Conducting Impact and Maturity Risk Assessments to Prioritize Areas for Auditing and Monitoring

The 14th Pharmaceutical Compliance Congress and Best Practices Forum

Pre-Conference II: Auditing & Monitoring Boot Camp

October 28, 2013

Presentation Agenda

Compliance Risk Assessments	
I. The Need for Compliance Risk Assessments	
II. Preparing for the Compliance Risk Assessment	
III. Conducting the Compliance Risk Assessment	
IV. What to do with the results of the Compliance Risk Assessment	
V. Questions	

Why Is It Important To Conduct A Compliance Risk Assessment?

A periodic risk assessment is the foundation of an effective compliance and ethics program.

Risk Assessments support the compliance program in a number of strategic areas:

- Identify potential risk exposures
- Identify sources of risks across business operations
- Understand perceived level of management control
- Evaluate if and how compliance controls have been integrated into the business
- Provide insight to allocating limited compliance and legal resources
- Prioritize risk areas into high, medium and low risk buckets
- Forms the basis for developing annual auditing and monitoring plan

In this session, we will explore key components of an effective compliance and ethics risk assessment and discuss ways to implement such a process at your company.

This Is A Dynamic Industry Subject To Stringent And Evolving Regulations

Many seemingly routine activities for other industries are fraught with risk for the Life Sciences Industry:

Interactions with consumers (patients)

Interactions with customers (Healthcare Professionals and Organizations)

Interactions with customers (Wholesalers and Group Purchasing Organizations)

Interactions with customer insurers / payers

Interactions with advocacy groups

Charitable Contributions

Relationships with ex-US distributors

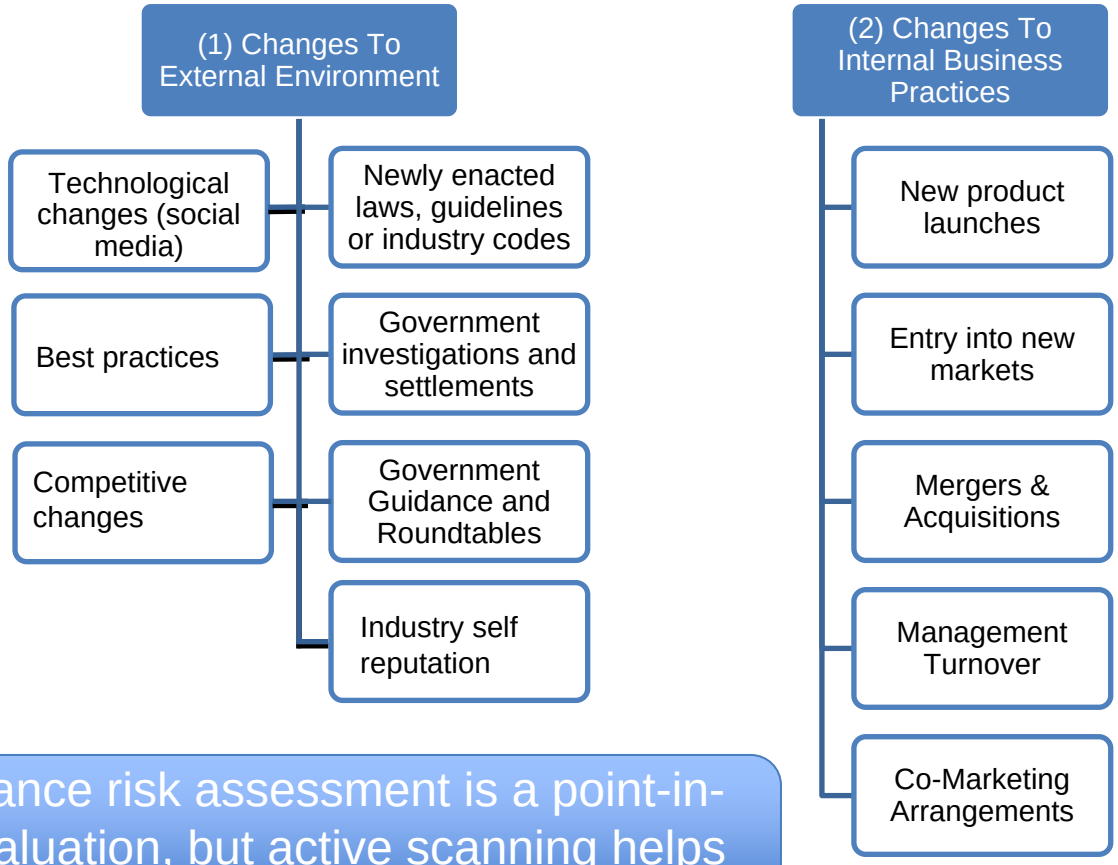
To eliminate the activities is not a practical means of doing business.

