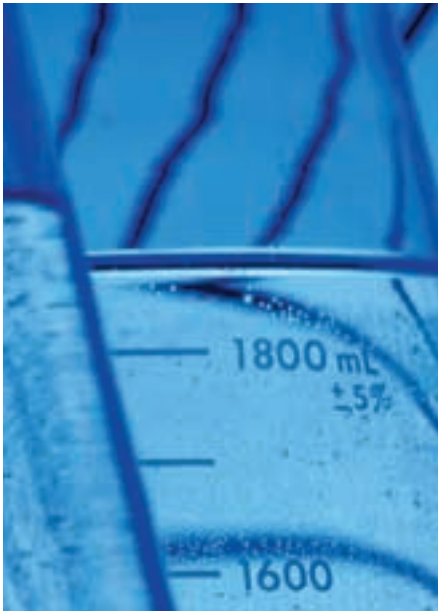
Boards and management are looking to better understand, anticipate, and be able to mitigate business risk in order to deliver the rewards of risk taking, and to minimize the frequency and impact of risk on the downside. As boards and their audit committees contend with their new responsibilities for risk oversight, they are looking for greater assurance that there is a system in place, with well-documented, effective controls and accountability, that provides relevant information for decision making to the appropriate people in a timely manner.

KPMG believes companies must be more proactive in their efforts to manage risk on an enterprisewide basis. This will help them comply with the corporate governance requirements of the New York Stock Exchange and those of the Combined Code on Corporate Governance contained in the Turnbull Report, which is supported and endorsed by the London Stock Exchange. It also will help their presentation to bond-ratings agencies, which are now examining the effectiveness of governance, including risk-management processes. In fact, a recent report by The Conference Board* indicated more than half of the companies they survey from various industries are already actively moving forward with enterprise risk management and another third are positively endorsed.

As the foundation for improving their approach to risk management, some companies may have looked to compliance with the Sarbanes-Oxley Act of 2002, especially section 404 of the Act, which requires stronger controls around financial reporting. But, compliance with Sarbanes-Oxley is aimed at preventing the financial reporting issues rooted in the manipulation of GAAP. The Act does not necessarily address issues for pharmaceuticals companies when their root causes are in operations such as research, clinical testing, channel management, pricing, and patient communications. And, while pharmaceuticals companies already have a strong controls culture from being in a highly regulated

* “From Risk Management to Risk Strategy,” The Conference Board, 2005.

There is no one “shrink-wrapped” solution; the approach to managing risk may differ from one company to another.



industry, risk today goes beyond regulatory compliance to other aspects of the business, including intangibles such as reputation. Nevertheless, both the lessons learned from compliance with Sarbanes-Oxley and their embedded focus on regulatory compliance create a strong foundation for pharmaceuticals companies to improve controls over their management and mitigation of risk going forward.

To gain insight into the changing nature of risk in the pharmaceuticals industry, to learn about leaders' perspectives on risk management, and to identify effective, practical ways to improve management and mitigation of risks, KPMG's Pharmaceuticals practice commissioned a research program with S.P. Kothari, Head of the Department of Economics, Finance, and Accounting, and Gordon Y. Billard Professor of Management at Massachusetts Institute of Technology Sloan School of Management. Professor Kothari was joined in the research by colleagues from The Wharton School of the University of Pennsylvania and The Darden Graduate School of Business Administration of the University of Virginia.

Along with KPMG's research findings, *Pressure Points: Risk Management in the Pharmaceuticals Industry* offers insights from work done by KPMG LLP in the United States on the changing roles and responsibilities of the board and management regarding risk assessment and risk management.

The purpose of this paper is to put forward ideas on how risk management can be improved. We present the view that a new environment exists, one in which “business as usual” may fail. While pharmaceuticals companies have their processes and controls in place to manage risk, it is now time to reassess their risk framework and to make any modifications that are needed to stay current with the evolving business model and the changing industry risk profile. These improvements need to address the company's risks in a more comprehensive manner, across silos and with the goal of enhancing the ability to anticipate risk in line with the goals and the culture of the organization.

KPMG believes that pharmaceuticals companies need:

- An organizational response to assess their risk framework
- An operational response to improve their risk-assessment and risk-management processes
- A governance response to improve risk oversight

There is no “shrink-wrapped” solution that fits every company. There are certainly ways to build on the current foundations, to improve the existing risk framework, and to leverage the investments companies have made in improving controls. This is important, as management will support a plan to invest in improving risk management only if the plan builds on existing activities and processes, does not increase bureaucracy, and is not seen as yet another corporate-sponsored initiative, the value of which has not been fully articulated.

Most important, it is a critical time to share ideas, thinking, and views as to what is working best, and our intention is to have *Pressure Points: Risk Management in the Pharmaceuticals Industry* serve as catalyst and contributor to this exchange.

Research Findings



Risk is defined as anything that impedes an organization from achieving its goals.

