

# Monitoring Based on Risk Open Forum

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Panel and participants will share ideas and best practices for how to identify, prioritize and monitor risk

The materials provided and respective discussions from moderator and panelists are for informational purposes only and not for the purpose of providing legal advice. You should contact your attorney to obtain legal advice with respect to any specific issue or topic. The opinions expressed during this presentation are individual opinions and do not necessarily reflect the opinions of the companies they represent.

# Monitoring Based on Risk

- Panelists:

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- Moderator:

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# Monitoring Based on Risk

## Identification of Risk

- Know your Business – Stay Connected
- Strategy, Business Objectives, Performance Plans, Business Activities
- Follow the \_\_\_\_\_ (money, prescriptions, patients...etc.)
- Across all Levels and Functions
- Know the Environment – Stay Informed
- Review your data...program data, deviations, policy violations, allegations

# Monitoring Based on Risk

## Prioritization of Risk

- Likelihood and Impact (Risk Matrix)
- Planned Response
- Resource constraints
- Brand characteristics
  - New area, new indication, life cycle, competitive landscape
- Level of Control and Visibility
  - Internal, Sales, Vendor

# Monitoring Based on Risk

## Know the Environment

- Recent Enforcement Efforts
  - CIA's and Warning Letters
- Government Opinions and Guidance Documents
- Regulations – State and Local

# Monitoring Based on Risk

- Potential Monitoring Tactics based on Activity

## Individual Risk Activities with Direct Interactions

- Promotional Interactions by Sales Representatives
- Consumer Interaction
- Disease Awareness
- Promotional Materials
- Off Label Inquiries
- AE/PC Process
- PAP, Reimbursement Support
- TOV
- Licensing and Registration
- Samples and Vouchers
- Co-Pay Programs
- Speaker Programs
- Role of Medical Affairs

# Monitoring Based on Risk

- Potential Monitoring Tactics based on Activity

## Corporate Risk Activities

- Distribution and Wrap-Around Services, e.g. Specialty Pharmacy
- Post Marketing Requirements, e.g. REMS
- Speaker Programs
- Targeting
- Advisors and Consultants
- Buy and Bill Products
- Promotional Materials
- Pre-Approval Activities
- Replacement Programs
- Corporate Communications
- Hotline

# Monitoring Based on Risk

- Potential Monitoring Tactics based on Activity

## Vendor Risk Activities

- Vetting Process
- Contract, Business Rules, Quality Agreements
- Escalation and Notification Requirements
- Business Owner clearly identified
- Business Owner responsibility and level of oversight
- Risk based on Specific Service



# Monitoring based on Risk Summary

- Must know your business and the environment
- Ever Changing
- Considers Multiple Levels in Organization
- Considers all Corporate Functions
- Considers all Corporate Partners and Providers