THE FIFTEENTH ANNUAL PHARMACEUTICAL COMPLIANCE CONGRESS

Mini Summit I: Compliance Risk Assessments

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DISCLAIMER

- Eric Siegel, Elizabeth Jobes and Tom Cornely are employees of pharmaceutical companies, however the viewpoints they share with us today are their own, and not representative of their employers.

COMPLIANCE-RELATED RISKS INHERENT IN THE PHARMACEUTICAL INDUSTRY

- Promotional practices
  - Off-label promotion (including violations of Food Drug & Cosmetic Act)
  - Anti-Kickback Statute violations
  - False Claims Act violations
  - Bad Ad or Whistleblower claims (may include violations of any of the above)
- Litigation
  - Products liability
  - SEC matters
  - Securities Litigation
- Manufacturing/Quality/Supply Chain Management*
  - Single source API
  - Critical suppliers identified and evaluated
  - Adequacy of manufacturing capacity
  - Product integrity
  - Quality assessments conducted at both owned and vendor sites
  - Business Continuity: Are sufficient controls in place relative to key product ingredients and materials?

COMPLIANCE-RELATED RISKS INHERENT IN THE PHARMACEUTICAL INDUSTRY

- Anti-Bribery Statutes (including third party diligence re: marketing and distribution ex–U.S.)
- IT Risks/ Data Privacy, Data Security and Document Retention*
  - IT Infrastructure
  - Access to confidential information
  - Personnel: Adequate levels of support? Sufficiently strategic? Client oriented?
  - Adequacy of current Business Continuity and Disaster Recovery capabilities?
  - Strength of IT security?
- Crisis Management Infrastructure – In place and current? Tested? Training of critical personnel?
- Competition/Generic Competition/Paragraph IV Challenges*
- Clinical Trials – including Adverse Event management
- U.S. Changing Healthcare Landscape
  - Federal and State Reimbursement
  - Affordable Care Act
- Economic Growth
  - Shareholder value
  - IP concerns
  - Forecasting and Modeling

COMPLIANCE ASSESSMENTS

- What are they?
- How is this different from an Enterprise-Wide Risk Management [ERM] Assessment?
- Overview of the process
- What is the purpose of conducting them?
- When and how do I decide I need one?
- Who in the organization should own the process?
- How do I get senior management buy-in?
- Who should conduct the assessment?
- Should it cover the entire company or one function at a time or should it be conducted by therapeutic area?
- Is this process and the final assessment report privileged?
- Who should see the results?
- Who is responsible to track remediation and mitigation of all perceived risks that are identified in the assessment?

WHAT ARE COMPLIANCE ASSESSMENTS?

- Review of Company's compliance program to assess alignment between current processes and controls with various laws, guidances, and regulations that apply to pharmaceutical companies.
  - PhRMA Code
  - OIG
  - Anti-Kickback Laws
  - Food Drug & Cosmetic Act/Regulations
  - ACCME, ICMJE and other guidances
  - Best practices – CIAs, DPAs, etc.
- Policy/Process Gap Assessment
- Assessment of the relative risk of any one business activity against other activities (i.e., risk ranking); can assess within and/or across brands
- Remediation/Mitigation Planning and Execution

WHAT IS THE DIFFERENCE BETWEEN A COMPLIANCE ASSESSMENT AND AN ENTERPRISE WIDE RISK MANAGEMENT ASSESSMENT?

- ERM Assessment: A comprehensive, in-depth assessment of specific events and/or circumstances (risks and opportunities)that could impact a Company's ability to achieve its enterprise-level goals and objectives. ERM provides a framework for assessing such events and circumstances so that an effective response strategy (including objective metrics to measure progress) can be proactively put in place.

- Compliance Assessment: Can be a component of an ERM assessment or a distinct assignment. Using ERM tools, a focused, comprehensive assessment is performed to identify compliance-related gaps and risks. Such gaps and risks *do not* need to reach "enterprise-level" materiality or impact to be identified for Mitigation consideration.