To add bureaucracy and rigid oversight is often impractical

To ignore the potential risk exposure is naïve

Compliance Risk Arises From Both The External Business Environment AND Changes To Internal Business Practices

Compliance departments must establish processes to “Scan” The Business Environment for emerging or changing risks. The process of scanning for risks must *continually* take into account both internal and external factors. Examples are:



Compliance risk assessment is a point-in-time evaluation, but active scanning helps to make it a dynamic program

Presentation Agenda

Compliance Risk Assessments	
I. The Need for Compliance Risk Assessments	
II. Preparing for the Compliance Risk Assessment	
III. Conducting the Compliance Risk Assessment	
IV. What to do with the results of the Compliance Risk Assessment	
V. Questions	

The Objectives Of The Assessment Are To Identify The Relative Risk Of Each Identified Area And Prioritize For Deeper Analysis

Six Key Objectives Of The Compliance Risk Assessment

1.Identify areas of risk to be evaluated as part of the company's compliance program

2.Define compliance and magnitude parameters to be used in the compliance risk assessment

3.Evaluate high level processes and controls in place for each risk area as well as existing control documentation

4.Complete a risk assessment matrix which applies a rating to each risk areas parameters

5.Calculate an overall risk rating to each area and rank from lowest number to highest

6.Prioritize each risk area to a high, medium or low risk bucket for consideration in the annual auditing and monitoring plan

It Is Important To Determine Focus Areas for Assessment Based On Trends Identified in External Guidelines and Recent CIAs

Risk Area	OIG Guidance	PhRMA Code	Recent CIA Settlements	State and Federal Disclosure Requirements
Continuing Medical Education Grants and Charitable Contributions	X	X	X	X
Field Interactions with Healthcare Providers (HCPs)	X	X	X	X
HCP Meals and Gifts	X	X	X	X
Consulting Arrangements and Ad Boards (Clinical)	X	X	X	X
Consulting Arrangements and Ad Boards (Promotional)	X	X	X	X
Speaker Programs	X	X	X	X
Publications	X		X	X
Investigator Initiated Trials (or Studies)	X			X
Clinical Trials	X			X
Promotional Materials		X	X	
Samples	X			X
Exhibits/Sponsorships			X	X
Medical Information Requests		X	X	
Reimbursement	X			

Critical Activities For Planning The Impact Assessment

1. Obtain buy-in for the methodology
    1. Senior leadership
    2. Establish a steering committee
2. Conduct kickoff meeting with all interviewees and related parties
    1. Project scope, objectives
    2. Work plan
    3. Deliverables
    4. Roles and responsibilities
3. Review strategic plans
    1. Map all sales, marketing and medical activities
    2. Review budgets
4. Conduct interviews
    1. Develop interview guides
    2. Identify key business leaders to interview – schedule interviews
5. Schedule status updates to the stakeholders – share findings and obtain feedback

Many Risk Generating Activities Affect Both Sales & Marketing Activities AND Medical & Clinical Activities, Some Examples Are:

Sales & Marketing

- Consulting Arrangements / Ad Boards
- Publications
- HCP Meals, Gifts & Entertainment
- Exhibits & Sponsorships
- Field Interactions with HCPs
- Fair Market Value
- Promotional Materials
- Samples & Free / Discounted Product
- Reimbursement Support
- Patient Support Programs

Medical & Clinical

- Consulting Arrangements / Ad Boards
- Publications
- HCP Meals, Gifts & Entertainment
- Exhibits & Sponsorships
- Field Interactions with HCPs
- Fair Market Value
- Promotional Materials
- Samples & Free / Discounted Product
- Reimbursement Support
- Patient Support Programs
- IIS/IIT Grants
- IME/CME Grants & Contributions

The Risk Assessment Will Require Interviews With Numerous Stakeholders Across Various Business Activities

Presentation Agenda

Compliance Risk Assessments	
I. The Need for Compliance Risk Assessments	
II. Preparing for the Compliance Risk Assessment	
III. *Conducting the Compliance Risk Assessment*	
IV. What to do with the results of the Compliance Risk Assessment	
V. Questions	

A Standard Evaluation Method Across Risk Areas Is Critical To Executing A Balanced Approach

1 = Highest Impact 4 = Lowest Impact

Factors \ Rating	1	2	3	4
Policy	Policy does not exist	Policy exists, but is broad	Policy exists, is specific but requires revisions & socialization*	Policy exists and is specific, recent, centrally located and socialized
Process	Standardized & documented process does not exist	Process exists, but is not documented	Process exists & is documented	Standardized & documented process does exist & is socialized
Document	Supporting documentation does not exist	Supporting documentation is limited	Supporting documentation is more robust, but is still missing critical elements	Supporting documentation exists & is centrally located, recent and socialized
Prior Audit	No prior audits	Audit completed more than 3 years ago	Audit completed in last 3 years	Audits completed in past year
Prior Monitoring	No prior monitoring	Regular monitoring	Regular monitoring with remediation	Regular monitoring with formalized corrective action
Issues	Large # of issues are known to exist either through prior audits or compliance observations	Many issues are known to exist either through prior audits or compliance observations	Few issues are known to exist either through prior audits or compliance observations	No issues are known to exist either through prior audits or compliance observations
Training	Training does not exist	Training conducted for new employees only	Periodic [annual] training for all employees	Training is more than once/year for all employees
Departments/Groups Responsibility	Multiple departments have control over the risk area	More than one department has control over the risk area	One department has majority control over the risk area with other departments involved	One department has influence over the risk area

*Socialization refers to the communication of developed policies or procedures to all stakeholders to raise awareness and gain buy-in. This typically includes email notifications, training, meetings and internal publications

The Compliance Parameter Risk Score Should Be Adjusted For External Factors As Well As Certain Magnitude Parameters

Low = Decreased Impact, Medium = Same Impact, High = Increased Impact

Rating	External Environment	Volume of Transactions	Annual Expenditures (as a % of total budget)
Low	Only one of four categories of external regulations applies to the risk area	As determined relative to both information gathered during interviews as well as knowledge of industry benchmarks	As determined relative to both information gathered during interviews as well as knowledge of industry benchmarks
Medium	Two of four categories of external regulations apply to the risk area		
High	Three or four categories of external regulations apply to the risk area		
Weighted Average for Magnitude Parameter	**50%**	**33.33%**	**16.66%**

.5(External Environment) + .33(Volume of Transactions) + .166(Annual Expenditures) =
Average Magnitude Multiplier

Low Average

- Implies magnitude multiplier should be applied
- Recommend multiplying compliance score by **1.2**
- Decreasing overall compliance impact - increasing risk score

Medium Average

- Implies magnitude multiplier should not be applied
- Recommend compliance score **does not change**
- Overall compliance impact of risk score does not change

High Average

- Implies multiplier should be applied
- Recommend multiplying compliance score by **0.8**
- Increasing overall compliance impact – decreasing risk score

