Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

Compliance and Enterprise Risk Management: Leveraging Opportunities

Caroline H. West
Vice President
Global Legal Compliance
Aventis

Brian Riewerts
Senior Manager
Global Pharmaceuticals and Health Sciences
PricewaterhouseCoopers

November, 2003

PRICEWATERHOUSECOOPERS

Evolving Marketplace Definitions and Trends

- In many organizations, risks are separately managed as part of the functional responsibilities of disparate departments, such as insurance, finance, legal and human resources.
- Commonly, individual business units within an organization tend to vary in their appetite and ability to bear risk successfully, creating unique management challenges
- Often there is no mechanism to integrate the information on various risks or their cumulative or interactive impact on an organization.
- Also, some organizations tend to focus on containing hazard or financial risks, giving less consideration to general risks posed by rapidly changing business environment or the risk / reward balance associated with its strategies.
- Clearly, risks presented on multiple fronts demand coordinated, enterprise-wide responses.

Evolving Marketplace Definitions and Trends

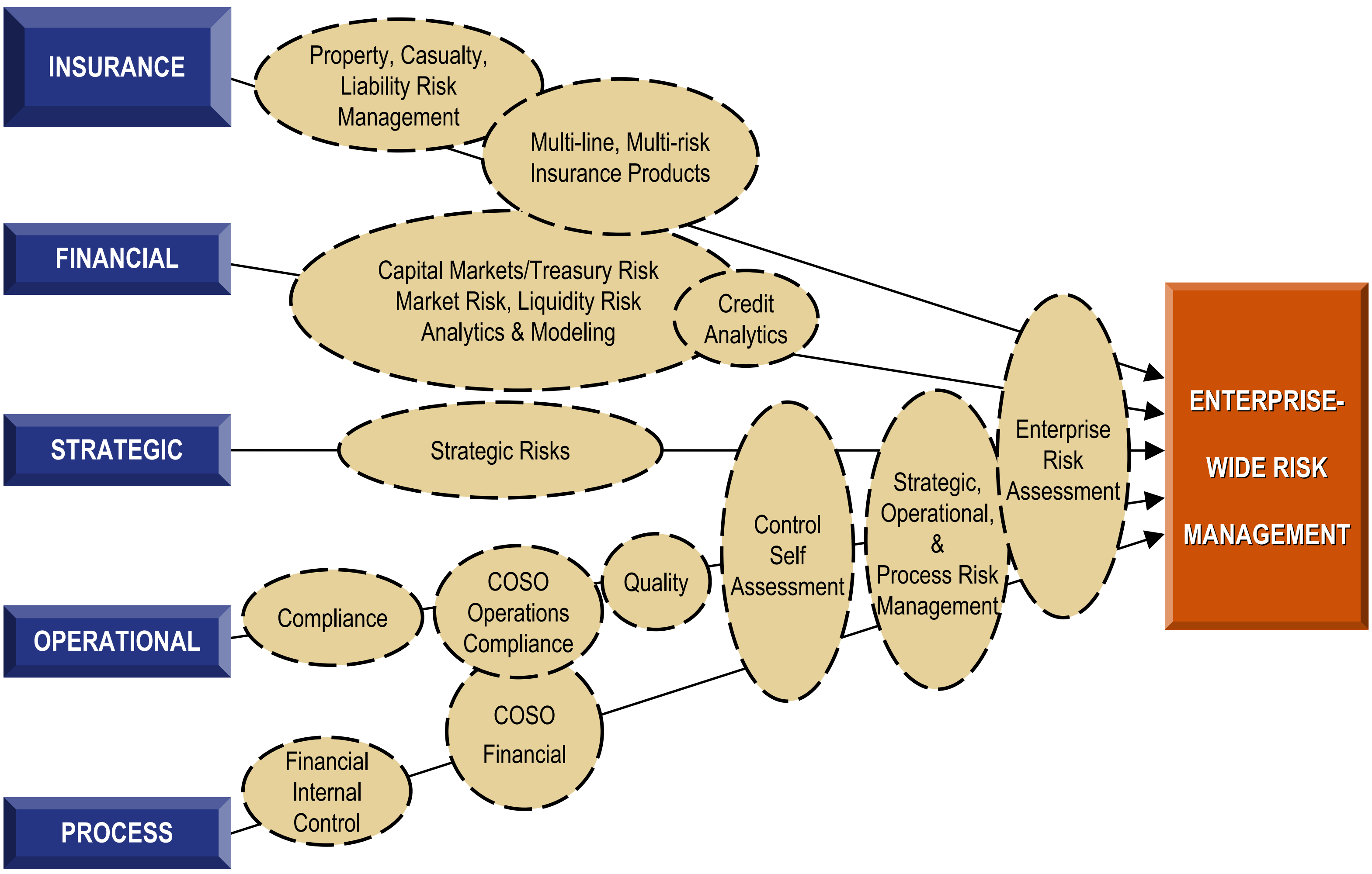
Corporate Compliance Program

- A management process comprised of formal reporting structures and risk mitigation systems.
- Designed to motivate, measure, and monitor an organization's legal and ethical performance around complex business practices.

Enterprise-wide Risk Management

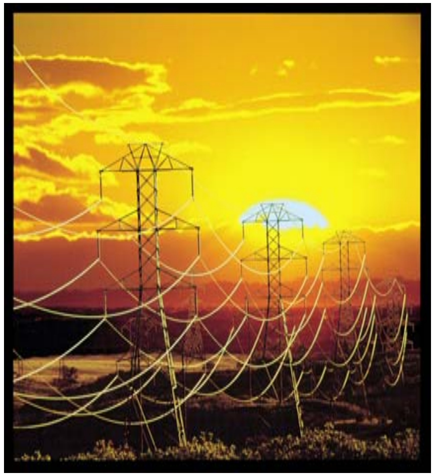
- Sees risks as events or activities that can affect the achievement of an organization's goals.