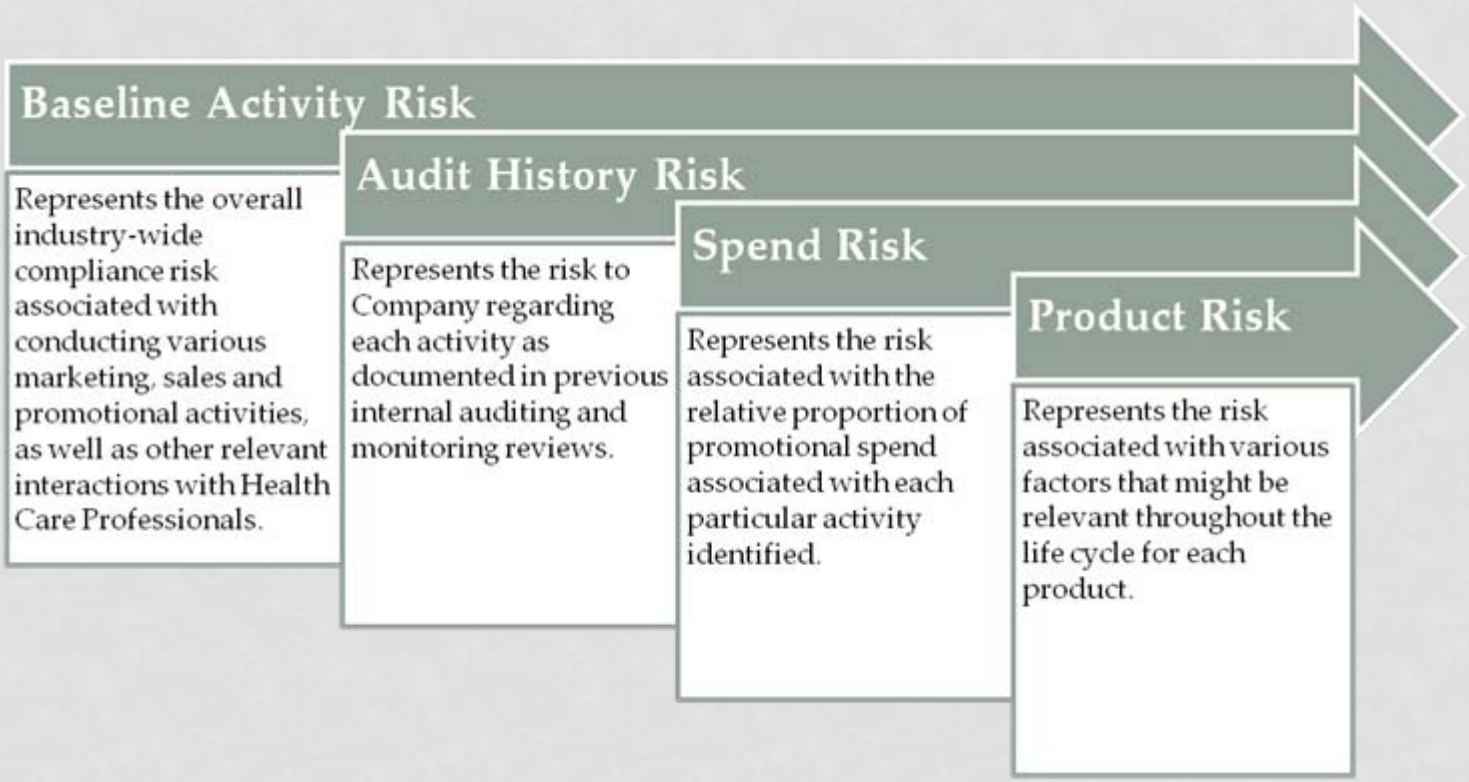
OVERVIEW OF THE PROCESS

- Review previous assessments, as well as recent audit reports (internal and external)
- Perform a gap assessment relative to Policies and SOP (usually focused on Commercial policies and SOPs but can include R&D, Medical Affairs and Regulatory)
- Confidential Interviews
- Consolidate document review findings and interview feedback to develop a list of unvalidated, Perceived Compliance Gaps
- Review Perceived Compliance Gap list with Compliance Assessment oversight committee; prioritize Gaps for Mitigation