Risk Assessment Matrix: Calculation Summary

	Sample Risk Areas			
Assessment Categories	**Consulting Arrangements**	**Speaker Programs**	**Field Interactions**	**Investigator Initiated Trials**
Compliance Factors				
Policy	C			
Process	C			
Documentation	C			
Prior Audit	C			
Prior Monitoring	C			
Issues	C			
Training Plans	C			
Departments Involved	C			
Compliance Rating	C/8			
Magnitude Parameters				
External Environment	m1*.5			
Volume of Transactions per year	m2*.33			
Annual Expenditures	m3*.167			
Weighted Magnitude Average	.5(m1) + .33(m2) + .167(m3)			
Magnitude Multiplier	M			
Total Score	**(C/8)*M**			

Risk areas are identified according to external factors

Compliance rating is calculated average across compliance factors

Magnitude average is calculated weighted average across magnitude parameters

Risk Assessment Matrix

	Risk Areas						
Assessment Categories	**Advisory Boards**	**Clinical Ad Boards**	**Speaker Programs**	**Publications**	**IIS/IIT**	**Clinical Trials**	**Promotional Materials**
Compliance Parameters							
Policy	4	3.5	4	4	1.5	4	3.5
Process	4	3	3	4	2.5	4	4
Documentation/Tools	4	3	3	4	3	4	4
Prior Audit	1	1	1	1	4	1	1
Prior Monitoring	4	4	3	2	1.5	1	4
Issues	3	3	2	2	3	3	3
Training Plans	3.5	3.5	2.5	2	2	4	2
Departments/Groups Involved	3	1	2	1	3	3	3
Compliance Rating	**3.31**	**2.75**	**2.56**	**2.5**	**2.56**	**3**	**3.06**
Magnitude Parameters							
External Environment	High	High	High	High	Medium	Medium	Medium
Volume of Transactions per year (Rounded Estimate)	25-30 programs 2 ongoing CAs	57 ongoing projects	4500	8 Submissions	61 Submissions 41 Approvals	~300	3600 Submissions
Volume Rating	Medium	Medium	High	Medium	Medium	Medium	High
Annual Expenditures ($/yr)	2-2.5 Million	>2 Million	10 - 11 Million	Rating Only	4.6 Million	TBD	N/A
Expenditure Rating	Medium	High	High	Low	Medium	Medium	N/A
Magnitude Average	HIGH	HIGH	HIGH	MEDIUM	MEDIUM	MEDIUM	MEDIUM
Magnitude Multiplier	**0.8**	**0.8**	**0.8**	**1**	**1**	**1**	**1**
Total Score	**2.65**	**2.2**	**2.05**	**2.5**	**2.56**	**3**	**3.06**

Risk Assessment Matrix

	Risk Areas					
Assessment Categories	**Samples**	**Field Sales Interactions w/HCPs**	**HCP Meals and Gifts**	**Exhibits/ Sponsorships**	**CME Grants and Charitable Contributions**	**Medical Information Requests**
Compliance Parameters						
Policy	4	3.5	3.5	4	4	3.5
Process	4	3.5	4	4	4	4
Documentation/Tools	4	4	4	4	4	4
Prior Audit	4	1	4	3.5	3	3
Prior Monitoring	4	4	4	4	4	3
Issues	3.5	2	2.5	3.5	3	3
Training Plans	4	4	4	4	3	2
Departments/Groups Involved	4	3	3	3	4	3
Compliance Rating	**3.94**	**3.13**	**3.63**	**3.75**	**3.63**	**3.18**
Magnitude Parameters						
External Environment	Medium	High	High	Medium	High	Medium
Volume of Transactions per year (Rounded estimate)	660,000	7-20 people per rep per day (Sales)	~113,500 meals	~120 sponsorships ~1200 exhibits	submitted/approved 208 / 44 CC 918 / 274 CME	12,000 inquiries
Volume Rating	Medium	High	Medium	High	Medium	High
Annual Expenditures ($/yr)	N/A	N/A	17.5 Million	1.6 - 1.8 Million	428,000 CC 10 Million CME	N/A
Expenditure Rating	N/A	N/A	Medium	Medium	Medium	N/A
Magnitude Average	MEDIUM	HIGH	HIGH	MEDIUM	MEDIUM	MEDIUM
Magnitude Multiplier	**1**	**0.8**	**0.8**	**1**	**1**	**1**
Total Score	**3.94**	**2.5**	**2.9**	**3.75**	**3.63**	**3.18**