- It addresses all organizational goals, activities and relations with key stakeholders.
- It is anticipatory, proactive process that becomes a key part of strategy and planning.
- Pulling together the disciplines that address both sides of risk -- minimizing uncertainty and maximizing opportunities -- the concept pushes an organization to address risks and their management explicitly.

Evolving Marketplace Definitions and Trends



PRICEWATERHOUSECOOPERS

Evolving Marketplace Definitions and Trends



- In recent years, the definition of risk has taken on a broader definition, i.e., any event or condition that impedes the achievement of an organization’s objectives. The narrow notion of risk as loss has become dated.
- At the same time, the traditional notion of risk management as a purely support function designed to reduce losses through insurance and financial hedging activities is being seen by some as incomplete in managing the entire array of risks facing today’s complex enterprises.
- Many traditionally uninsurable business risks such as new product failures, regulatory changes and movements in the prices of key raw materials have come onto the radar screens of informed managers wishing to optimize the risk/reward trade-off associated with these events.
- These same managers are also seeking to understand the sources of business risk in all areas: strategic, financial, operational, regulatory and technical.
- Enterprise-wide Risk Management entails seeing business risk through this broader “lens” and building the appropriate mechanisms (people, processes and systems) into the business to anticipate and proactively manage the impact of all types of business risks

The Market Continuum - How do you view risk?