- Present findings to senior management and secure needed approvals and budget to commence approved Mitigation initiatives
- Identify Mitigation Leaders for each approved initiative. Mitigation Leaders develop mitigation/remediation plans
- Once approved Mitigation initiatives commence, develop mechanisms to track progress compared to pre-established milestones

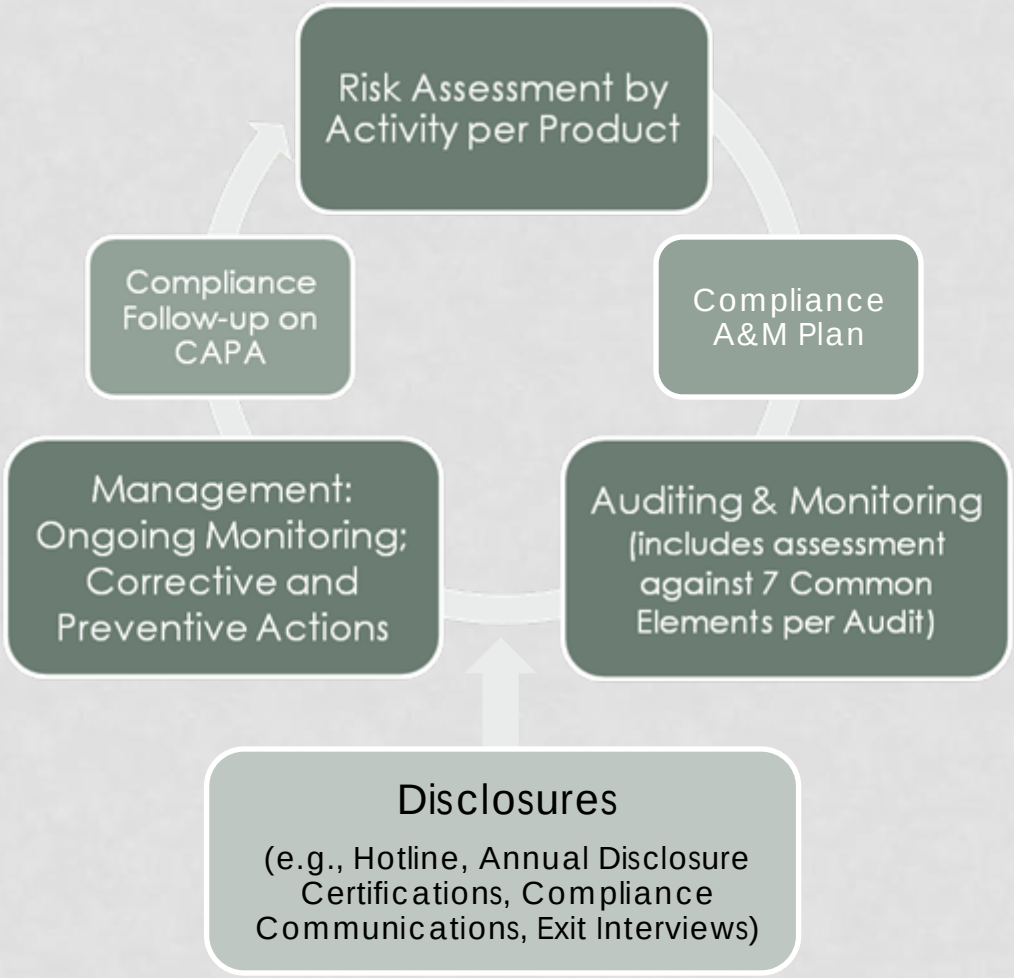
COMPLIANCE RISK/GAP ASSESSMENT PROCESS COMPONENTS

Risk Activity Catalogue

Various activities identified by the Compliance department associated with various marketing, sales and promotional activities, as well as other relevant interactions with Health Care Professionals/ Institutions.