In summary, KPMG's research shows that:

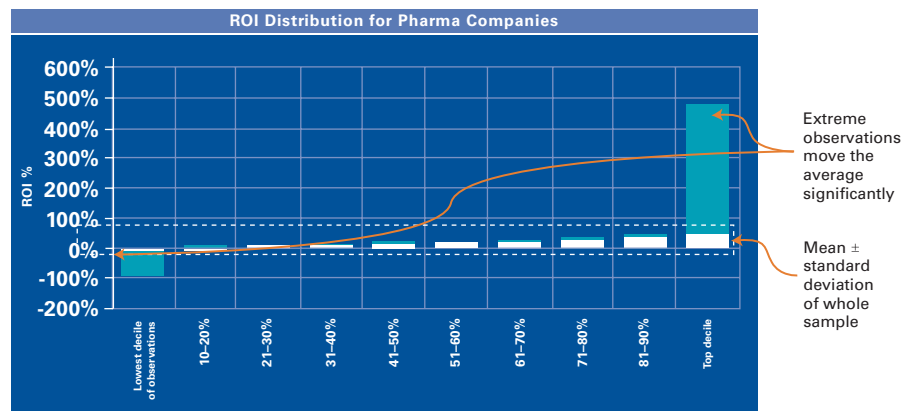
- The pharmaceuticals industry is 50 percent riskier than the overall S&P 500
- Industry risks are dramatically changing
- Pharmaceuticals companies are struggling to take a more comprehensive view of risk
- Companies have a risk framework in place but it may not have kept pace with the changing business models
- The management of risk is silo-based
- There is a need for senior management involvement in risk oversight

Key Findings

The pharmaceuticals industry is 50 percent riskier than the overall S&P 500

An analysis of pharmaceuticals companies' key performance measures by Wayne Guay, Associate Professor of Accounting at The Wharton School of the University of Pennsylvania, showed that over the past 13 years, pharmaceuticals companies in the aggregate are as much as 50 percent riskier than the overall Standard & Poor's (S&P) 500. Positive and negative events in this industry are extraordinarily pronounced with dramatic effect on shareholder value and reputation. These extreme events are generally not the result of manipulation of GAAP, but have their root causes in operational areas.

The statistical research focused on pharmaceuticals industry data on cash flow, net income, sales, and return on investment as a percentage of assets, and compared the findings with those for the same categories for the S&P 500. Thirty pharmaceuticals companies, each having at least US\$500 million in sales, were studied, and the data comprised results over a 13-year period, ending in 2004.



Source: KPMG LLP (U.S.), 2005

Analysis of the data showed the average annual standard deviation in cash flow and net income as a percentage of assets was much higher for the 30 pharmaceuticals companies than it was for the S&P 500 in the same period. (In statistics, the standard deviation is the average amount a number varies from the average number in a series of numbers.) Specifically, the average annual change in cash flows as a percentage of assets that a pharmaceuticals company experienced was 8.8 percent for that 13-year period. The average change in cash flows as a percentage of assets for the S&P 500 in the same period was 5.7 percent. The average annual standard deviation in net income as a percentage of assets for the period was 5.3 percent for the S&P 500 and 8.4 percent for the group of pharmaceuticals companies.

Looking at sales and return on investment in the same period, and comparing them with the same measures for the S&P 500, the data suggests a similar amount of volatility for both groups.

The challenge now for the industry is that the upside seems harder to achieve, while on the downside there are a growing number of risks and potentially greater impact.

	Pharmaceuticals Companies	S&P 500	Pharmaceuticals with one low point deleted	Pharmaceuticals with one low and one high deleted	Comments
Cash Flow scaled by assets	8.8%	5.7%	7.7%	4.8%	After including size effects, 50% riskier for pharmaceuticals than S&P
Net Income scaled by assets	8.4%	5.3%	6.4%	5.2%	Similar risk profile
Sales scaled by assets	23.9%	28.4%	22.4%	14.9%	Sales are more steady
Return on Investment	22.0%	23.1%	18.9%	12.9%	ROI is also significantly impacted by extreme values

Source: KPMG LLP (U.S.), 2005

Industry risks are dramatically changing

The risk profile of the pharmaceuticals industry has changed dramatically in the past seven years. This is demonstrated by a comparison of the risk factors disclosed by 18 major pharmaceuticals companies and medical-device manufacturers in their 1998 and 2003 SEC 10-K filings.

