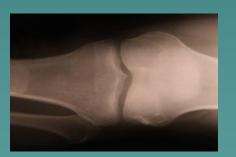
16th Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

Getting Ahead of the Game – Utilizing Data and Other Operational Indicators to Identify Potential Compliance Issues Early









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<u>Speakers:</u>

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Traditional Auditing & Monitoring Plan Development - Potential Risk Area Sources

- Industry Corporate Integrity Agreement Compliance Monitoring Requirements
- Industry Government Investigations/Settlements
- OIG Annual Workplans
- OIG Fraud Alerts
- Industry Compliance Conferences
- Compliance Hot-line Submissions

Potential Compliance Related Data Analytics – Key Benefits

- Supplements/helps prioritize auditing & monitoring activities
- Early detection of potential regulatory compliance issues to further investigate
- Leveraging of data already being collected for regulatory/operational purposes
- Early detection and potential explanation of publically available data and other operational anomalies potentially identified or targeted by enforcement agencies
- Early detection of potential business reputational risk

Potential Compliance Related Data Analytics – Key Benefits (Cont.)

- Key approach to demonstrating an effective compliance program in today's compliance focused environment
- Monitoring adherence to internal Policies & Procedures
- Certain indicators a potential benefit to the business side of the organization

Potential Compliance Related Data Analytics – Example Data Sources

- Meals & Entertainment
- Education Grants & Sponsorships
- Samples
- Speaker Programs and Related Payments
- Research Payments
- Consulting Arrangements/Payments
- Employee Social Media Activity
- Medical Science Liaisons Activity
- Publications/Reprint Activity
- Rebates & Discounts
- Service Fee Arrangements/Payments
- Sales Activity by Employee, HCP
- Call plans
- Medical Information Requests (MIRs)

Potential Compliance Related Data Analytics – Example Data Indicators

- Correlation of fees paid to HCPs (consulting, speaker programs, research, etc.) against sales activity (amount and timing)
- Correlation of HCP reimbursed meals & entertainment against sales (amount and timing)
- Increased sales force interaction with HCP's who do not traditionally treat approved product indications
- Correlation of increased MSL activity against sales (amount and timing)
- Correlation of increased service fees paid against sales (amount and timing)

Potential Compliance Related Data Analytics – Key Risks to Consider

- Potential inaccurate conclusions based on missing data sets or incorrect/incomplete data
- Too much focus on the data analytics collection/process/"tool" – focus can be lost on basic "blocking and tackling" of auditing & monitoring
- Determining Internal distribution or access rights to compliance related data analytics dashboards/reports
- Inaction on identified/internally distributed anomalies and/or potentially concerning trends

Potential Compliance Related Data Analytics – Key Risks to Consider (Cont.)

- Balancing appropriate coordination with the business side of the company
- Coordination Between Compliance Department/General Counsel Office when inquiring/analyzing further anomalies and/or potentially concerning trends
- Coordination with Internal Audit initiatives

Potential Compliance Related Data Analytics – Other Considerations

- Government enforcement agencies' increased use of data mining/data analytics during investigations
- Plaintiffs Bar's increased use of data mining/data analytics during Qui Tam litigation
- Requests of certain manufacturer HCP data by Healthcare institutions
- CIA compliance certification requirements

Potential Compliance Related Data Analytics – Other Considerations (Cont.)

- DOJ Individual Accountability for Corporate Wrongdoing memo ("Yates Memo")
- Responsible Corporate Officer Doctrine
- New DOJ Compliance Counsel position

Audience Q&A

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