Best Practices for Compliance Monitoring Programs

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Agenda

8:30 AM  Introductions, Monitoring 101, & Top 10 Risk ‘Hot Spots’
9:30 AM  Monitoring & Auditing with Limited Resources
10:00 AM Break
10:30 AM  Monitoring & Auditing with Limited Resources, continued
11:00 AM  Utilizing Dashboards for Enhanced Monitoring
12:00 PM Close of Workshop
Disclaimer

• The information shared by workshop leaders:
  – Represents their own opinions and not necessarily those of their respective organizations
  – Does not constitute legal advice, and should not be relied upon as such
Meet your Workshop Leaders and Fellow Participants. Learn what Compliance Monitoring is and how it works in our industries.

INTRODUCTIONS & MONITORING 101
Compliance Monitoring is...  

Defined:
- Compliance Monitoring is how we assess our adherence to the company’s policies and procedures governing activities that pose compliance risk to the business and help the business effectively manage risks on an ongoing basis.
- Compliance monitoring demonstrates our commitment to maintaining an effective compliance program.

Monitoring vs. Internal Audit:
- While Audit tests the assurance of control effectiveness, Monitoring tests adherence to controls.
- Monitoring samples are targeted; Audit samples randomly.
- Monitoring is conducted real-time; Audit conducts retrospectively.
- Monitoring is ongoing; Audit runs annually or longer.
A Strong Monitoring Program...

✓ Allows for consistency in locating and monitoring key business activities for compliance risk throughout your organization.

✓ Provides visibility of monitoring results and remediation actions to help management oversight of your company’s compliance initiatives.

✓ Aligns with other risk management functions (compliance & internal audit activities) to maximize efficiency and value of your risk mitigation activities.

✓ Documents the effectiveness of your compliance program.
Monitoring Life Cycle

1. Risk Assessment
2. Develop Workplan
3. Prepare Protocol
4. Execute the Monitoring
5. Reporting and Feedback

The cycle is continuous, with each step feeding into the next and back again.
EXPLORING THE TOP 10 RISK HOT SPOTS FOR 2017
Group Exercise

• Please introduce yourself to your neighbors and briefly discuss your risk “hot spots” and priorities for the new year

• We’ll regroup in a few minutes to talk about the items you identified, as well as our “Top 10” list
Risk ‘Hot Spots’...the survey¹ says:

**Pharma**
- Kickbacks
  - AKS
  - FCPA
- Due diligence
  - Third parties
  - M&A
- Pricing
- Off-label concerns
- “Information age” issues
  - Social media
  - Real-world data
  - Data privacy (EU focus, but global)
  - Inadvertent disclosure of PHI
  - Hacking (compromised PHI, stolen IP)

**Device**
- Higher-Risk Third Parties
  - Due diligence
- Emerging Markets
- Kickbacks
- Mergers & Acquisitions
  - Compliance integration
- Pricing
  - Discounts
  - Rebates

¹ Or in this case, the Risk Assessment.
Your company’s unique overall compliance risk profile, gaps and risk mitigation, oversight for third party vendors.

MONITORING AND AUDITING WITH LIMITED RESOURCES
Considerations: Monitoring & Auditing Plans

• Company viewpoint on:
  – Guidance from, or statements made by, regulatory authorities (guidance documents, memos, work plans, etc.)
  – Recent enforcement actions
  – Political environment

• Company-specific risks should heavily inform your annual monitoring and auditing plan. Examples:
  – Product at high risk for theft or diversion
  – Entry into a new area (therapeutic or geographical) of which the company has limited knowledge / experience
  – Any prioritized risk identified during risk assessment process

• The need for ad-hoc monitoring and auditing can arise at any time – must be prepared to meet demand
Risk Assessment / Risk Profiles

- Annual or bi-annual comprehensive risk assessment
  - Geographical or business unit “risk profiles”
  - Individual entity risk profiles
- Compliance SWOT Analysis
- Mix qualitative interviews with quantitative survey data
  - Ask the “front line” employees
- Benchmark
Gaps & Risk Mitigation

• Action plan...with a realistic timeline
  – Cross-functional ownership
    • Build into goals & objectives
  – Cross-functional oversight/steering committee
• Bite off quick wins, strategize for the long-term items
Third Party Oversight

1. Conduct Due Diligence on higher risk third parties prior to contract & engagement.
2. Ensure audit rights are within the written contract with your higher risk third parties.
3. Conduct compliance training annually... in the local language.
4. Have third parties certify to your Code of Conduct annually.
5. Try to conduct an on-site compliance review every 2-3 years (depending on volume of third parties, risk profile). Exercise those audit rights!
6. Support the commercial team and third party relationship owners to include compliance as a topic in their regular check-ins with third parties.
Monitoring Org Structure Ideas

