Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

Advanced Compliance Strategies: Conducting an Enterprise-wide Risk Assessment

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Evolving Marketplace Drivers

- New laws, SEC and stock exchange rules, investor pressure, media scrutiny and public expectations mandate substantial changes in:
  - corporate governance
  - business ethics
  - compliance management
  - transparency and disclosure requirements
- Aggressive Congressional view of recent failures
- Aggressive enforcement attitude and increased whistleblower complaints
- Government budgets for enforcement and monitoring increasing
- Emerging governance standards (e.g. Global Reporting Initiative and Sustainability Reporting, Open Compliance & Ethics Group)
- General Counsel identified compliance as their #1 priority in the coming years
- More complex business environments
- Need to drive more efficient, better controlled business processes

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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.
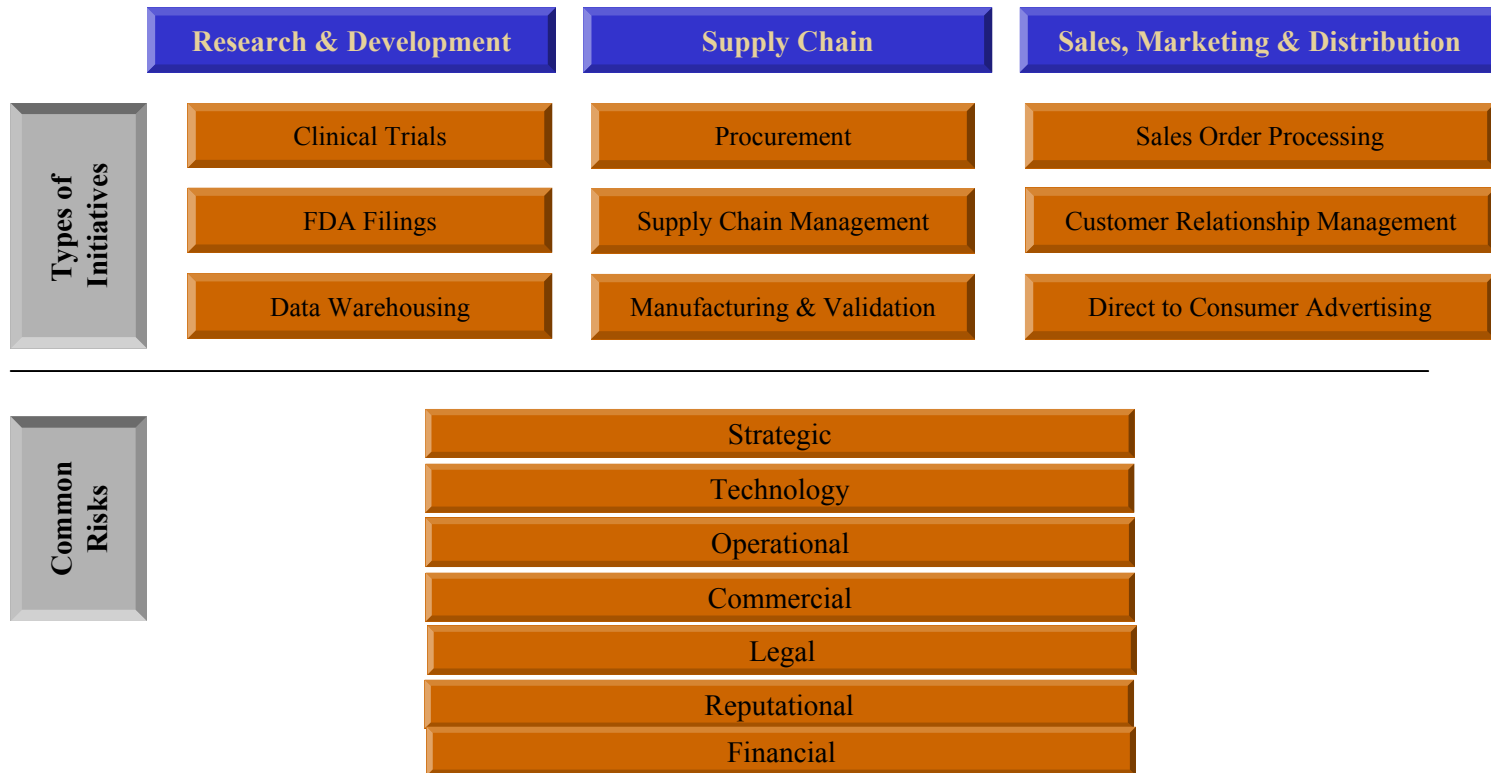
Evolving Marketplace Definitions and Trends

