

# **The FIFTEENTH ANNUAL PHARMACEUTICAL REGULATORY AND COMPLIANCE CONGRESS**

## **Pre-Conference II: Innovations in Auditing and Monitoring**

11.03.14 | Presented by L. Stephan Vincze

# Innovations in Auditing and Monitoring

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# The OIG's View on the Importance of Staying on Top of Risk

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**“Board Members:  
Stay informed on risk areas and  
compliance issues”**

Greg Demske, Chief Counsel to the  
Inspector General, HHS



# The OIG's View re: Audits and Effective Compliance Programs

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- **One of Six Steps for an Effective Compliance Program:**

- ***Conduct Regular Audits***

- OIG HHS Website Compliance 101 Training and Videos:
      - Tips for Implementing an Effective Compliance Program



# Agenda

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- **8:30 Welcome & Introductions**
- **8:45 The Use of Risk Assessments to Guide Audit Planning and Ensuring Alignment with the Business**
- **9:25 Compliance Monitoring Best Practices**
  - Drivers for Continued Focus on Compliance Monitoring -- CIA's, Commercial, R&D, etc.
  - Types of Monitoring -- Physical, Electronic, Risk-Based Targeting and Scoring Process
  - Strategies for Identifying Trends in Monitoring Results
  - Maintaining Appropriate Stakeholder Awareness of Compliance Risk through Effective Reporting
  - Panel/Audience Discussion on Different Approaches, Perspectives and Practices
- **10:05 BREAK**
- **10:20 Compliance Auditing Best Practice**
  - Drivers for Continued Focus on Compliance Auditing -- Data Collection, Analysis and Reporting, etc.
  - Compliance Audit Focus Areas -- Where are We Seeing the Highest Risks?
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- **11:00 Maintaining Appropriate Stakeholder Awareness of Compliance Risk through Effective Reporting**
- **11:40 A Look to the Future: What's Needed, What's Wanted, and What Do We Need to Get There in the Next 2-5 Years?**
- **12:00 Adjourn**



# Moderators

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L. Stephan Vincze, LD, LLM, MBA  
Partner, Polaris; Former Senior Vice President, Chief Compliance Officer,  
Warner Chilcott; Former Vice President, Ethics and Compliance  
Officer/Privacy Officer, TAP Pharmaceutical Products Inc., Boston, MA



Paul J. Silver  
Practice Leader and Managing Director, Huron Consulting Group,  
Atlanta, GA



BJ D'Avella, MBA  
Director, Huron Consulting Group,  
New York, NY



Darren R. Jones  
Director, Polaris, New York, NY



# Panel of Industry Compliance Professionals

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Jae Burnett, Director of Compliance, Masimo, Los Angeles, CA



Eve Costopoulos, Vice President, Chief Ethics and Compliance Officer, Eisai Inc., Woodcliff Lake, NJ



Kevin L. Espinoza, MBA  
Vice President, Ethics & Compliance, BTG International,  
Raleigh, NC



David Gherlein, Esq.  
Director, R&D Compliance at Takeda Pharmaceuticals USA,  
Chicago, IL



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THE FIFTEENTH ANNUAL

# Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

TRANSFORMATIONAL LEARNING -  
EFFECTIVE KNOWLEDGE EXCHANGE



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Global Health Care, LLC

Preconference II: Innovations in Auditing and Monitoring:

## The Use of Risk Assessments to Guide Audit Planning and Ensuring Alignment with the Business

November 3, 2014



# Compliance Auditing Best Practice

# Identify Potential Risk Exposures



- Understand your risk exposures is the cornerstone for audit/monitoring activities
  - Risk Assessment is considered a leading practice and widely adopted
  - Additional, less formal, methods can also be used to identify risks:
    - Business partnership
    - Internal Audit
    - Hotline/Investigations
    - External factors (e.g., expanded markets or regions)
  - Data Analytics
    - Use a “risk lens” when analyzing your data
    - Identify the anomalies and outliers