Pharmaceuticals Disclosures

Risk Factor Matrix – 1998/2003

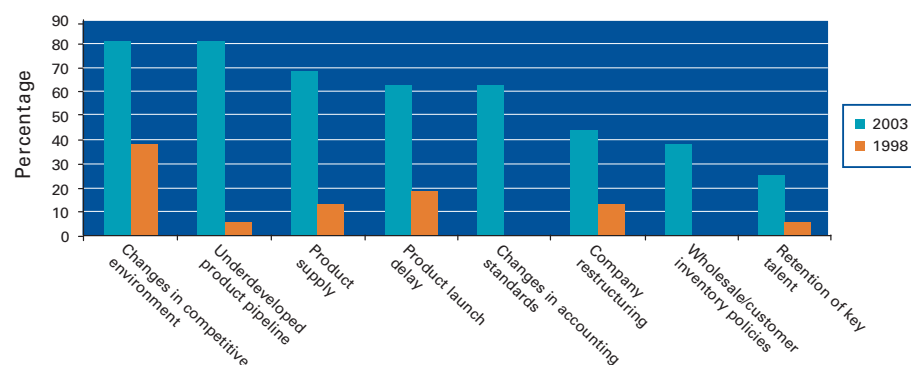
	Number of companies disclosing risks		Percentage of companies disclosing risks	
	1998	2003	1998	2003
Underdeveloped Product Pipeline	1	13	6	81
Patent and Product Protection	10	11	63	69
Legal Liability	14	16	88	100
Retention of Key Talent	1	4	6	25
Price Controls	10	16	63	100
Product Launch Delay	3	10	19	63
Regulatory Approval	10	15	63	94
Foreign Exchange Exposure	13	11	81	69
Product Supply	2	11	13	69
Wholesaler/Customer Inventory Policies	0	6	0	38
Company Restructuring	2	7	13	44
Changes in Competitive Environment	6	13	38	81
Legislation	4	6	25	38
Changes in Accounting Standards	0	10	0	63
Year 2000	14	0	88	0
Euro Conversion	10	0	63	0
Competition, Distribution, and Customers	2	0	13	0
Research and Development	2	0	13	0
Regulation	6	0	38	0
Managed Care Organizations	1	0	6	0
Environmental Law Compliance	1	0	6	0



Source: KPMG LLP (U.S.), 2005

In 1998 no single risk was mentioned by all 18 companies. The risks that pharmaceutical companies mentioned most frequently in that year (over 80 percent) were associated with legal liability, foreign exchange exposure, and Year 2000, which was a one-time event. The next four risks mentioned most frequently in 1998 were those associated with currency issues, price controls, patent and product protection, and regulatory approval.

Disclosed Risks: Pharmaceuticals Industry Gained Significance in the Five-Year Period



Source: KPMG LLP (U.S.), 2005

Interviewees Highlighted Several Difficulties with Current Risk-Management Practices

- **Reactive vs. proactive approaches**

- Lack of well-structured, formal risk-management programs is the major reason
- Companies have only recently begun to recognize risk management extends beyond financial and operational risk

- **Subjectivity**

- The unique risks facing the pharmaceuticals sector are difficult to measure
- “Risk” has different connotations in different companies. Action or inaction today can impact the company over many years, and affects many people

- **Difficulty in forecasting**

- Risks eventually do impact financials (earnings per share and net income), but how and when is unclear
- Limited toolkit (e.g., compared with the other sectors)

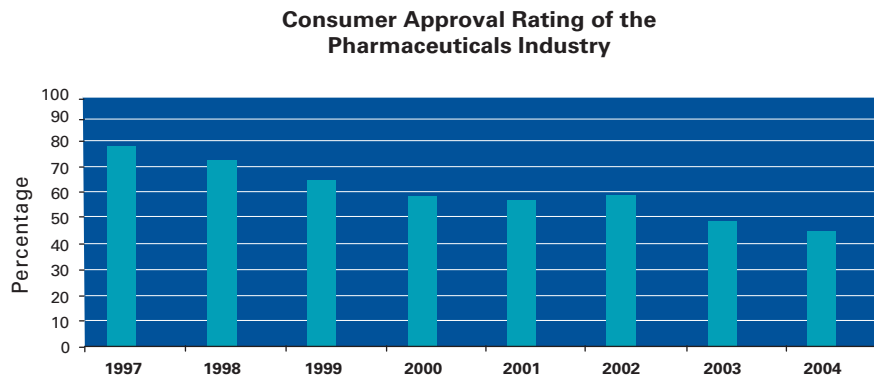
- **Weak feedback mechanism in place**

- Dedicated teams for risk management are rarely present
- Lines of communication are not clear
- Past experience and anecdotal evidence may not always apply

Five years later, in their 2003 disclosures, there was a change in their identified risks. All of the companies in the study disclosed legal liability and price controls as risks followed by an underdeveloped product pipeline, product supply, and changes in their competitive environment. While many of these risks may have existed in 1998, it is not clear whether they were identified or anticipated.

It is interesting to note that reputational risk was not disclosed as, we believe, it is hard to quantify and is, to some degree, the result of public exposure to adverse events. In 1997, the Harris Interactive Inc. survey on how industries rated in serving their customers found that 79 percent of adults in the United States believed that the pharmaceuticals industry was “doing a good job for their customers.” By 2004, that rating had plummeted to 44 percent. We believe that this decline in consumer respect for the industry not only reflects past events but also contributes to a more hostile overall business environment, with greater scrutiny by legislators, regulators, and litigators on a global basis.

Reputation Risk Has Increased Significantly



Based on the Harris Interactive Inc. survey that was conducted by telephone within the United States between April 8 and 15, 2004, among a nationwide cross-section of 979 adults (ages 18+).