An EWRM framework provides organizations with a process for identifying and communicating risk, the ability to assess the impact of risks and determine the most effective approach to risk management, as well as an ability to monitor compliance with the established risk management program.
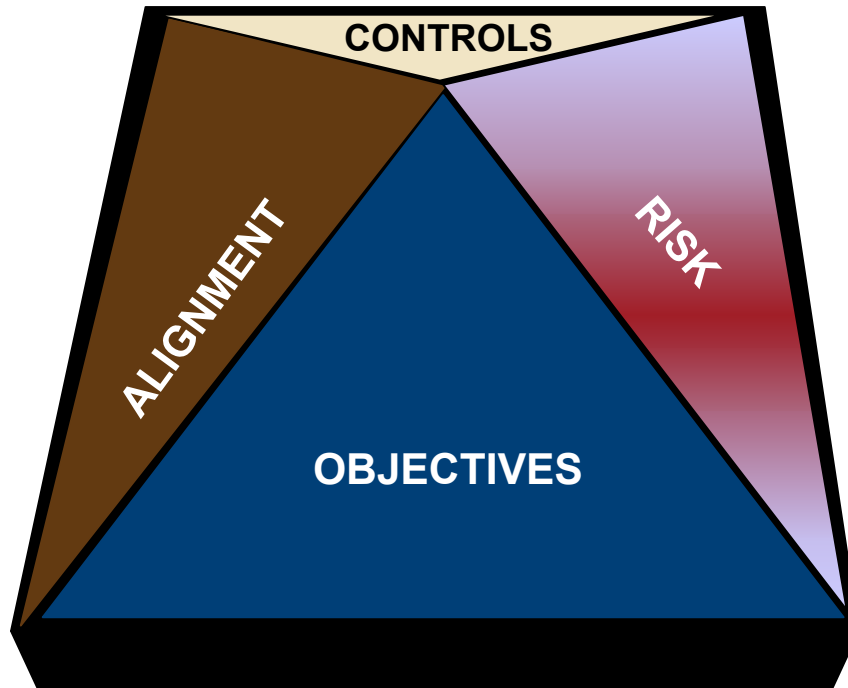
Benefits include:

- Enhanced competency for dynamic identification, assessment and management of risk, focusing management's attention on key issues and enabling more effective decision-making

- Early warning systems

- Mitigated impact of risk issues on the business, both proactively and in response to risk events

- Prevention, detection and resolution of improper behavior

- Improved compliance effectiveness across the organization

- Increased efficiency and reduced costs associated with an integrated risk management approach

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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
Clinical Trials	Procurement	Sales Order Processing
FDA Filings	Supply Chain Management	Customer Relationship Management
Data Warehousing	Manufacturing & Validation	Direct to Consumer Advertising