It Is Important To Document Rationale For Given Compliance Risk Ratings For Each Parameter

Speaker Programs	
Policy	• Speaker Program Policy exists but has not been socialized across the organization
Process	• Procedural and control documents are in DRAFT form and have not been finalized
Documentation/Tools	• Control Documentation is not being used as directed
Audit	• No prior audits
Monitoring	• Field monitoring via well developed plan and prioritization process; reach limited by manpower constraints
Issues	• Issues with awareness and understanding of policy and procedures, identified through field monitoring and Compliance inquiries
Training	• Speaker training occurs regularly, while internal training is mainly for new employees only
Departments Involved (w/ influence)	• Many

Risk Area Rankings

Risk Area	Relative Ranking
Speaker Programs	2.05
Advisory Boards	2.2
Publications	2.5
Field Interactions with HCPs	2.5
IIS/IIT	2.56
Clinical Advisory Boards	2.65
HCP Meals and Gifts	2.9
Clinical Trials	3
Promotional Materials	3.06
Medical Information Requests	3.18
CME Grants and Charitable Contributions	3.63
Exhibits/Sponsorships	3.75
Samples	3.94

Presentation Agenda

Compliance Risk Assessments	
I. The Need for Compliance Risk Assessments	
II. Preparing for the Compliance Risk Assessment	
III. Conducting the Compliance Risk Assessment	
IV. What to do with the results of the Compliance Risk Assessment	
V. Questions	

The Results Of The Compliance Risk Assessment Will Create Several Actionable Recommendations For Improvement & Oversight

As you conclude the compliance risk assessment, you will likely identify several concurrent efforts for the Compliance Office and other process owners.

1.Process Remediation – Internal controls, aligned with risk management competencies, may need to be refined or developed by process owners. These efforts should be overseen by compliance to ensure timely and effective practices are adopted.

2.Compliance Audit Areas – Some processes and organizational units which may have mature internal controls will require periodic audits to verify that management's control activities are being adhered to.

3.Compliance Monitoring – Some activities which pose significant risk exposure (e.g. speaker programs, advisory boards, etc.) may necessitate periodic monitoring to ensure internal controls are being adhered to.

For Each Recommendation, Develop Specific Tasks To Be Completed As Well As Timeline And Responsibility For Completion

		Timeline (Months)				
Action Item	**Key Tasks**	**F**	**M**	**A**	**M**	**J**
Policies and Procedures	• Review and Approve SOPs	■				
	• Revise and Update SOPs	■				
Training and Communication	• Create Communication Plan	■				
	• Develop Training Materials – Enhance existing – Develop checklists – Create online modules	■	■	■		
	• Conduct Training Pilot for Home office				■	
	• Revise and Edit, as needed				■	
	• Conduct Field Force Training	■				■
	• Conduct Vendor Training					■
Disciplinary Procedures	• Develop Disciplinary Procedure – Policies – Guidelines	■				
	• Include in Training Materials		■	■		
	• Require Employee Sign-off		■	■		
Routine Monitoring and Auditing	• Maintain Existing Program	■	■	■	■	■
	• Develop Centralized Documentation Process	■	■	■		

Lessons Learned

The analysis is important to convince people and to keep the process transparent and consistent

However, Compliance is a *change agent*!

•The process of change is more important

•It's about getting the organization to agree what is important to change: obtain buy in

How to get buy in?