Source: Harris Interactive Inc., 2004

Pharmaceuticals companies are struggling to take a more comprehensive view of risk

As part of the research for this project, interviews of pharmaceuticals companies’ chief financial officers and other senior executives were conducted from June 2004 through September 2004. These executives highlighted a variety of financial, strategic, regulatory, and external risks. However, their key focus is increasingly on operational risks, according to Professor Kothari. The picture that emerged, he said, was one where problems in operations typically “mushroom into a huge problem that eventually affects the bottom line in a significant fashion.” CFOs and the leading executives in internal audit are positioned, Kothari believes, to see the root causes because, “they are the ones that get the financial information from all corners of the organization. They are getting the rich information that transcends different departments.”

As the number and severity of risk events involving pharmaceuticals companies have increased, the debate about the adequacy of their risk-management and internal-control processes has intensified. Companies perceive different degrees of risk exposure, and the risk forecasting and management methods are evolving.

There apparently is no single, uniform approach: risk-assessment and risk-management processes vary widely. For the most part, companies appear to be working on several independent initiatives, and the process for prioritizing risk is largely subjective and detective in nature involving the cataloging of risk after the fact.

While the financial audit processes have been largely risk-based, focusing on the areas of greatest potential importance and likelihood of occurrence across the business, it is not clear that operational risk assessments deploy the same kind of mindset. And, while companies recognize a need to improve their risk-management processes, the research shows some are struggling to find ways to take a more comprehensive view across the strategic, financial, operational, and regulatory risk dimensions. Part of that difficulty is weak feedback mechanisms for identifying and managing risk, not having dedicated teams to address risk-management issues, unclear lines of communication about risk processes, and an ad hoc nature to the current risk-management practices. In addition, they lack an effective network of risk sensors—scanning both internally and externally—to better anticipate emerging risks and recognize patterns of problems coming out of operations.

The management of risk is silo-based

There is a significant perception that risk and control processes for product discovery, research and development, clinical testing, manufacturing, distribution, and sales and marketing operate largely in silos with substantial gaps in each one's understanding of the risks inherent in other processes.

Although the larger pharmaceuticals companies in the study appeared to be more focused on risk management, size was not always indicative of effective risk management. Companies judged by Professor Kothari to fall at the “poor” end of the scale for risk-management preparedness had significant silos that separated their operations—research and development, manufacturing, and marketing—from each other. Businesses that were judged to have better risk management had cross-functional teams to assess risk and make recommendations to mitigate them. These companies also focused more on communication and training of staff about risk-management practices. There was a consistent top-down communication effort, as well as broad directives from senior management who engaged in were personally involved in risk-management decisions.

There is a need for senior management involvement in risk oversight

Our research indicates boards are sensitive to financial risks but often overlook other kinds of risk. KPMG's review of the audit committee charters of 17 pharmaceuticals companies shows a variety of formal approaches at the board level to managing risk. Some companies direct their audit committee to lead the effort; others create separate bodies, such as GlaxoSmithKline's Risk and Oversight Compliance Council and AstraZeneca's Risk Advisory





“Some boards could do more to explain to their shareholders...how they are managing risk.”

Douglas Flint,
Chair, The Turnbull Review Group,
and Group Finance Director,
HSBC Holdings plc

Source:
Financial Times, June 16, 2005, London Edition

Group, which report to the full board. And Bristol-Myers Squibb has reported that its chief compliance officer reports to senior management, the board, and the audit committee.

As part of their new responsibilities, audit committees may be asking themselves questions such as the following:

- Do we meet the standards for oversight set by the New York Stock Exchange?
- Do we understand and can we communicate the key risks that the company faces and the risk tolerance of the enterprise?
- Are we comfortable with the company’s approach and risk profile?
- How do we measure up to our peers?
- Do we have a defined framework for risk management and what in addition to risk assessment does it include?
- How do we know that the key risks identified are indeed the ones that should receive management’s attention?
- Are risks assessed and prioritized consistently?
- How are mitigating actions followed up and closed?
- How are identified risks changing over time?
- Are risks identified in relation to business objectives and planning?
- Is risk appetite defined and is it used to establish risk-measurement criteria?
- How do we assess future risks?
- Are we able to demonstrate compliance? Do we have enough formality in the process?
- Does risk reporting include commentary on the business environment and trend analysis?
- How is management made aware of their risk-management responsibilities and is it held to account?

NYSE Corporate Governance Rules Section 303A – NYSE-listed Company Manual

“While it is the job of the CEO and senior management to assess and manage the company’s exposure to risk, the audit committee must discuss guidelines and policies to govern the process by which this is handled. The audit committee should discuss the company’s major financial risk exposures and the steps management has taken to monitor and control such exposures. The audit committee is not required to be the sole body responsible for risk assessment and management, but, as stated above, the committee must discuss guidelines and policies to govern the process by which risk assessment and management is undertaken. Many companies, particularly financial companies, manage and assess their risk through mechanisms other than the audit committee. The processes these companies have in place should be reviewed in a general manner by the audit committee, but they need not be replaced by the audit committee.”