Impact of the New View of Risk

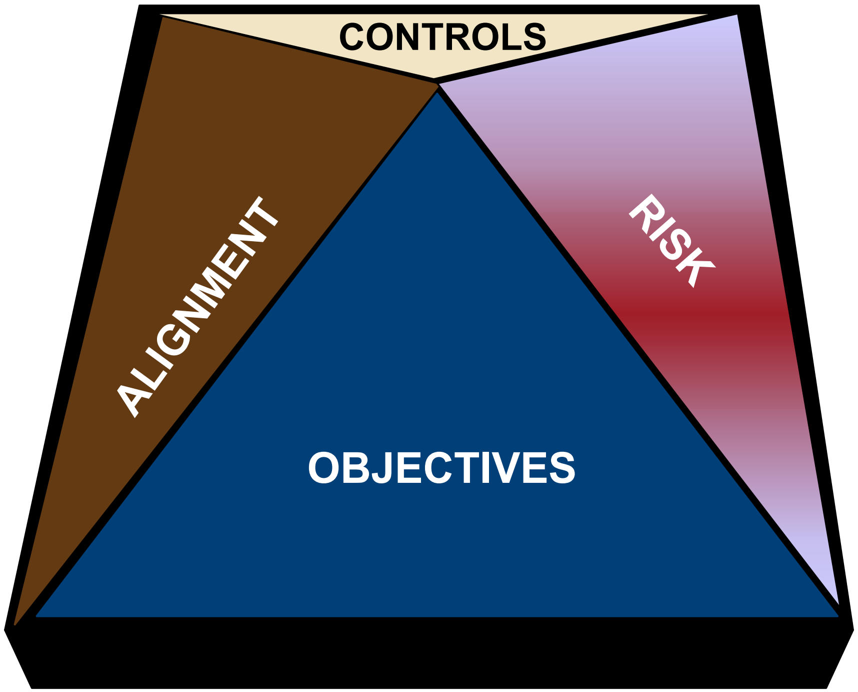
Traditional view	New view
Risk as a negative factor to be controlled	Risk as an opportunity
Risk managed in organizational silos	Risk managed in an integrated, enterprise-wide fashion
Responsibility for risk management is delegated to lower levels	Risk management responsibility accepted by senior and line management
Risk measurement is subjective	Quantification of risk
Unstructured and divergent risk management functions	Risk management is built into all corporate management systems
The board had an audit committee to police internal control	The board has a risk committee to ensure an effective risk management structure exists

Required Elements of a Risk Management Architecture

An "Eight-Point" Plan:

- **Acceptance of a risk management framework**
- **Senior Management/Board commitment**
- **Risk response strategies**
- **Change management responsibility**
- **Resourcing**
- **Communication and training**
- **Reinforcement through HR mechanisms**
- **Monitoring of risk management**

A Methodology for Enterprise-wide Risk Management



Though risk thinking can be viewed as management 'common sense,' it is not often exhibited as common management practice. Therefore, a framework and methodology are useful in bridging the gap and creating real management action toward managing Enterprise-wide Risk in the business.

Objectives - Risks - Control - Alignment (ORCA) methodology creates a language for common understanding of risk

Transforming "Common Sense" into Common Practice

Articulate organizational OBJECTIVES

Assess RISKS across the entire spectrum

Build in balanced CONTROLS to manage organizational risks

Ensure ALIGNMENT of objectives, risks and controls across the enterprise

PRICEWATERHOUSECOOPERS

Articulate Business Objectives

What does the organization need to do to satisfy:

Shareholders

Employees

Customers

Suppliers

Regulators

Local community

Government

Others?

Assess Risks

What could keep the company from achieving its objectives?

Systems fail to perform to specification

Business interruptions

Distribution channels are insufficient

Lack of central coordination to minimize operating costs

Unauthorized access to sensitive information

Hazard	Uncertainty/Variance	Opportunity
• Regulatory • Ethics violations • Fraud	• Forecasting/ Budgeting • Performance against goals • Efficiency	• Competitive advantage • Market innovations • Strategic flexibility

Build in Balanced Controls

Could control weaknesses keep the company from achieving its objectives?