•Take enough time to explain the methodology to the business owners and stake holders

•Explain the findings to each of the areas you have reviewed, review findings and be willing to make changes if additional information has impacts on the finding

•Prioritize and pick your battles – don't attack 150 risk areas, focus on the top 3-5

Show how issues can be resolved – show light at the end of the tunnel

•Don't just present findings, but provide solutions, and an implementation plan

Presentation Agenda

Compliance Risk Assessments	
I. The Need for Compliance Risk Assessments	
II. Preparing for the Compliance Risk Assessment	
III. Conducting the Compliance Risk Assessment	
IV. What to do with the results of the Compliance Risk Assessment	
V. *Questions*	

Mark Scallon
Partner

Contact Information:
Direct: +1.415.432.4367
Mobile: +1.646.554.1167
eMail: mscallon@polarismanagement.com

Areas of Expertise:
- Domestic and Int'l Aggregate Spend Disclosure
- Independent Review Organization (IRO) Assessments
- Compliance Auditing & Monitoring
- Compliance Risk Assessments
- Compliance Strategy & Governance
- International Compliance

Professional Experience:
- PricewaterhouseCoopers - Manager
- Merck Medco – Sr. Financial Analyst
- New York Presbyterian Hospital – Financial Administrator for Ambulatory Care

Education / Qualifications:
- Cornell University– MHA
- SUNY Geneseo - BA

Professional Accomplishments:
- Presented numerous presentations at industry conferences on topics ranging from aggregate spend to compliance risk assessments
- Published over 5 articles on Auditing Monitoring, Risk assessments, Off Label Marketing compliance and Aggregate Spend
- Led IRO assignment for 7 pharmaceutical company
- Successfully opened Polaris' San Francisco office

Polaris Management Partners

Mark is a Partner at Polaris and leads its San Francisco office. Mark has over 13 years experience advising on domestic and international compliance matters for the life sciences industry. Specifically, Mark leads Polaris' Aggregate Spend Practice and co-leads its Auditing and Monitoring practice. As such, Mark has been involved in a wide variety of pharmaceutical and device manufacturer compliance related engagements ranging from IRO assessments to aggregate spend strategy and solution engagements. Mark has conducted risk assessments and compliance audits related to a number of risk areas such as off label marketing, CME, Speaker Programs, Advisory Boards, HCP and Patient Interactions, Publications, etc.

As the leader of Polaris' Aggregate Spend Practice, Mark has extensive knowledge of state, federal and international spend disclosure requirements and advises clients on how to strategically set up client operations to ensure compliance with all applicable reporting laws and regulations. In addition, Mark has facilitated the dissemination of this knowledge through industry webinars and forums.

Major Projects

- *Independent Review Organization.* Mark has led IRO engagements for 7 companies, which have included systems and transaction testing audits based on client CIAs.
- *Aggregate Spend Assessments. Mark has conducted over 45 aggregate spend assessments and strategic roadmaps for clients. Mark advised these clients on organizational structure, spend discovery, gap identification/mitigation and strategic solutions for aggregate spend.*
- *Compliance Audits.* Mark has conducted over 100 compliance audits of multiple risk areas across client operations. Audits have included policy, system/process and transaction testing reviews associated with off label marketing, CME, aggregate spend, speaker programs, advisory boards, publications and many other areas of concern.
- *Compliance Monitoring*. Mark has conducted numerous compliance monitoring activities for clients. These monitoring activities have included live attendance at speaker programs, fielf force ride-alongs, exhibits/conferences and patient advocacy programs.
- *Compliance Risk Assessments.* Mark has conducted a large number of compliance risk assessments and advised his clients on which risk areas should be considered high, medium and low risk based on certain compliance and magnitude parameters. Mark has helped his clients prioritize their risk areas, allowing them to strategically develop their annual compliance programs/initiatives
- *FCPA Compliance Assessments. Mark has led FCPA compliance assessments to identify risks across the international compliance matrix. In addition, Mark has worked with these companies in developing communication, training, and compliance solutions related to the FCPA and helped clients implement these solutions.*