Responsibilities of Audit Committees Regarding Risk: Selected Examples

Company	Source	Summary
Abbott Laboratories	Audit Committee Charter	Review and discuss (with management, the internal auditors, and the independent auditors, as appropriate) Abbott's major financial risk exposures and the steps management has taken to monitor and control those exposures, including Abbott's risk-assessment and risk-management policies.
Bristol-Myers Squibb	Audit Committee Charter	Discuss periodically with management the company's policies and guidelines regarding risk assessment and risk management, as well as the company's major financial risk exposures and steps management has taken to monitor and control such exposures.
GlaxoSmithKline	Annual Report Constitution	To assist in the performance of its duties, the audit committee will review information and reports from the Risk Oversight and Compliance Council.
Johnson & Johnson	Audit Committee Charter	The audit committee shall discuss with management the guidelines, policies, and processes relied upon and used by management to assess and manage the company's exposure to risk.
Novartis	Audit Committee Charter	<p>Review the processes and procedures for management's monitoring of any significant risks or exposures the group may face. To this end, at least once per year, the Audit Committee will review reports submitted by management and give guidance and direction on how risk management is to be conducted.</p> <p>Review with management, internal auditors, and external auditors any significant risks or exposures the group may face, and assess the steps management has taken to minimize such risks.</p>
Pfizer, Inc.	Audit Committee Charter	Discuss company policies with respect to risk assessment and risk management, and review contingent liabilities and risks that may be material to the company and major legislative and regulatory developments that could materially impact the company's contingent liabilities and risks.
Roche	Audit Committee Charter	Discuss policies with respect to risk assessment and management.
Sanofi-Aventis	Proxy – Board Practices (<i>Audit Committee</i>)	The audit committee is responsible for evaluating the existence and efficacy of the company's financial controls and risk management.
Schering-Plough	Audit Committee Functions Audit Committee Charter	<p>The audit committee and the other committees of the board will coordinate their compliance and risk oversight efforts to the extent necessary or appropriate to ensure the complete and proper exchange of information.</p> <p>Legal, compliance, and risk-management matters: Discuss with management the company's major financial risk exposures and the steps management has taken to monitor and control such exposures, including the company's risk-assessment and risk-management policies.</p>

Source: Information obtained from individual company Web sites and then compiled by KPMG International, 2005.

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Path Toward Increasing Value



Overall Response

Confirmation that the pharmaceuticals industry is riskier than the overall S&P 500 with a changing business model and risk profile provides a strong case for improving the approach to risk management and internal control. Our research indicates that the industry recognizes it has systemic flaws and is looking now for better, timelier information for decision making and better communications about risk internally and with the board. Pharmaceuticals companies also expect their investment in risk management to deliver greater management consensus and accountability, smoother governance practices, and enhanced ability to meet strategic goals and to serve as a competitive tool.

Companies also expect better risk management to help reduce earnings volatility and increase profitability. Professor Kothari, however, notes the difficulty of measuring the return on investment in these terms so that these end-benefits may play a lesser role in the specific discussion about investing in improving risk management. In addition, it is useful to note that companies from various industries that are already well on the road to making enterprise risk management a part of their culture have seen significant benefits, as indicated in the chart below.

Benefits Experienced by Companies with Advanced Enterprise Risk Management

Benefit	Rank	Percent
Better-informed decisions	1	86
Greater management consensus	2	83
Increased management accountability	3	79
Smoother governance practices	4	79
Ability to meet strategic goals	5	76
Better communication to board	6	69
Reduced earnings volatility	7	62
Increased profitability	8	59
Use of risk as a competitive tool	9	46
Accurate risk-adjusted pricing	10	41

Source: "Beyond Compliance—The Future of Risk Management," The Conference Board, (January 2005)

Communication barriers within the patchwork of risk-management activities must be overcome and clear communication around risk must be facilitated.

KPMG believes that while pharmaceuticals companies have processes and controls in place to manage risk, it is now time to reassess their risk framework and to make any modifications that are needed to stay current with the evolving business model and the changing industry risk profile. These improvements need to address the company's risks in a more comprehensive manner, across silos and with the goal of enhancing the ability to anticipate risk in line with the goals and the culture of the organization.