Significant reconciling items

Unsatisfactory credit risk diversification

Regulatory violations and findings

Inadequate information systems

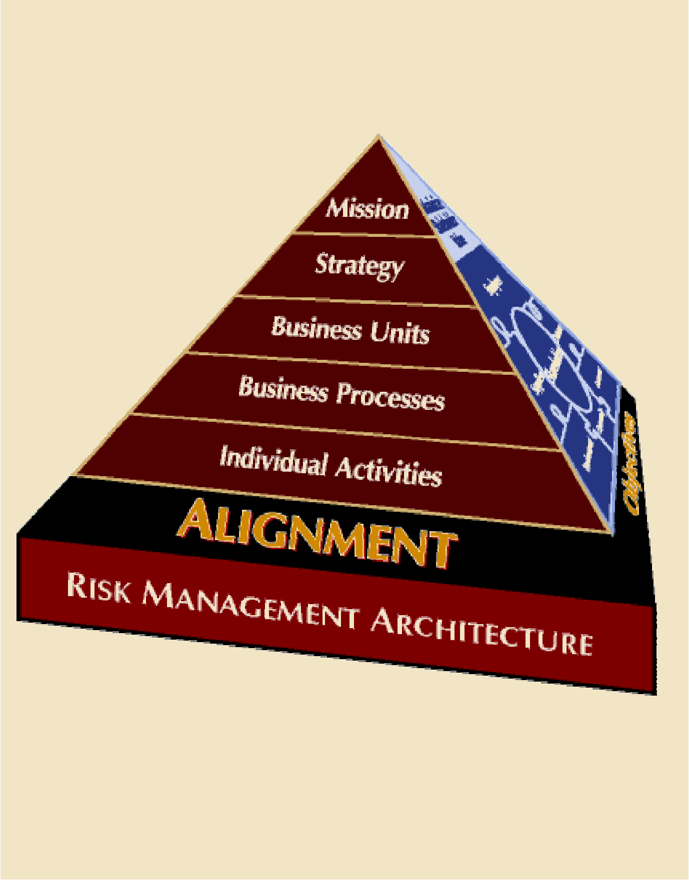
Earnings and share price volatility

Excessive funding costs

Ineffective analysis and allocation of capital

Controls are based in silos

Ensure Alignment



Are all organizational groups pulling together in the same direction?

Company-wide: Minimize cost increases to participants

Business unit: Expand customer base

Business processes: Implement pricing structure proposal

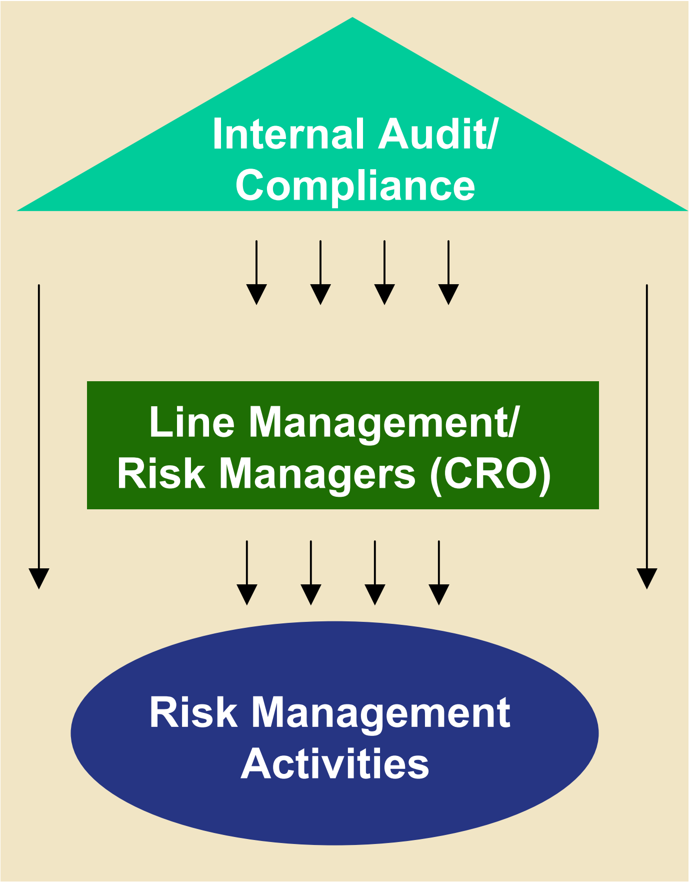
Individual activities: Ensure bills are processed accurately

The Benefits of Good Risk Management are Significant

When organisations cultivate good risk management practices, the benefits are pervasive:

- Better allocation of capital
- Increased reputation assurance
- Better operational integrity
- Fewer surprises in the business
- Higher quality of external reporting
- Consistently sustained stakeholder trust

Monitoring of Risk Management



The effectiveness of the organization's risk management process must be monitored continuously.

