

Best Practices for Risk Assessment

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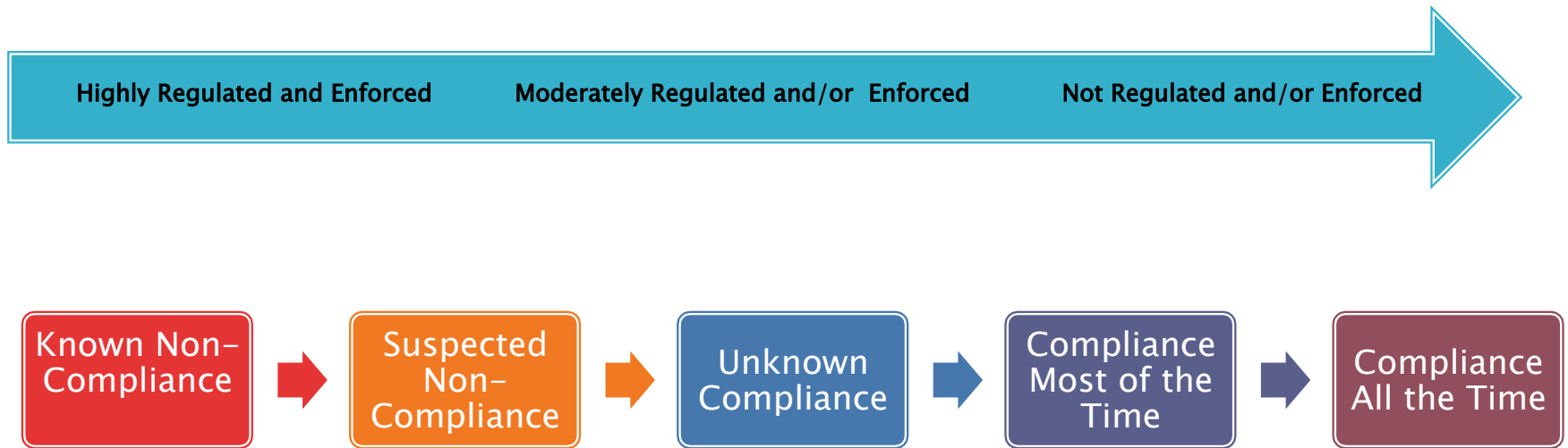
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Disclaimer

The views expressed during this presentation do not constitute legal advice and are the views of the moderator and panelists in their personal capacities. They do not reflect the views of any of their respective employers.

“Risk” Comfort Levels Vary



“Risk is like fire: If controlled it will help you; if uncontrolled it will rise up and destroy you.” – *Theodore Roosevelt*

“We assess relative risks in the programs for which we have oversight authority to identify the areas most in need of attention and, accordingly, to set priorities for the sequence and proportion of resources to be allocated.”

– OIG Work Plan, Fiscal Year 2016

Agenda

- ▶ Objectivity While Leveraging Resources
- ▶ Focus vs. Response to Environment
- ▶ Assessing Risk Within Your Culture

Our panel discussion is intended to be interactive and audience participate is encouraged.

Objectivity While Leveraging Resources

- ▶ The compliance organization serves an “oversight” function and should have sufficient resources
- ▶ In practice, Compliance Departments need help to assess risk, monitor activities and effectuate change

“The extent and frequency of the compliance audits may vary depending on variables such as the pharmaceutical manufacturer’s available resources, prior history of noncompliance, and the risk factors particular to the company.” – OIG Compliance Guidance

Hypothetical

You are the Compliance Officer at a small pharma company. The company has one product on the market in the area of pain management, which was launched in 2013. The Head of Sales has come to you expressing some concerns about market share numbers in a particular region of the country. He has witnessed a spike in sales, but personnel have not changed in any way. One of their KOLs, who happens to be a speaker, is located in that area but he is not sure if this is related to the increase. He asks you to look into the issue and commits fully to help with the review and analysis. Should the Head of Sales play a role in this risk assessment? How will you proceed? What factors and findings will influence the risk assessment? (e.g., nature of the product, off-label use, history of dealings with KOL)

Focus vs. Response to Environment

- ▶ Compliance is a “moving target”
- ▶ Work plans are important to help stay on track, but are subject to change based on company activities and challenges
- ▶ Compliance Departments have to be accessible and responsive – always – and be flexible when they can

“[T]he OIG strongly encourages pharmaceutical manufactures to develop and implement or refine (as necessary) compliance elements that uniquely address the areas of potential problems, common concern, or high risk that apply to their own companies (or, as applicable, to the U.S. operations of their companies).”
– OIG Compliance Guidance

Hypothetical

You and your small compliance team (including an outside resource) are in the middle of your annual PhRMA Code audit. It is late March and you are aiming to complete the audit by the end of April in order to certify for Nevada requirements. In the middle of the process, your Compliance Department receives an anonymous call from someone claiming to be a sales representative. He says that he has facts that demonstrate another representative is involved in the diversion of drug samples. He has connections at a local "mom and pop" pharmacy and has talked to employees there. You know this needs immediate attention. What do you do? Do you report potential sample diversion to FDA? What happens to the ongoing PhRMA Code audit? How do you allocate resources in order to properly address both tasks?

Assessing Risk Within Your Culture

- ▶ To have credibility and to be able to effectively assess and manage the company's risk profile, Compliance should understand what drives the business
- ▶ Once a compliance organization has an understanding of a company's risk tolerance, challenges may still arise in dealing with third parties and outside organizations

“Coordination and communication with other appropriate individuals or business units are the key functions of the compliance officer with regard to planning, implementing or enhancing, and monitoring the compliance program.”

– OIG Compliance Guidance

Hypothetical

You are the Head of Compliance at a life sciences company. You co-market your product with a larger company and have in place, as part of the co-marketing contract, an agreement for each company to notify the other of sales and marketing compliance issues in a timely manner. The other company has learned that one of your vendors may have made misrepresentations regarding its compliance training program and employee vetting process and the other company has initiated its own investigation. Generally, is it acceptable for your compliance team to utilize the results of another company's audit or risk assessment to help identify compliance risks? Can these other processes satisfy your obligations and internal metrics? Does your answer change if your compliance department is involved in the review from the beginning? How does each company's culture affect the analysis?