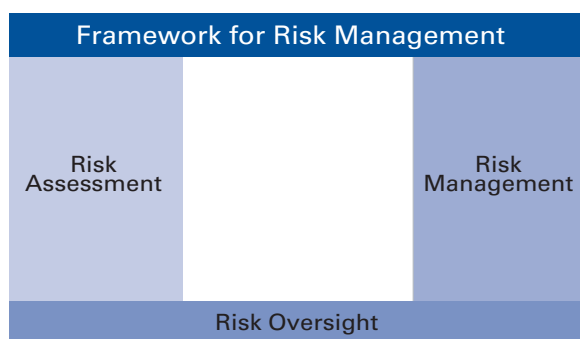
KPMG believes that pharmaceuticals companies need:

- An organizational response to assess their risk framework
- An operational response to improve their risk-assessment and risk-management processes
- A governance response to improve risk oversight

They need to undertake a significant analytic review of their current risk-management framework: their organizational approach to risk management, their operational approach to risk assessment, and their governance approach to risk oversight. They need to answer the following:

- Do we have in place well-documented and well-controlled processes for managing and mitigating risk that align with our appetite for risk and advance our strategic goals?
- Is our assessment of risk as robust as it needs to be for well-informed decision making?
- Is the framework adequate for the evolving business model?
- Are we comfortable that we can communicate the answers to these questions to stakeholders and to legal authorities if needed?

Once management and the board are comfortable with their understanding of the current state and have remedied any issues in the current framework, they can perform a controls review of the risk-management processes and a gap analysis of the risk assessment. This, in turn, will help enable the company to reevaluate the effectiveness of its overall risk framework—its operating effectiveness—on an ongoing basis.



Source: KPMG LLP (U.S.), 2005

Risk Management

The industry's organizational approach to managing risk ranges from an ad hoc process to the consolidation of the risk-management function under a chief risk officer (CRO). At the ad hoc end of the continuum, this might entail a pattern of reacting to problems by identifying their root causes and recommending solutions. In the middle are various approaches that involve representatives from different functions and business units who work together on risk management on a regular basis, in addition to their other responsibilities.

KPMG believes that companies should not remain on the "siloed" and reactive end of the spectrum. They should have some regular, systematic process with a goal of anticipating risk and deterring adverse consequences. The decision to invest in an independent CRO seems to be a function of the companies' culture or its view of an independent CRO as a strategic initiative for cultural change.

Risk Assessment

The scope of risk assessments now ranges from "siloed" to a comprehensive, enterprisewide perspective. While companies may tend to work in silos, different business units, especially in highly decentralized companies, are likely to have different risk profiles from each other. KPMG believes that companies need some degree of coordination so that the "hand-offs" of information is effective and gaps in the process can be identified and remedied as needed.

Risk Oversight

The options for risk oversight range from the audit committee to a subcommittee of the board to the full board. KPMG does not perceive any best practice among these options so long as one or more risk stewards are "literate" in understanding risk in the same way that financial expertise is required for the audit committee.



While the efforts to comply with Sarbanes-Oxley 404 did not deal directly with operational controls, the process did create a focus, especially among U.S.-based pharmaceuticals companies, on the necessity for well-documented and effective controls. And companies acquired significant learning and competencies around documenting and assessing controls that can be leveraged to deal with the root causes of financial performance in operations as well as financial reporting.

This is important, as management will support a plan to invest in risk management only if that plan builds on existing activities and processes, does not increase bureaucracy, and is not seen as yet another corporate-sponsored initiative, the value of which has not been fully articulated.



Source: KPMG LLP (U.S.), 2005

Enterprise Risk Management: A Practical Option for Managing Risk

Pharmaceuticals companies are searching for a practical approach to risk management that fits their unique cultures. One option is a broad-ranging program of enterprise risk management, whether linked to the Committee of Sponsoring Organizations of the Treadway Commission’s Enterprise Risk Management (COSO ERM) framework, or to the recommendations of the Turnbull Report on internal control, or to any other similar frameworks. COSO ERM, which was issued in September 2004, uses a framework for a business to bring together previously disparate roles and activities. And it entails the development of a unifying framework to articulate how these activities interrelate.

It must be admitted that some companies have deployed an approach to managing risk that starts and ends with an assessment of key risks and the effectiveness of the associated controls. The results of such assessments are all too often left to gather dust on a shelf until an approaching financial year-end requires them to be updated. Treating risk management in this manner leaves the identification and understanding of how risk really impacts the organization isolated from its core operations and the decision-making processes. Not surprisingly, companies that operate this way may not have realized a return on their investment in risk management and better internal control.

COSO ERM

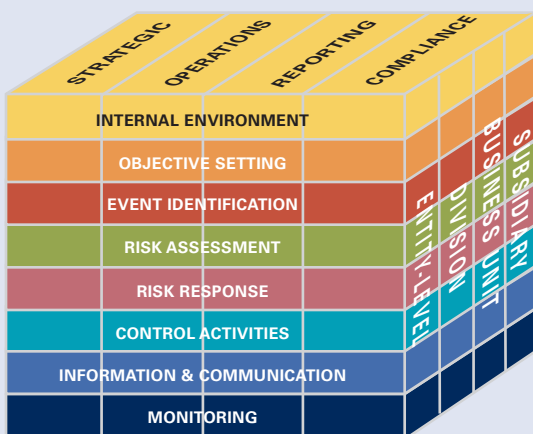
Definition by Committee of Sponsoring Organizations of the Treadway Commission

Enterprise risk management deals with risks and opportunities affecting value creation or preservation. It is defined as follows:

Enterprise risk management is a process, effected by an entity's board of directors, management and other personnel, applied in strategy setting and across the enterprise, designed to identify potential events that may affect the entity, and manage risk to be within its risk appetite, to provide reasonable assurance regarding the achievement of entity objectives.