Types of Initiatives

Common Risks

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

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
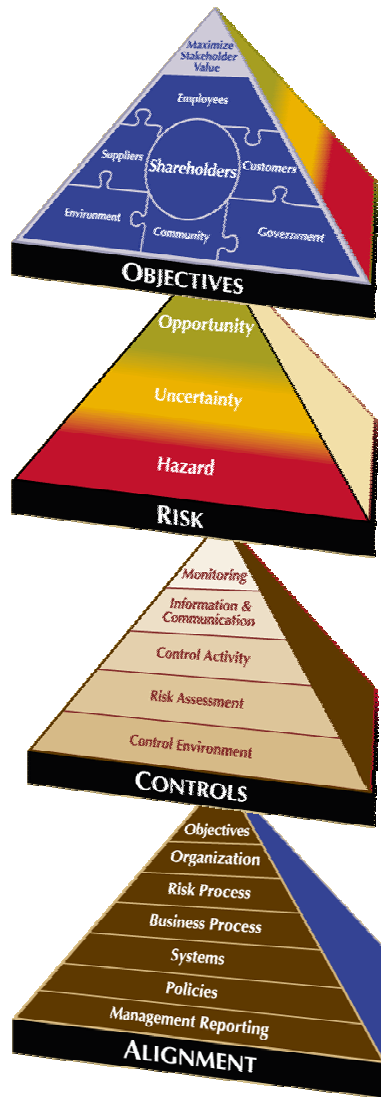
Articulate organizational OBJECTIVES

Assess RISKS **across the entire spectrum**

Build in balanced CONTROLS **to manage organizational risks**

Ensure ALIGNMENT **of objectives, risks and controls across the enterprise**

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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	• Forecasting/ Budgeting	• Competitive advantage
• Ethics violations	• Performance against goals	• Market innovations
• Fraud	• Efficiency	• Strategic flexibility

Assess Risks

OBJECTIVE OF RISK ASSESSMENT IS TO

– Separate minor acceptable risks from major risks

– Provide data to assist in evaluation and consideration of risk response

NEED TO CONSIDER

– Sources of risk

– Consequences - worst case or likely case?

– Likelihood of the consequence

PwC Governance, Risk and Compliance Model
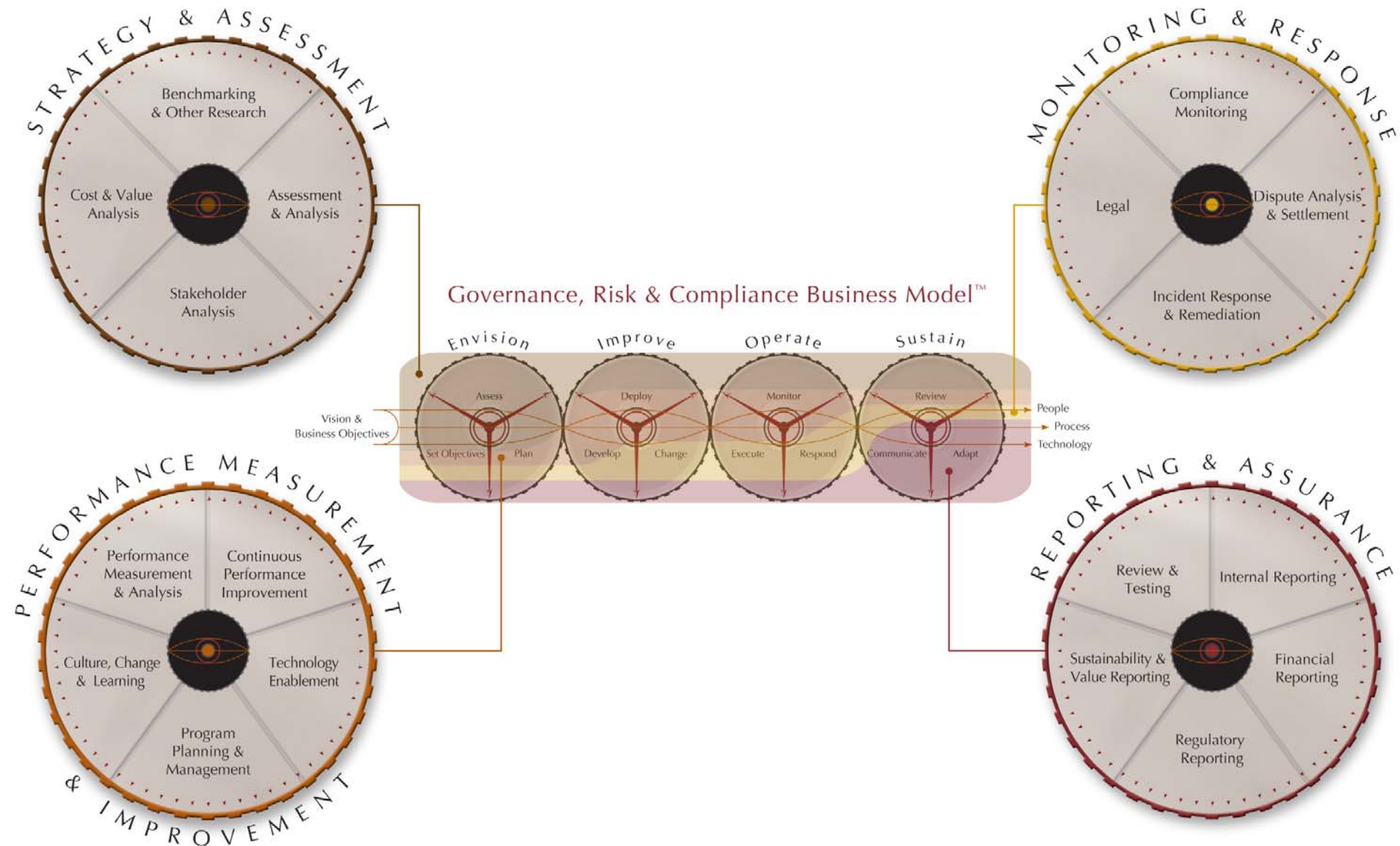
Risk Assessment Types