While line managers should be primarily responsible for risk management activities (self-assessment, reporting, etc), internal audit can monitor the effectiveness of the entire risk management architecture.

Goals for the Strategic Risk Process

Create an Organization where Risk Intelligence is embedded in the way we do business

- Proactive process to identify potential risks and seek alternative solutions

Create a culture where "bad news" travels fast

Ensure that a risk management process encompasses both the downside risk of loss as well as the upside risk of gain

Effectively implement an Enterprise Risk Management process

- Focus on those areas where risks have not been well characterized
- Embed it in the core business process

Goals for a Compliance Process

Create a culture where compliance programs are embedded in the business process

- Proactively identify and address compliance risk areas

Create a culture where compliance issues are communicated quickly

Understand that there is an "upside" to strong compliance processes

Create a Compliance Structure that

- Focuses on key risk areas
- Does not create a "separate" bureaucracy

Monitor and audit

PRICEWATERHOUSECOOPERS

Observations

- Limited number of companies have initiated an ERM process;
- Given the current external environment, a functioning ERM process is a positive step
- Given the current external environment, a strong and effective Compliance program is a given
- The overlaps with Compliance are clear – how to link the two and leverage the efforts is the challenge

Risks in the Pharmaceutical Value Chain

There are common risks that must be addressed to realize the benefit of any pharmaceutical industry business initiative. These risks are often not considered or not addressed in a consistent and coordinated manner.

	Research & Development	Supply Chain	Sales, Marketing & Distribution
Types of Initiatives	Clinical Trials	Procurement	Sales Order Processing
	FDA Filings	Supply Chain Management	Customer Relationship Management
	Data Warehousing	Manufacturing & Validation	Direct to Consumer Advertising

Common Risks

- Strategic
- Technology
- Operational
- Commercial
- Legal
- Reputational

Managing a Breadth of Risk

External risk factors

- Competitive marketplace
- Economic Changes
- CRO Performance
- HIPAA
- EU Data Protection Directive
- Globalization
- Industry Consolidation
- E-Trials
- 21 CFR Part 11
- GCP and GLP Compliance

Core Clinical Processes

Study Planning

- Protocol Design
- CRF Design
- Database Dev
- Entry Screen Dev
- Report Templates
- Drug Supply Ordering

Study Initiation

- Investigator Selection
- IRB Approval
- Document Collection

Study Conduct

- Monitoring
- Data Collection
- Query Mgmt
- AE monitoring

Study Completion

- Data Cleaning
- Query Mgmt
- Database lock

Data Analysis

- Table/Figure Development
- Analysis
- Clinical Input
- Review & Approval

Internal risk factors

- In-source vs. Outsource
- Changing Strategy
- Ineffective Project Management
- Retaining Quality Personnel
- Portfolio Prioritization
- Process Inefficiencies
- Budgeting Process
- Grants Payment Process
- Managing CRO
- Organizational Culture

PRICEWATERHOUSECOOPERS

Implementation of an Effective Strategic Risk Management Process

Scan and Identify – both internal and external examined to create a comprehensive understanding of risk exposures

Quantify and prioritize – identify those risks that have the most severe impact on shareholder value

Design Solutions – decide how to manage the risks

Plan and Manage – implement decisions

Monitor – ensure that actions are completed, processes are in place, and are continuously improved

NOT THAT DIFFERENT FROM COMPLIANCE!