Enterprise risk management encompasses:

- **Aligning risk appetite and strategy.** Management considers the entity's risk appetite in evaluating strategic alternatives, setting related objectives, and developing mechanisms to manage related risks.
- **Enhancing risk response decisions.** Enterprise risk management provides the rigor to identify and select among alternative risk responses—risk avoidance, reduction, sharing, and acceptance.
- **Reducing operational surprises and losses.** Entities gain enhanced capability to identify potential events and establish responses, reducing surprises and associated costs or losses.
- **Identifying and managing multiple and return cross-enterprise risks.** Every enterprise faces a myriad of risks affecting different parts of the organization, and enterprise risk management facilitates effective response to the interrelated impacts and integrated responses to multiple risks.
- **Seizing opportunities.** By considering a full range of potential events, management is positioned to identify and proactively realize opportunities.
- **Improving deployment of capital.** Obtaining robust risk information allows management to effectively assess overall capital needs and enhance capital allocation.



Source: Committee of Sponsoring Organizations of the Treadway Commission, 2005



In contrast, by developing a structured yet simple risk-management framework that is aligned with the business's operations and strategy, companies will be better able to coordinate their risk-management activities and provide a unified approach that delivers value and supports overall business success.

A framework for enterprise risk management can take many forms, but it should broadly cover the following areas: Strategy, Structure, Portfolio, Measuring and Monitoring, and Optimization:

1. Risk Strategy

The risk strategy is the backbone for embedding enterprise risk management into the organizational culture: as business strategy provides direction for the company, risk strategy provides direction for its risk-management activities. Setting clear objectives for risk management and communicating these to the business is essential to ensure that risk-management activities are focused and aligned with other business processes such as corporate planning.

2. Risk Structure

A clear organizational structure for risk management will help to ensure that the risk strategy is effectively and efficiently executed, with clear responsibilities and accountabilities across the business. Increasingly, risk management is becoming an explicit aspect of the terms of reference of the board and an executive risk-management committee is established to oversee the implementation of the risk strategy.

However, in an effective risk-management structure, responsibilities should be clear for all managers and the application of the risk strategy should be transparent, not just within the core business but also to extended areas such as subsidiaries and joint ventures.

As part of their risk-management structure, organizations are increasingly creating the role of a chief risk officer to integrate and coordinate all risk-management activity. In many businesses, the head of internal audit performs this role. If the head of internal audit performs this role it will not change the fact that responsibility and authority for risk management rests with executive management.

3. Risk Portfolio

Organizations have commonly invested in methods of identifying risks and assessing them in terms of their probability and impact, and in classifying risks as part of a wider governance exercise. Such assessments add value, but further benefits can be realized by integrating this practice into day-to-day management activities to form an organizational risk portfolio. This allows diverse risk categories, such as reputation, process, or strategic risk, to be considered alongside risk interrelationships. It allows the organization to consider the effects of changes to risks, thereby providing valuable information for decision making. It can also serve to prioritize risks so that the board receives concise information about the key risk exposures.

Ensuring that the risk-management information within the business is accurate and robust is a key challenge, and an essential one to overcome if risk management is to support internal business decision making and provide increased value above and beyond compliance with corporate codes or regulatory standards.

4. Risk Measuring and Monitoring

Risk measuring and monitoring is required as a means of understanding and reporting the status of risks. It can be implemented simply by defining risk-measurement methods and by incorporating risk assessments into normal reporting processes. More sophisticated measuring and monitoring can be developed through risk tracking, benchmarking, internal audit performance reporting, and using key performance indicators as early warning mechanisms.

Many organizations have successfully implemented monitoring and reporting processes and now face the challenge of integrating diverse sources of risk-management information from across different business functions into a single view of risk that can support business decision making at all levels.

5. Risk Optimization

Reliable information about business risks and their controls creates the opportunity to improve the way in which investment is made in mitigating risk, allowing the organization to take and avoid risk with more confidence. On a basic level, this involves managing risk limits and financing to understand total exposures to risk and to determine options for managing risk. Since the September 11 attacks on the United States, risk-financing costs have increased, causing additional focus on risk improvement to challenge the value of existing risk-financing strategies. At a more complex level, it involves using risk-management information to challenge business assumptions and bring new and improved insight into business issues.

