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Mini Summit 2

HCP Engagement: The Road to Proactive Risk

Management

November 7th from 10:45-11:45am

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Brian Conner	Michelle Murphy
Strongbridge BioPharma plc	Regeneron Pharmaceuticals, Inc.
Vice President, Head of Corporate Compliance	Director, Corporate Compliance
Thomas M. Glavin, JD	Laura Skinner (Moderator)
Olympus Corporation of the Americas	Deloitte & Touche LLP
Chief Compliance Officer	Senior Manager, Life Sciences Regulatory
	and Operational Risk



How big is your company in terms of annual revenue (roughly)?



\$1 billion to \$5 billion B

>\$5 billion to \$15 billion C

>\$15 billion to \$30 billion D

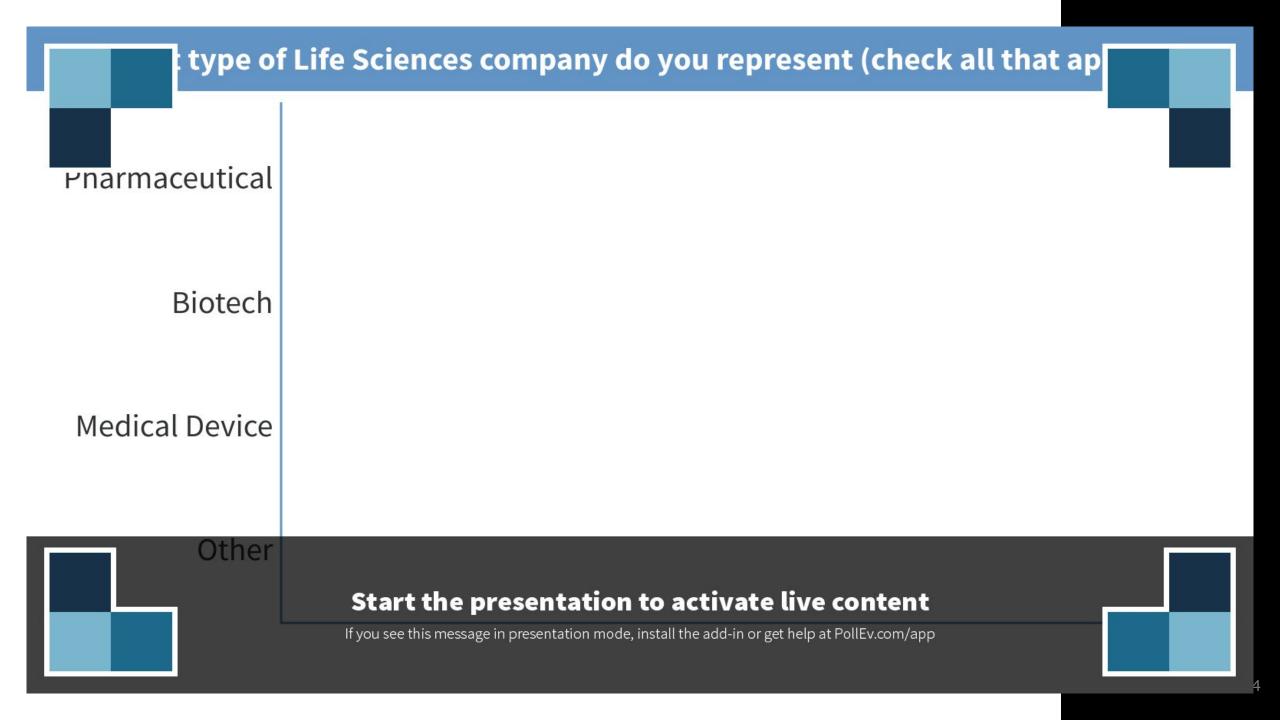


>\$30 billion E

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How many FTEs work in your US Compliance function?

<10 FTEs

10 to 20 FTEs

21 to 35 FTEs

36 to 75 FTEs

>75 FTEs

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What is proactive risk management as it relates to the HCP engagement process?



your company proactively manage risk as it relates to the HCP engage process?