The <u>High-Level Evaluator Diagnostic</u> provides organizations with a high-level assessment of key risk areas that will result in the following benefits:

- Identification of preliminary portfolio of risks across the organization

- Senior Management focus on key areas of exposure

- Baseline of risks that can subsequently be validated and addressed by management

The <u>Drill-Down</u> provides a more detailed assessment of the organization's [internal control and] risk management activities. Benefits include:

- Views of various functional areas and staff levels of the organization on current risk management practices relative to best practice

- Detailed assessment of risk management strong points and opportunities for improvement

- Action plans for improvement of risk management practices and integration across the organization

Analyze Business Processes Along Two Dimensions

Risk

"Soft Controls"

"Hard Controls"

People & Culture

Business Process

Control Survey

Objective, Risk &
Control Alignment

Control Environment

Risk Assessment

Control Activities

Information & Communica...

Monitoring

Define
Objectives

Assess
Risks

Action Planning/
Accountabilities

Analyze
Controls

Performing a Risk Assessment

Enterprise-Wide Risk Assessment

Step **1**   **2**   **3**   **4**   **5**

| Project Launch | Shelf Data Review | Conduct Surveys & Interviews | Analyze & Validate Results | Reporting |

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Performing a Risk Assessment

Enterprise-Wide Risk Assessment

Step 1	2	3	4	5
Project Launch	Shelf Data Review	Conduct Interviews	Analyze & Validate Results	Reporting

Step 1 – Project launch

➢ Initial team work-streams:

- Validate project objectives, scope and timing; develop project check points
- Identify and gain consensus of major risk areas
- Based on risk areas identified, select business lines and key point people who will be responsible and accountable for their respective areas
- Validate selection with senior management
- Communicate nature of project and expectations to key point people

➢ Develop and gain consensus on data collection template that will be utilized to capture key risk and control information, including how to determine and document the level of risk for each area, activity, function, etc.

