Mini Summit 20:
Best Practices when Transitioning from Healthcare Compliance Risk to Enterprise Risk Assessments

November 7, 2019

THE PHARMACEUTICAL COMPLIANCE FORUM

NAVIGANT
A Guidehouse Company

Panelists

Ann E. Beasley, JD, Director, Life Sciences, Governance, Risk and Compliance, Navigant, Former Senior Vice President, Chief Compliance Officer, Biogen, Boston, MA

Christie Camelio, Vice President, Deputy Global Chief Compliance Officer, Celgene, Former Executive Director, Head of Risk Management Center of Excellence, Novartis Pharmaceuticals, Florham Park, NJ

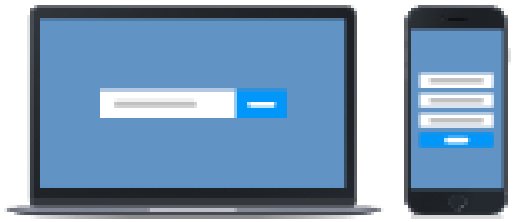
Christian A. Dingler, Associate Director, Navigant Life Sciences, Richmond, VA

Jenny McVey, PhD, Compliance Risk and Mitigation, Novo Nordisk, Inc. Former Compliance Officer, Hands International, Princeton, NJ

Kristin Rand, JD, MA, Vice President and Compliance Officer, Seattle Genetics; Former Compliance Director, Policy, Ethics, Training & Communication, Genentech, New York, NY

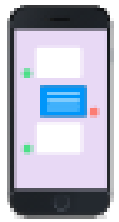
How to join

Web



1. Go to **PollEv.com**
2. Enter **PETERGRANT179**
3. Respond to activity

Text



1. Text **PETERGRANT179** to **22333**
2. Text in your message

1. How would you describe your organization?

Large Pharma

Small / Mid Size Pharma

Large Medical Device

Small / Mid Size Medical Device

Consultant or Service Provider

2. How would you describe your knowledge of risk assessment?

Little to None

Some Exposure

Mid to Advanced Knowledge

Put me on the panel

3. What is your experience with risk assessment?

None

Exposure to healthcare compliance risk assessments

Exposure to Enterprise Risk (ERM) assessments

Exposure to both healthcare compliance and ERM risk assessments

4. What is your biggest pain point related to risk assessments?

We don't do a risk assessment, our compliance program is not risk-based

Risk assessment roles and responsibilities: who does what by when, etc.

Risk assessment design: we are missing or misusing valuable information

Communicating risk assessments results: we are not reducing risk or not acting on the output

Other

Key Takeaways

There is no one size fits all approach to ERM and the program MUST evolve year after year to be effective. Stay flexible and curious and maintain communication with key stakeholders throughout the year – not just during "risk calibration" season.

-Christie

Try not to lose steam after the risk assessment. Creating and following a risk mitigation plan is critical.

-Christian

It's important to drive ownership and accountability down past the most senior functional leaders. If you want to have a clear and accurate assessment of the impact of mitigation efforts, it's essential to get the people who are close to the work engaged in the risk management process.

-Anna

As with any new or evolving program, continue to foster innovation, flexibility, and open minds – this parallels the dynamic environment by which we operate in.

-Jenny

Within complex, typically silo'ed life sciences companies, compliance personnel have a unique opportunity to help identify and manage integrated risks – risks that overlap between functions or departments and where there are gaps - where lack of clear ownership of oversight of a risk might create risk crisis. Developing a forum to identify, discuss, share and manage integrated risk is a good first step.

-Ann

You are not alone. This approach is a new concept for many companies and there is no one size fits all approach. Reach out to compliance colleagues for support. Garner a few supporters within your companies to help champion the cause (IT is usually a good ally).

-Kristin