We are a small organization. We don't have formal policies/procedures/systems, but those who hire HCPs have clear instructions on core requirements and/or we monitor HCP engagement activities to look for risk-producing activities

We have policies in place that all must follow, but no formal process.

We have policies and procedures in place which are managed through the needs assessment process from initiation through payment reconciliation.

We have an automated system that accounts for our policies/procedures that generates an approval or rejection that accounts for the needs assessment process from initiation through payment reconciliation.

Some combination of A, B, C, D

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What should companies consider when deciding how to proactively manage risk?

- How does company size come into play?
- How much sophistication do companies need and when?
- What is your first line monitoring, i.e., what is the business doing before it even gets to compliance?

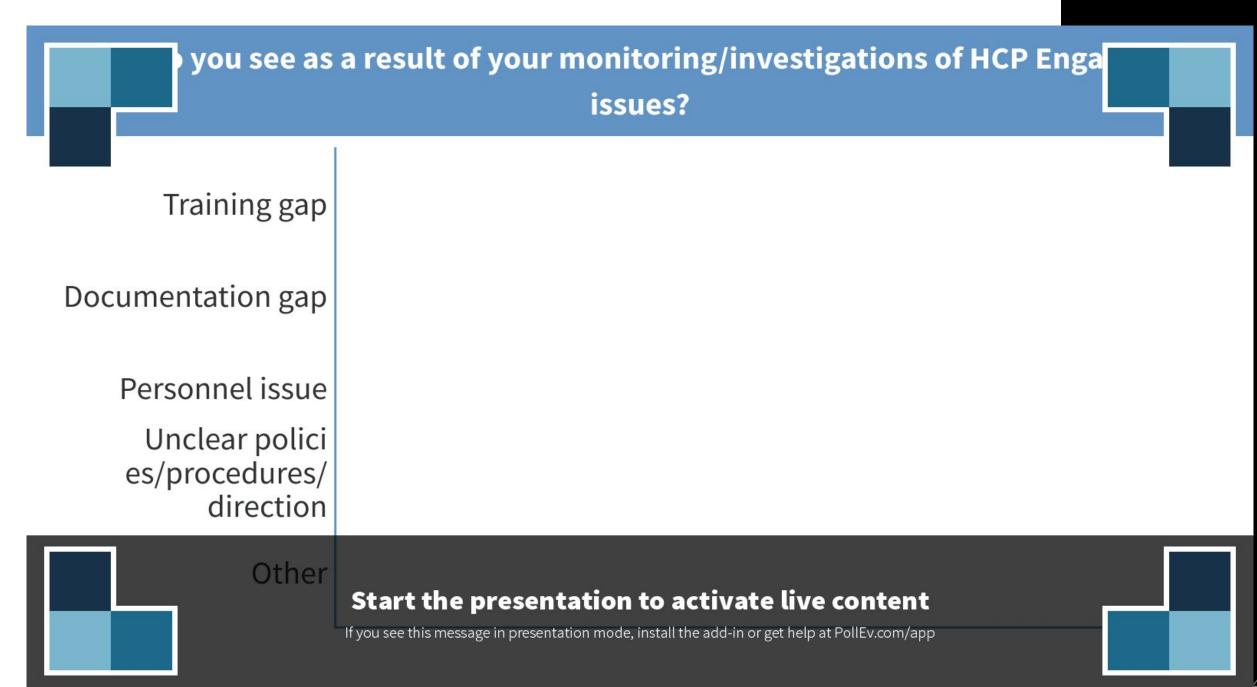


The role of Compliance in Strategic Planning

- What role does compliance play in the strategic planning process?
- Are you involved as a strategic partner or just a reviewer?
- How can we become a more strategic partner?
- Can anyone share best practices?
- What post planning follow ups?
- How does company size lifecycle come into play?

How is managing HCP engagement risk different or more challenging globally?





How can companies use past results to monitor future risks?

 How can companies evolve from being reactive to proactive.

 How does technology fit in and how are companies using technology?



Summary

- As Business evolves... so do the risks
- New Strategies...Tactics... Roles... Customers...
- Need to be ahead of the curve
- Strong connection to business is critical to understand activities and develop risk mitigation strategies
- Compliance must show value offer strategic guidance to the business

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