Consequences and Likelihood

Level of Risk (LR) = Consequence x Likelihood

- **Statistical analysis and calculation**

- **Subjective estimates - confidence level on estimates**

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Consequences and Likelihood

SOURCES OF INFORMATION FOR CONSEQUENCE AND LIKELIHOOD :

- Past record

- Industry practice and experience

- Relevant published literature

- Test marketing and market research

- Experiments and pilot projects

- Economic or other models

- Specialist and expert judgement

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Consequences and Likelihood

Typical parameters to rate levels of risk in terms of their likelihood of occurrence and impact on objectives can be represented as:

Likelihood		Negligible	Low	Medium	High	Extreme
	Extreme					
	High					
	Medium					
	Low					
	Negligible					
		Negligible	Low	Medium	High	Extreme
		Impact on Objectives				

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Performing a Risk Assessment

Enterprise-Wide Risk Assessment

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Step 1 – Project launch

➤ Train key point people to help identify:
  - Key data sources that should be requested and reviewed such as policies, procedures, audit reports, etc.
  - Personnel who should be considered for interviews and detailed analysis
  - Relevant control mechanisms that should be analyzed
  - Appropriate level of detail for each area

➤ Mobilize resources for scheduling and conducting interviews (Interviews will be conducted by key point people

➤ Solicit senior management feedback on the process, risks targeted, information to be collected, depth of analysis and data collection tool

Enterprise-Wide Risk Assessment

Step 1	2	3	4	5
Project Launch	Shelf Data Review	Conduct Surveys/ Interviews	Analyze & Validate Results	Reporting

List of functional areas considered in scope included:

- ➢ Sales and Marketing

- ➢ Legal/Government Affairs

- ➢ Research and Development

- ➢ Manufacturing

- ➢ Regulatory Affairs and Quality Assurance

- ➢ Financial Reporting

- ➢ Treasury

- ➢ HR

- ➢ IT

- ➢ Environmental Health and Safety

- ➢ International

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Enterprise-Wide Risk Assessment

Step 1 — Project Launch | 2 — Shelf Data Review | 3 — Conduct Surveys/Interviews | 4 — Analyze & Validate Results | 5 — Reporting

Step 2 – Conduct a review of data sources to strengthen the understanding of control environment and business activities

➢ Key point people collect data sources from each line of business and area in scope.

➢ Key point people to review shelf data and evaluate:
- Organizational structure and reporting lines
- Policies and procedures
- Existing controls and audit mechanisms
- Management reports
- Other relevant materials

*** Goal is to use shelf data to tailor surveys and interview guides**

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Enterprise-Wide Risk Assessment

Step	1	2	3	4	5

Project Launch → Shelf Data Review → Conduct Surveys/Interviews → Analyze & Validate Results → Reporting

Checklists/Questionnaires

Strengths:
- Inexpensive way of gaining broad-based input
- Results can be summarized because the data is in a consistent format
- Reinforces understanding of key policies and controls

Weaknesses:
- Questions may not be fully understood
- Quality of results may be affected by response rate, and by time and attention given by respondent
- Can be time consuming to distribute, collate and summarize

Risk and Control Narratives

Strengths:
- More precise descriptions of risks and controls than checklists
- Can be customized to the businesses
- Provide an easy to follow record of judgments made

Weaknesses:
- Can be time consuming to develop
- Can become out of date in changing environments
- More difficult than checklists to aggregate and summarize

Group Facilitation Sessions

Strengths:
- Encourage development of group consensus
- Establish buy-in and commitment to proposed actions
- Technology provides for sharing of ideas with anonymity
- Can be effective in addressing "soft" controls

Weaknesses:
- Quality of results often dependent on skills of facilitator
- Time consuming to organize and conduct
- Technology adds to expense and complexity

Enterprise-Wide Risk Assessment

Step 1 — Project Launch | 2 — Shelf Data Review | 3 — Conduct Surveys/Interviews | 4 — Analyze & Validate Results | 5 — Reporting

Step 3 – Conduct management interviews

➢ Purpose of the interviews is to understand management's views on:
  - ✓ Identified risks, related control objectives and activities
  - ✓ Existing risk management practices
  - ✓ Any gaps that may exist
  - ✓ Mitigation plans