Successful Implementation

At a minimum, some basic principles of good practice in the approach for developing risk management include:

- Seek clear sponsorship from the board and communicate this to the organization
- Avoid re-inventing the wheel but build upon existing formal and informal risk-management mechanisms to improve overall coordination of risk management across the business
- Define achievable objectives and develop an understanding of the barriers to success
- Ensure that organizational roles and responsibilities are clearly defined and communicated
- Provide the company with a clear implementation plan
- Keep the approach simple to use and understand, ensuring management of new risks is escalated quickly and effectively
- Align the risk assessment and reporting cycles with the company's business strategy, vision, objectives, and initiatives for growth and sustainable development
- Establish clear mechanisms for monitoring and reporting and ensure that the board receives regular information on risk management and internal control.
- Remain flexible to the needs and culture of the organization

Remaining in line with these simple principles will help risk management become an embedded aspect of the way the business functions, providing increased insight into business performance and the threats to ongoing success and avoiding the pitfall of becoming bureaucratic and detached from everyday management.

Major Attributes of an Enterprise Risk Management Framework

Framework Component	Key Elements	Steps to Be Taken	Why Is This Important?
1. Risk Strategy	<ul style="list-style-type: none"> • Governance and regulations • Guiding policies, procedures, and objectives for risks and controls • Linkage of risk to business and operational planning and strategies • Change management • Risk and control environment 	Assess procedures, policies, and strategy to establish the extent to which your risk-management activity is aligned with business strategy.	It is the risk strategy and the associated “tone at the top” that provide the backbone for embedding risk management within the culture of the business.
2. Risk Structure	<ul style="list-style-type: none"> • Risk-management structure and steering committee • Risk terminology • Roles, responsibilities, and accountabilities of individuals and teams • Risk-management function • Communication of risk and collaboration across the organization • Knowledge sharing and management process • Risk training and education programs • Reporting structures • Use of technology 	Review risk and assurance structures, information requirements, risk-reporting processes, skill sets, roles, responsibilities, and accountabilities for managing risk within the company.	The risk strategy is executed by the risk structure. The roles and responsibilities for managing risk define accountability and clear reporting lines and set defined boundaries for risk taking.
3. Risk Portfolio	<ul style="list-style-type: none"> • Risk profiling process (identification, gross and residual assessment, prioritization) • Risk categories and risk model • Defined risk appetite and capacity 	Review existing risk data and risk and control identification processes and tools to ascertain how risk information is used in the business.	By understanding and mapping risk-portfolio interdependencies the company can begin to parcel risks into broad categories that will influence how these risks are managed and optimized.
4. Risk Measuring and Monitoring	<ul style="list-style-type: none"> • Use of risk warning mechanisms, metric dashboards, and key performance indicators • Benefit tracking of the risk-management investment • Monitoring and reviewing process • Tools and techniques • Assurance process 	Review early warning systems and key performance indicators (KPIs), and review existing tools and techniques for managing risk within the company.	Performance measures that can embody risk characteristics enable real-time monitoring and, if limits are exceeded, actions can be taken before rather than after the fact.
5. Risk Optimization	<ul style="list-style-type: none"> • Use of analytics • Use of risk appetite and capacity • Control design • Total cost of risk • Risk treatment focus on optimization and process improvement • Risk interrelationships 	Understand how risk appetite is used. Check for controls effectiveness and review how the total cost of risk is determined.	A key objective of the optimization process is to make sure that the risk limits are understood and that the risk appetite is apportioned appropriately, so as not to exceed the risk appetite for the enterprise as a whole.

A Final Note: Some Key Points to Remember



The pharmaceuticals industry has many established processes and protocols around risk management. Historically, these practices have focused on detecting compliance failures or breaches of laws and regulations. We believe it is time for boards and management to assess the effectiveness, efficiency, and appropriateness of existing frameworks for managing operational, regulatory, and financial risks as the industry's risk profile and the business models have changed dramatically over the past few years.

It is time for pharmaceuticals companies to decide whether their risk-management framework delivers the quality of information about risk that provides sufficient comfort to management, the board, and its stakeholders. We believe pharmaceuticals companies should:

- Perform an assessment of their risk framework
- Conduct a gap analysis of their risk assessment
- Review their controls relating to the risk-management processes to assure that they are measuring, managing, mitigating, and anticipating risks
- Periodically report on the outcome of these steps to the board, or to the subcommittees of the board that are responsible for risk oversight

The benefits of a well-understood, well-documented, well-communicated risk-management process go beyond helping a company boost revenue and profitability. Equally important are the benefits that accrue from avoiding the consequences of not recognizing and mitigating risks before they have a negative impact on a business. A vigorous risk-management process that enhances management decision making, assigns accountability, and alerts a business to risky activities is an asset that can provide a significant competitive advantage in the market.

Underpinning any good framework is a simple philosophy that management first must identify and own the risks that face a business and then assure the board that the risks can be managed to the advantage of the business. At the same time, the internal audit function can provide assurance that management's assertion is based on solid information.

We believe that organizations in the pharmaceuticals industry have a choice. They can rely on the risk-management framework that is embedded in their culture now but perhaps is not well understood across the enterprise and may not have kept up with the changing business model. Or, they can create an environment where a risk-management framework is more coordinated, where risks and controls are identified in key decision-making processes, and where senior management and the board can clearly describe the framework and feel comfortable that the framework is appropriate to help them support their chosen business model.

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