

# **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,  
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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



**GHC** LIFE  
SCIENCES  
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



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# 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

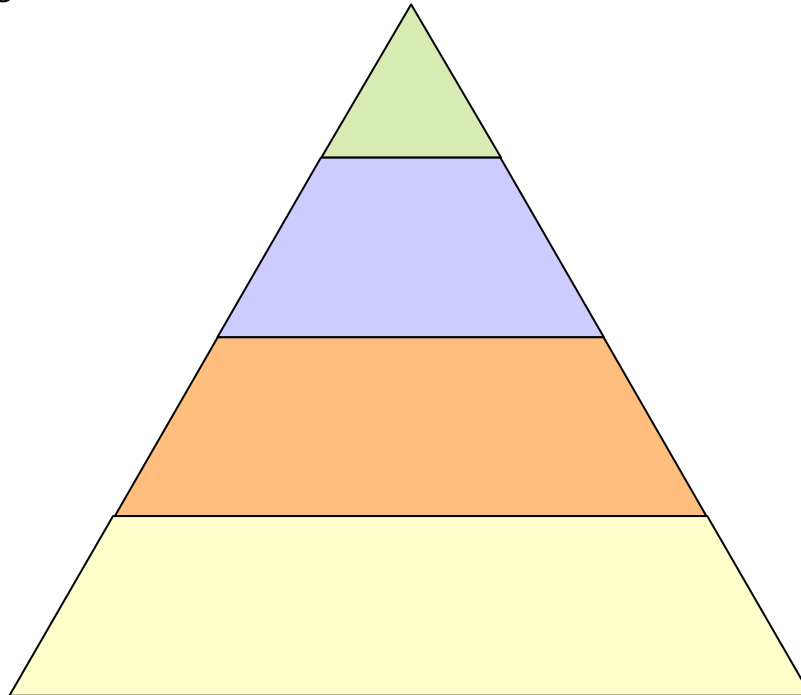


# Identify Sources of Risks Across Business Operations

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

# Establish Priorities in Your Auditing Plan

- Use a risk-based approach when developing annual audit plans
  - Considers recent CIAs, 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.

- 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
- CIAs, Product litigation, enforcement activities
  - Sector and Therapeutic specific
  - Emerging areas (e.g. R&D, Medical Affairs, Manufacturing)
- Merger and Acquisition Requirements
  - New acquisitions, valuation
- Transparency & Industry Scrutiny (governments, media , consumer)
  - State, Federal, Voluntary, Propublica effect
- BOD Assurance
  - Heightened engagement

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

Identify available data and observation opportunities

- Data informing interactions with HCPs and HCOs
  - CRM Records (Sales and Medical) & Customer materials
  - Medical Information requests
  - Verbatim Data or other market research
- Professional Service Payments and associated documents
  - Speaking and consulting payments
  - Other third-party payments (HCOs, GPOs, Advocacy)
  - Sponsorships
- Non-Promotional Funding
  - Grants and Donations
  - Advocacy Support
- Medical Affairs and Research Activities
  - Publications, Compendia, CME
  - Investigator Initiated Trials, Company Trials, Site & Investigator selection



# Strategies for Identifying Trends in Monitoring Results

- 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
- Report data to multiple stakeholders
  - Activity dashboard (departmental)
  - Compliance committee dashboard
  - BOD reporting
- Scoring
  - Tolerance within or outside of acceptable controls
- Report business and Risk trending insights (no measurements)
  - Demonstrates value of analytics to business

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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:**

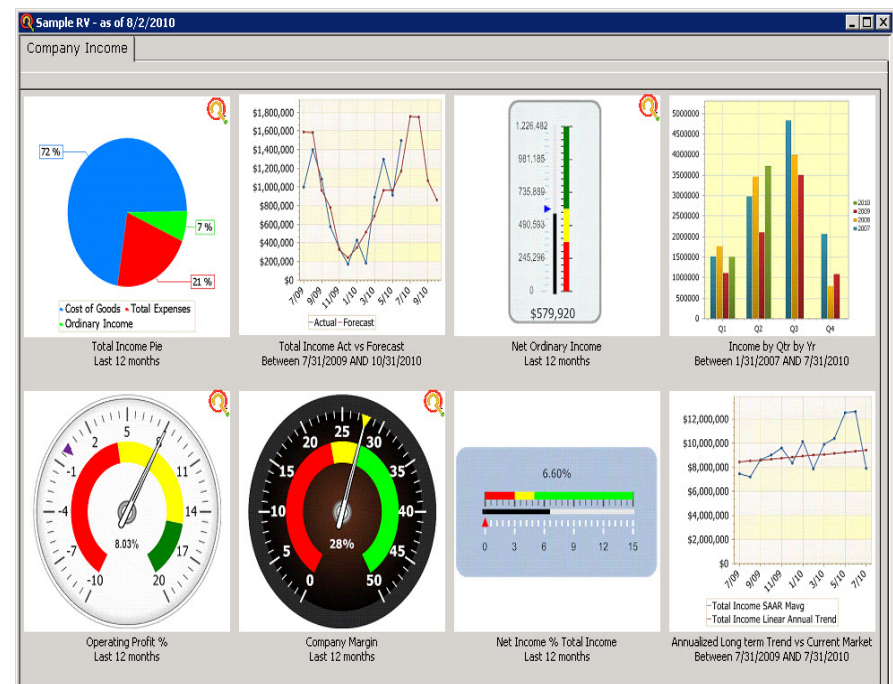
- Compliance Committee, Board Meetings, Website?

- **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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## futureagenda The World in 2020

- 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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