➢ Steps in conducting interviews
  - ✓ Introduction and Overview of the Risk Management Initiative
  - ✓ Overview of Area of Responsibility
  - ✓ Goals, Expectations and Accountability
  - ✓ Risks and Challenges
  - ✓ Risk Prioritization
  - ✓ Evaluation of the effectiveness of current risk management efforts
  - ✓ Areas of Focus and Improvement

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Enterprise-Wide Risk Assessment

Step	1	2	3	4	5
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Step 3 – Conduct management interviews

➢ Based on results of interviews, key point people to perform process "walk-throughs" to obtain a more in-depth understanding of the process and controls mechanisms

➢ Project team to debrief on all interviews

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Enterprise-Wide Risk Assessment

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Step 3 – Conduct Surveys

➢ Conduct Risk Culture Survey (RCS)

- Identify and coordinate with project sponsor about how to stratify the company for the survey Identify respondents
- Sample selection of Board Members, Executives, Senior Managers, Managers, and other personnel
- Determine which questions will be included
- Prepare communication for the project sponsor to send to respondents providing information about the RCS and ensure communication is sent

Statement	Key Indicator	1 = Strongly disagree 2 = Disagree 3 = Neutral 4 = Agree 5 = Strongly Agree					Please indicate any significant issues that come to mind when considering this question.
		1	2	3	4	5	
1. The leaders of my unit set a positive example for ethical conduct.	Personal ethical practices	O	O	O	O	O	
2. Individuals in my unit exhibit high ethical values at all times.	Personal ethical practices	O	O	O	O	O	
3. I find our company's code of conduct to be useful in guiding my actions.	Personal ethical practices	O	O	O	O	O	
4. I am expected to comply with all policies, laws and regulations to the letter.	Tone at the Top	O	O	O	O	O	
5. The leaders of my unit emphasize risk management and control in their day-to-day interactions.	Tone at the Top	O	O	O	O	O	
6. If I become aware of improprieties in our Company, I feel comfortable communicating issues to senior management	Tone at the Top	O	O	O	O	O	
7. The leaders I work with provide clear guidance and direction.	Top-down alignment of strategy	O	O	O	O	O	
8. I understand the organization's overall mission and strategy.	Top-down alignment of strategy	O	O	O	O	O	
9. I understand how my objectives link to the objectives of my unit.	Top-down alignment of strategy	O	O	O	O	O	
10. I understand how the objectives of my unit link to the overall mission of the company.	Top-down alignment of strategy	O	O	O	O	O	

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Enterprise-Wide Risk Assessment

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Step 4 – Analyze and validate results from data review, collection and interviews

- Analyze the results of data review and interviews
- Evaluate the magnitude of risks based on the analysis
- Evaluate the effectiveness and efficiency of control mechanisms in place
- Document the results in the data collection tool

Enterprise-Wide Risk Assessment

| Step 1 | 2 | 3 | 4 | |
| Project Launch | Shelf Data Review | Conduct Surveys/ Interviews | Analyze & Validate Results | Reporting |

Recommendations

- Produce project report, capture risk ratings and supporting discussion

- Design EWRM framework to meet the organizations needs

Implementation

- Determine objectives and scope of implementation
- Determine approach (e.g. pilot)
- Develop project plan
- Develop monitoring plan
- Implement the plan

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KEY POINTS TO REMEMBER

Define Project Parameters

Establish project objectives, scope and approach

Present risk assessment tool [and tailor as necessary]

Determine risk definition, categories, rating scales and other methodology elements

Shelf Data Review

Review selected shelf data

Define baseline of risk areas

Enhance interview template and surveys based on evaluation

Interviews/Surveys

Determine involved parties

Define areas of focus

Debrief on risk ratings and observations

Consolidate findings in risk assessment tool

Analysis of Results

Perform quality review of information collected

Validate findings

Identify strong points and areas for improvement, highlighting risk exposure

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