The Basics

Strategic Risk Officer will provide the leadership, vision and direction for the Enterprise Risk Management process

The Strategic Risk officer role should be primarily strategic, not operational and can be or coexist with a Global Compliance Officer role

Functions are accountable for risks in their areas

Do not build a large central strategic risk management function

Risk management process and reporting should be designed on a functional basis and fit in to their way of doing business

Identify, and examine critical processes that are used to make decisions to understand where company may “create” risks

The Basics

Output of risk reports need to be consistent across the organization

Need to agree on a common language

There is a need for a cross-functional dialogue to understand the impact of risks on the organization

Key functions need to assign an accountable person to manage the process for their function

A Risk Council made up of functional representatives should be charged with reviewing risks from across the organization and fostering cross-functional dialogue

The Risk Council should be charged with ensuring that the process used in each function works effectively

Possible Risk Council Members

Audit

Commercial Operations (Sales and Marketing)

Communications

Corporate Development

R&D

Finance

H.R.

Industrial Operations

Investor Relations

Information Systems

Legal

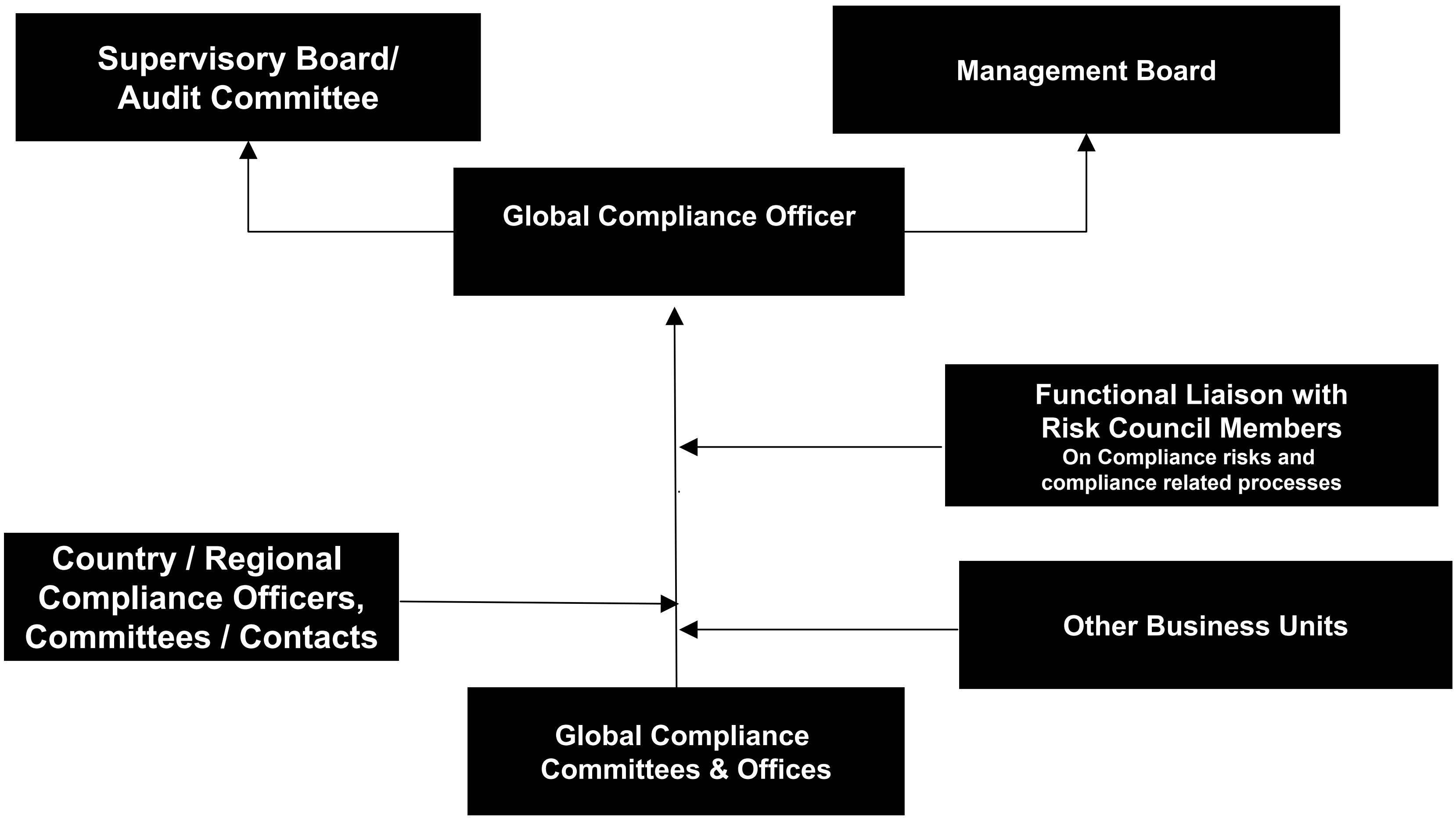
Patents

Risk Management

Risk Council - Purpose

The primary purpose of the council is to assist the Strategic Risk Officer in his duty of reporting to the Board on risks that could impact the company

The council members will serve as liaisons to the Global Compliance structure


Supervisory Board/
Audit Committee
Management Board
Global Compliance Officer
Functional Liaison with
Risk Council Members
On Compliance risks and
compliance related processes
Country / Regional
Compliance Officers,
Committees / Contacts
Other Business Units
Global Compliance
Committees & Offices

Risk Council – Specific Duties

Collection, cross-functional evaluation, and prioritization of risks across the company

Monitor implementation timelines of suggested action plans

Review of processes utilized by functions to report risk

Recommendations to the Management Board on key business processes that should be reviewed

Build risk anticipation and pro-activity in the company. Foster a culture of courage in risk reporting

Functional Risk Representatives

The responsibility of the functional representative is to oversee the risk reporting process in that function. The functional head is ultimately accountable for all risks within that function.

<u>Specific duties:</u>

– Ensure that a process is in place to routinely collect information regarding risk from the respective function