# Identify Sources of Risks Across Business Operations



1. Organizational Capabilities
  - Outsourcing, Vendor Reliance, Partnerships, Investment
  - Sales, R&D, and Medical Affairs structure
2. Business Objectives and Channels
  - Today and Tomorrow
  - Recent acquisitions, new businesses/organizations
  - Product Portfolio (e.g. Primary Care, Specialty, Generics)
3. Business performance measurements and/or KPIs
4. Corporate Integrity Agreements, Enforcement Activities
5. Organizational Interactions with governments and other reimbursement sources
6. Processes and People that impact patient safety
7. Customers (HCPs, HCOs, GPOs, others?) and touch-points
  - Promotional and non-Promotional
8. Research and Medical Affairs Activities
9. Control Documents
  - Previous evaluations (monitored, independently audited)

# Establish Priorities in Your Auditing Plan



- Use a risk-based approach when developing annual audit plans,
  - Consideration recent CIA's, regulatory notices, industry-specific data, and known company risks
  - Prioritizes resources by known or perceived risks
  - Plans should also account for other lower risk areas not covered in previous audits

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# Compliance Monitoring Best Practices

# Drivers for Continued Focus on Compliance Monitoring - CIA's, Commercial, R&D, etc.



1. Data in-house informing risks can't go un-monitored at some level
  - CRM and other records informing HCP interactions
  - Professional services records (e.g. ad boards, Speaking, Publication Support)
  - Financial payments to HCPs, HCOs, Advocacy Organizations
2. CIAs, Product litigation, enforcement activities
  - Sector and Therapeutic specific
  - Emerging areas (e.g. R&D, Medical Affairs, Manufacturing)
3. Merger and Acquisition Requirements
  - New acquisitions, valuation
4. Transparency & Industry Scrutiny (governments, media , consumer)
  - State, Federal, Voluntary, Propublica effect
5. BOD Assurance
  - Heightened engagement



# Types of Monitoring -- Physical, Electronic, Risk-based Targeting



- Identify available data and observation opportunities
  1. Data informing interactions with HCPs and HCOs
    - CRM Records (Sales and Medical) & Customer materials
    - Medical Information requests
    - Verbatim Data or other market research
  2. Professional Service Payments and associated documents
    - Speaking and consulting payments
    - Other 3<sup>rd</sup> Party payments (HCOs, GPOs, Advocacy)
    - Sponsorships
  3. Non-Promotional Funding
    - Grants and Donations
    - Advocacy Support
  4. Medical Affairs and Research Activities
    - Publications, Compendia, CME
    - Investigator Initiated Trials, Company Trials, Site & Investigator selection

# Strategies for Identifying Trends in Monitoring Results



## 1. Inventory and Analysis

- Generate data streams for data obtained electronically or through observation
- Identify potential non-compliance and investigate accordingly
- Use large data sets to trend for risk insights
- Don't limit analysis to single data streams and cross-reference for insights

## 2. Report data to multiple stakeholders

- Activity dashboard (departmental)
- Compliance committee dashboard
- BOD reporting

## 3. Scoring

- Tolerance within or outside of acceptable controls

## 4. Report business and Risk trending insights (no measurements)

- Demonstrates value of analytics to business

# Q&A



**Huron**LifeSciences

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**Take a break!**

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**Please be back  
in 15 minutes!**



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# Some Questions re: Auditing & Monitoring

