

*Pharmaceutical Regulatory and Compliance Congress  
and Best Practices Forum*

**Special Program for**

**Internal/Compliance Audit Professionals:**

**Enterprise Risk Management; Tactical Audit  
Considerations; Reporting; Key Issues Noted in Compliance  
Audits**

# Agenda

- Using Enterprise-wide Risk Management to establish the compliance audit plan
- Tactical Audit Matters/Best Practices Sharing
  - Organizational Considerations
  - Auditor Competencies
  - Integrating Compliance Audits into SOX
  - Audit Cycle
  - Reporting Considerations
- Key Compliance Audit Issues and Findings

# The Need for a Focused Approach

- Internal Audit groups under resource and time pressures
  - Sarbox 404 Testing/Involvement
  - Greater emphasis on systems
  - Qualified personnel in high demand
- Boards/Audit Committees focused on effectiveness of organizational risk management
- Compliance risks continue to multiply with increasing regulation and regulatory dicta.

# Why ERM?

- Pharmaceutical and Biotech industries are among the most highly regulated industries.
- Risks arise from all aspects of the value chain.
- “Proactive” approach necessary to identify and manage risk before problems occur.
- Comprehensive, to improve efficiency and effectiveness.

# Using ERM to Focus the Audit Plan

Enterprise Risk Management is a **process**, effected by an entity's board of directors 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

# Using ERM and Risk Profiling

1. Identify and categorise risks

Risk Category

Risk Type

Category 1

Risk A

Risk B

Risk C

Category 2

Risk F

Risk G

Risk H

Category 3

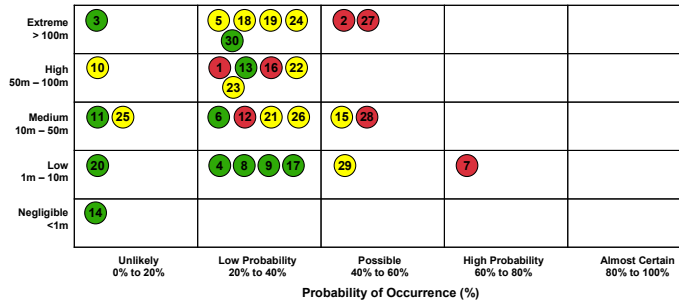
Risk I

Risk J

Risk K

2. Prioritise Risks and Generate Risk Profile

Impact on Three-Year Profit (\$m)



Probability of Occurrence (%)									
1. Macroeconomic	7. Industry	13. Environmental	19. Product Quality	25. Supplier					
2. Market Price	8. Regulatory	14. Finance	20. Credit	26. Organizational					
3. Natural Disaster	9. Intellectual Property	15. Litigation	21. Customer Satisfaction	27. Human Resources					
4. Weather	10. Compliance	16. Information and Technology	22. Dealer	28. Communication					
5. Competitive	11. Health and Safety	17. Integrity	23. Marketing	29. Governance					
6. Customer Preference	12. Privacy	18. Supply Chain	24. Product Returns	30. Stakeholder					

Low Risks  
Moderate Risks  
Major Risks

3. Adjust audit universe

4. Adjust for comfort obtained from other groups, and prioritize rotation plan.

# Selecting Risks to Audit

- Highest control weighted risk
- Controls with greatest control benefit
- Uncontrolled risks
  
- Based on dollar exposure
- Focus of testing will differ between these risks
- Priority will be driven by judgement.

# Possible Audit Areas

- *Discretionary Spending*
- *Speaker programs*
- Other local events
- *Consulting agreements and advisory boards*
- *Grants*
- Phase IV studies
- Contracting
- PBM/GPO relationships
- Adverse Events Reporting
- *Government pricing*
- *CME/ME*
- Samples
- Value-added services
- Advertising/professional communication agencies
- Third party sales forces
- Off-label “promotion”
- Executive education
- Off-contract discounts and concessions
- Training/Education
- Exception reporting
- Disciplinary action
- Privacy
- Human Subject Protection
- Clinical trials (GCP)
- CFR Part 11
- Animal rights
- Relationships with clinical investigators



# Audit Committee Considerations

- Present the Top 10/20/25 risks and how they are:
  - Addressed/covered by the organization and
  - Reflected in the audit plan/rotation
- Review “legacy” audits for continued relevance
  - Is that aircraft usage audit worth risk 21 falling off the audit rotation?
- Reporting: As many right answers as there are boards.

# Organizational Considerations

- Where should compliance auditors reside in an organization?
  - Internal Audit?
  - Compliance Office?
  - Legal?
  - Functions (Regulatory, QA)?
  - Other?

*Where are your compliance auditors located?*

# Auditor Competencies


- Independent of function audited
- Industry knowledge
- Knowledge of the laws and regulations
- Skepticism
- Process Excellence
- Use of specialists (internal or external)

*How are your auditors being trained in compliance subject matters?*

# Interaction with Sarbanes-Oxley

- Time allocated to compliance auditing.
  - What % of time can you spend on compliance auditing vs 404?
- Integrating compliance auditing into 404 work.
  - Taking the next step to maximize efficiency
    - Assessing compliance controls during financial controls transaction testing
    - Maintaining compliance focus during 404 testing
    - Testing of company level controls

# Changes to the Audit Cycle

- Training
  - Risk Assessment
  - Scheduling
  - Planning
  - Execution
  - Reporting
  - Risk Re-assessment and Planning
- 
- Laws and Regulations
  - Use of ERM/Cross-function
  - Prioritization from weighting
  - Process vs Transaction
  - Process Improvement
  - Privilege/Care in Drafting
  - Risks need to be re-assessed each year.

# Reporting Considerations

- 4 Things to Consider:
  1. Evaluate your findings to assess if they can be reasonably implemented
  2. Always discuss your findings with senior management prior to developing the report
  3. Solicit management's support for your findings
  4. Simplify your reporting format
    - Use an Executive Summary

# Reporting Considerations

- Work-Product Privilege
  - Should your audit be performed under privilege?
    - Planning phase
      - What is your expectation that your findings may have legal implications? Privilege applies only if in anticipation of litigation.
    - Execution
      - Procedures and work-product should reflect the appropriate approvals by legal counsel and be documented to indicate such
    - Reporting
      - Discuss with counsel the method and level of detail for your findings

# Reporting Considerations

- Self-evaluation Privilege

- Applies to certain types of reviews performed either within the company or on its behalf that are designed to detect or prevent wrongdoing.

- Adopted by legislation in 5 states

- New Jersey, Illinois, North Dakota, Oregon, and Michigan
- Each of these states has adopted its own interpretation of this privilege

- The weakest of all privileged communication

- Discuss with your general counsel applicability in your state

- Significant distinction is that it cannot be used as protection from the government, only from private litigants



# Key Issues to Consider

- Have you evaluated your audit plans to assess the risk with business partners or contractors?
  - Do your contracts provide for audit rights?
  - Have you developed an audit plan for assessing both compliance and financial risks?
    - Have you considered ways in which your partners or contractors may be violating your agreement?
      - Are their compliance standards adequate?
      - Are they appropriately meeting the financial terms of the contract?

# Results of Recent Compliance Audits

- Speaker programs
- Speaker training programs
- Advisory boards
- CME
- Discretionary spending
- Vendors
- Other

## *Questions?*

**Name** Greg Crouse  
**Company** Ernst & Young LLP  
**Phone #** 813 225 4997  
**E-mail address** Gregory.Crouse@ey.com

**Name** Peter J. Claude  
**Company** PricewaterhouseCoopers LLP  
**Phone #** 973 236 4289  
**E-mail address** Peter.Claude@us.pwc.com