– Ensure that an appropriate evaluation of the impact of each risk has been done by the function

– Ensure that a suggested action plan to manage risks has been developed

– Provide a quarterly risk report to the Strategic Risk Officer

– Attend Risk Council meetings and communicate functional risk to the council Ensure that information regarding risks that could impact the function is communicated back to the leadership of that function

– Serve as the point person for the function regarding all risk as well as liaise with Compliance structure

Risk Council - Process

The Risk Council will meet once a quarter

- Each representative is responsible for delivering the function's risk report to the Strategic Risk Officer
- Members will assist the Strategic Risk Officer in determining the possible impact of risks across Aventis and in preparing a prioritized list of specific risks to present to the Management Board
- Review suggested action plans, and monitor the implementation progress of approved action plans
- The Risk Council is an advisory group, and is not accountable for the management of risks, or the implementation of action plans
- The Risk Council may challenge a function on its assessment of a risk, or a suggested action plan
- The Risk Council may also recommend to the Board that a business process be examined

Role of the Strategic Risk Officer

Provide the leadership, vision and direction for the Strategic Risk Management process

Ensure that events that can materially impact the business objectives of Aventis are identified and understood

Make sure that senior management is made aware of which risks are most important and what is at stake

Ensure that the risk management process and actions are being executed and that corporate learning is taking place

Works towards the creation of a risk intelligent culture at Aventis

Role of the Function Heads

1. Implement risk policies and procedures
2. Identify specific functional business risks
3. Quantify and communicate specific risks
4. Propose action plans to manage risks
5. Implement approved action plans

Role of the Board

- Each quarter review prioritized risks provided by the Strategic Risk Officer and the Risk Council and decide on most significant issues for the Board to monitor. The Board will make the final determination on materiality of risks
- Review suggested actions plans corresponding to risks reported by the Strategic Risk Officer and approve appropriate plans
- Monitor the progress of implementation of approved action plans
- Review recommendations from the risk council on processes to be reviewed, and decide on appropriate follow-up
- Foster an environment within the company that will facilitate the development of a risk intelligent culture
- Provide guidance to the organization on the risk tolerance position that the management board wishes to follow