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- ***When developing a compliance oversight program it is important to include both auditing and monitoring activities. I think there has been a lot of confusion about the difference between these activities.***
  - For your respective organizations, how has the difference between auditing and monitoring been defined?
- ***When we say that auditing is to be more control based, what does that mean to you?***
  - Policies, Processes, People & Organization, Systems & Data, Management Reporting
- ***Presumably like most compliance functions you are resource constrained, so focusing on the right risks is critical.***
  - What are some of the emerging areas of concerns that you are seeing?
  - Have you used audits to consult with the business on appropriate process or control design?
  - Have monitoring results helped you in identifying areas to be audited?
- ***Some risk areas can impact a broad range of operations. One area of common concern is the dissemination of off-label information. In recent CIAs, the OIG has been silent on whether they are focused on written or verbal responses.***
  - So in this context, when looking at such a broad risk, how would you / or do you, scope such an effort?
- ***Audits need to identify and assess controls that both prevent and detect risk***
  - With regards to Sunshine reporting, what are some specific *preventative or detective* controls that you have been implemented and audited within your companies?
- ***What are the areas you would audit versus those that you would monitor?***
  - Reimbursement support
  - Sunshine data submissions
  - 3<sup>rd</sup> party due diligence
- ***The responsibility for conducting audits tends to vary across the industry. Some have it done by compliance, some by Internal Audit, or both.***
  - Who is responsible for setting the audit plan and executing compliance audits within your company?
- ***Many companies struggle with determining if audits should be done under privilege.***
  - How and when do you determine if an audit should be conducted under privilege?
  - How do you protect the privilege? Specifically, how do you establish that the work is being done at the direction of Counsel versus the Compliance or Audit departments?





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# Reporting: Who, What, When, Where, How & Why

- **Who:**

- To Whom? – Compliance Com.; Board?
- By Whom? – CCO, Others?

- **What:**

- Relevant Factors:

1. Maturity of Compliance Program (7 Elements)
2. CIA
3. Risk Areas
4. Hotline/Helpline Calls
5. Audit Results
6. Monitoring Results
7. Corrective Action
8. Annual Risk Assessment
9. Quarterly Updates
10. Others?

- **When:**

- Quarterly, Annually, Semiannually?

- **Where:**

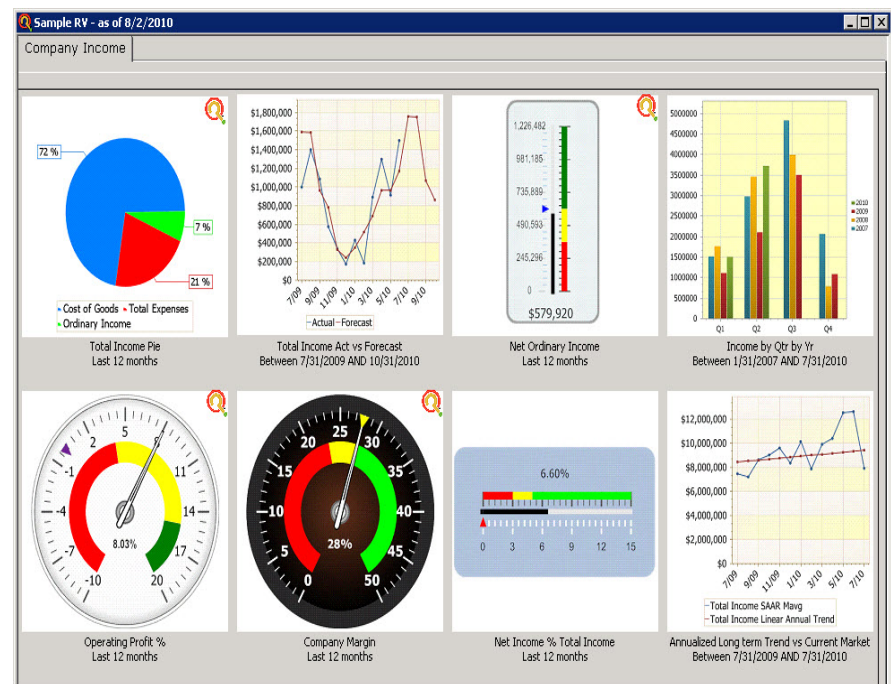
- Compliance Committee, Board Meetings, Website?

- **How:**

- Dashboards/Scorecards; Data; Reports?

- **Why:**

- Helps Boards and Executives meet their oversight responsibilities
- Answers Question: How do we know this program is working?
- Translates compliance performance into language of business – data/metrics
- Increases credibility of program to Board and OIG



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- What's Needed?
- What's Wanted?
- What Do We Need to Get There in the Next 2-5 Years?

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# Thank You!

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