As a stand-alone team

- Monitoring Leader
- Forensic Accountant
- Data Analyst
- Monitoring Lead – Region A
- Monitoring Lead – Region B
- Monitoring Lead – Region B

As an extended team

Leverage peers:
- Internal Audit

Use external resources for:
- Lower-risk repetitive projects
- High risk geographical areas with travel issues
- Monitoring program assessment
## Case Studies

### Small / Mid-size Pharma

- **Live Monitoring**: Ride-alongs & speaker programs; conventions
- **Data Monitoring**: Compliance with HCP meal spend limits

### Mid-size / Large Medical Device

- **Live Monitoring**: Tradeshows, Medical Education Events
- **Data Monitoring**: Payments to high risk third parties

### Auditing

- **Routine Auditing**: HCP payments and supporting documentation
- **Ad-hoc Auditing**: Transactions subject to newly implemented process

- **Routine Auditing**: Third party customs brokers, travel agents, distributors
- **Ad-hoc Auditing**: New acquisitions during or post-integration
Group Exercise

• Work with your neighbors to identify three (3) monitoring challenges and crowd-source best practices to address them

• After a few minutes, each group will share their list of challenges and best practices

• Time will be reserved to discuss monitoring challenges that have left everyone stumped!
Develop measurable compliance outcomes for specific risk areas, and understand what data should be integrated from other departments.

**UTILIZE DASHBOARDS FOR ENHANCED MONITORING**
Why Use Dashboards to Monitor?

Benefits

• Repetitive monitoring
• Comparative metrics: Region, country, business unit
• Design dashboards to seek anomalies
• Ability to forensically drill-down as needed
• Negative testing: what’s not being seen or reported on the surface? E.g., Agg Spend
• Compliance teams may benefit from a “real time” cost sensitive program that allows them to proactively monitor compliance issues before they become problematic.

• Resource heavy programs face risk from changing funding cycles & resource retention issues.

• Alerts created by leveraging central data repositories with compliance defined KCI’s (Key Compliance Indicators) could offer cost effective “real time” monitoring.

Find relevant risk monitors!
OPA Benefits – Manage risk & costs

This idea is not novel or innovative but compliance related central data repositories and existing commercial data stores can help start a program. KCI’s could include alerts related to CIA’s (Corporate Integrity Agreements), boundaries set by corporate compliance policies, FCPA guidelines, thresholds around state reporting laws, and more.

• Setting KCI (Key Compliance Indicators)
  • You control the criteria to answer the questions you need (set the indicators)
  • Compare spending patterns by amount, frequency, and other risk determinants
  • Use historic data to help find anomalies
  • Examine averages to determine limits and ranges

How to create KCIs?
Some ‘outlier’ ideas on data analysis/ data dashboards from workshop perspective are:

- Sudden spikes or decreases in certain distributor sales by country or market/region
- Increased payments to higher risk vendors
- Increased T&E spend on HCP meals, “misc” expenses, or T&E exceptions thrown by the system such as missing receipt affidavits, meal limit violations
- Increase in new vendor or customer set ups in a certain market or country
- Decrease in vendor payments but increase in T&E or other payment methods for which data is available
- Abnormal increase in product sales in countries that border sanctioned countries or bordering countries were products are not registered (this is very deep, feel free to not include!)
- Increase in discounts, rebates to certain customers or free-of-charge product (e.g. $0 products on invoices)

What do you need to know?
Example #1: Sudden spikes or decreases in certain distributor sales by country or market/region

Quarter over quarter spend by distributor
Q4 – 2016 spike triggers data alert

December displays visual alert

Details of monthly sales

Distributor Details:

- **Country:** Poland
- **Distributor:** Pharmacole S.A.
- **Account Executive:** Joseph Blanco
Analytics-based Monitoring

Key Compliance Indicators

Public datasets
  Subscription datasets

External Data

Workflow and Transaction

Automated Alerts

Selected Alerts

Internal Data

Compliance datasets
  Commercial datasets

ALERT Data Received

ALERT TRIGGER

Dashboard Summary

Dashboard Detail
Significant variance in travel cost versus consulting fees when compared with competitor.

Use benchmarking against historical data stores to spot anomalies.

Pharma, Inc.
OUTLIER 1: Total consulting fee HI for an HCP
TRIGGER 2: Exceeding Corporate single payment LIMIT

Monitor Outliers

Pharma, Inc.