ANNUAL CYCLE



WHAT IS THE PURPOSE OF CONDUCTING A COMPLIANCE ASSESSMENT?

- Why should a Company consider conducting such an assessment?
  - Support development of a company's compliance auditing and monitoring plan
  - Benefits
    - Valuable from M&A perspective
    - Proactively avoid expensive issues
    - Reinforce "tone from the top" culture
    - Holistic view of overall Compliance programming and linkages between various aspects
- Frequency
  - Generally recommended that a company perform a Compliance gap/risk assessment every 12-18 months
- Considerations when a company is under investigation or anticipating an investigation.

HOW DO I DECIDE IF I NEED ONE?

- New to the organization? New senior leadership?
- Acquired new product or company?
  - Compliance-related risks identified during diligence?
- Restructure of groups within the company/ Reduction in Force?
- High risks associated with products (look at enforcement actions against similarly situated companies or products)
  - Off-label
  - Safety
- Material change in sales volumes of one or more products
- Requirement of CIA, DPA or other government enforcement action
- Board requires annual compliance evaluation exercise

WHO SHOULD OWN THE COMPLIANCE ASSESSMENT PROCESS AND DELIVERABLE?

- Does it depend upon the specific areas to be assessed?
- Should Compliance be the sole owner of the process?
  - If not, who else?
  - Should the owner of the gap/risk assessment process also play a role in the mitigation process?
- Role of the Audit Committee or the Board in the Compliance gap/risk assessment and mitigation process?
- Role of Legal?

WHO NEEDS TO APPROVE OR "BUY–IN"?

- Senior management?
- Board?
- How do you get buy-in?
  - Review of External Environment
  - Government Enforcement Activity
  - Outside Counsel/Compliance expert evaluation
- Differences between large and mid-size/small?

WHO SHOULD CONDUCT THE ASSESSMENT?

- Internal?
  - Compliance
  - Audit
  - Legal
  - Finance
- External?
  - Consultant
  - Law firm
  - Combination
- Factors to consider when making the determination:
  - Budget
  - Company culture
  - Company size
  - Pending/possible government investigation

WHAT AREAS WITHIN THE COMPANY SHOULD BE ASSESSED?

- Focus of assessment
  - Commercial only? R&D? Mfr/Supply Chain? Safety? Clinical Trials? Medical Affairs?
  - Entire company
  - By Therapeutic area
  - Products with high off label sales?
  - Resource-dependent
- Challenges
  - Challenges with doing assessments for entire company?
  - Challenges with doing assessments for departments by themselves?
  - Risk/Benefit of all of the above options for assessment

THE GAP/RISK ASSESSMENT PROCESS AND LEGAL PRIVILEGE

- Can the assessment process be performed under legal privilege? Can the resulting Report(s) and work product be prepared and distributed under legal privilege?
- Should they be? What legal privilege applies?
- How to attach legal privilege?
- Could the use of legal privilege to prevent disclosure of a gap/risk assessment be used against a company in an investigation or lawsuit?

WHO SHOULD SEE THE RESULTS?

- Senior management
- Audit Committee
- Board
- All managers, VP and above
- How should the information be presented?

HOW DO YOU TRACK REMEDIATION AND MITIGATION?

- Importance of objective, pragmatic metrics
- Appointing "Mitigation Leaders"/"Risk Owners" to coordinate each approved remediation/mitigation initiative
- Key considerations - development and selection of remediation/mitigation options
- Project management tools, such as reporting template and "dashboards"
- Oversight/coordination of ongoing remediation/mitigation activities
- "Close-Out" of a remediation/mitigation initiative

QUESTIONS?