

## ***Mini Summit 3:***

---

# ***Ethics and Compliance Programs of the Future: New Strategies for Integrated Assessment and Management of Risks***

**Ann BEASLEY**

**George FIFE**

**Isaure KERGALL**

**Dominique LAYMAND**

**Ariadna QUESADA**

**- SVP & Chief Compliance officer - Biogen**

**- Executive Director, EY**

**- Compliance & Business integrity Director France - Sanofi**

**- President - ETHICS Association**

**- International Compliance Manager - MicroPort Orthopedics**

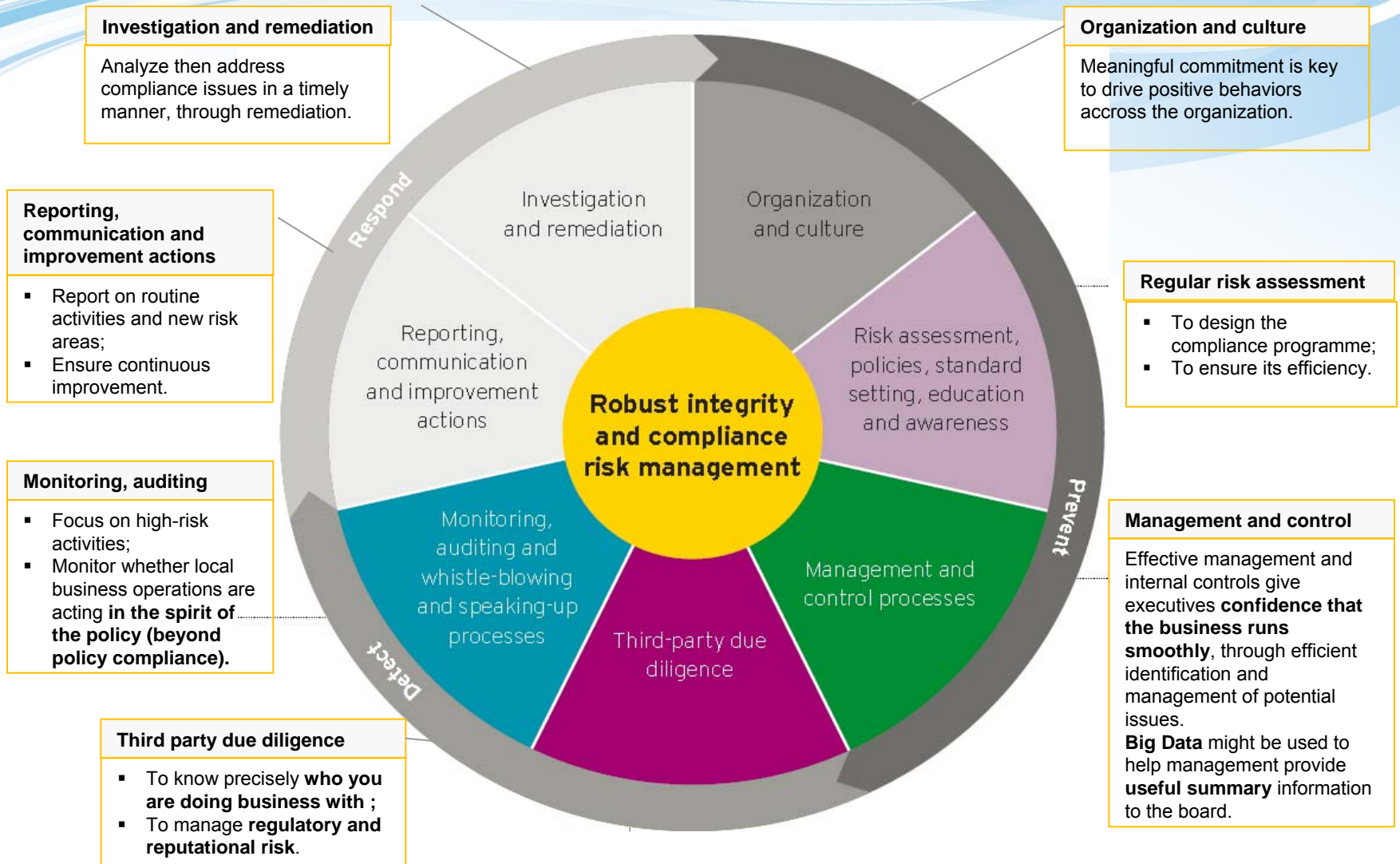
**PCF Pharma Compliance Congress - Warsaw, 10 May 2016**

# Key Components of an Effective Compliance Program

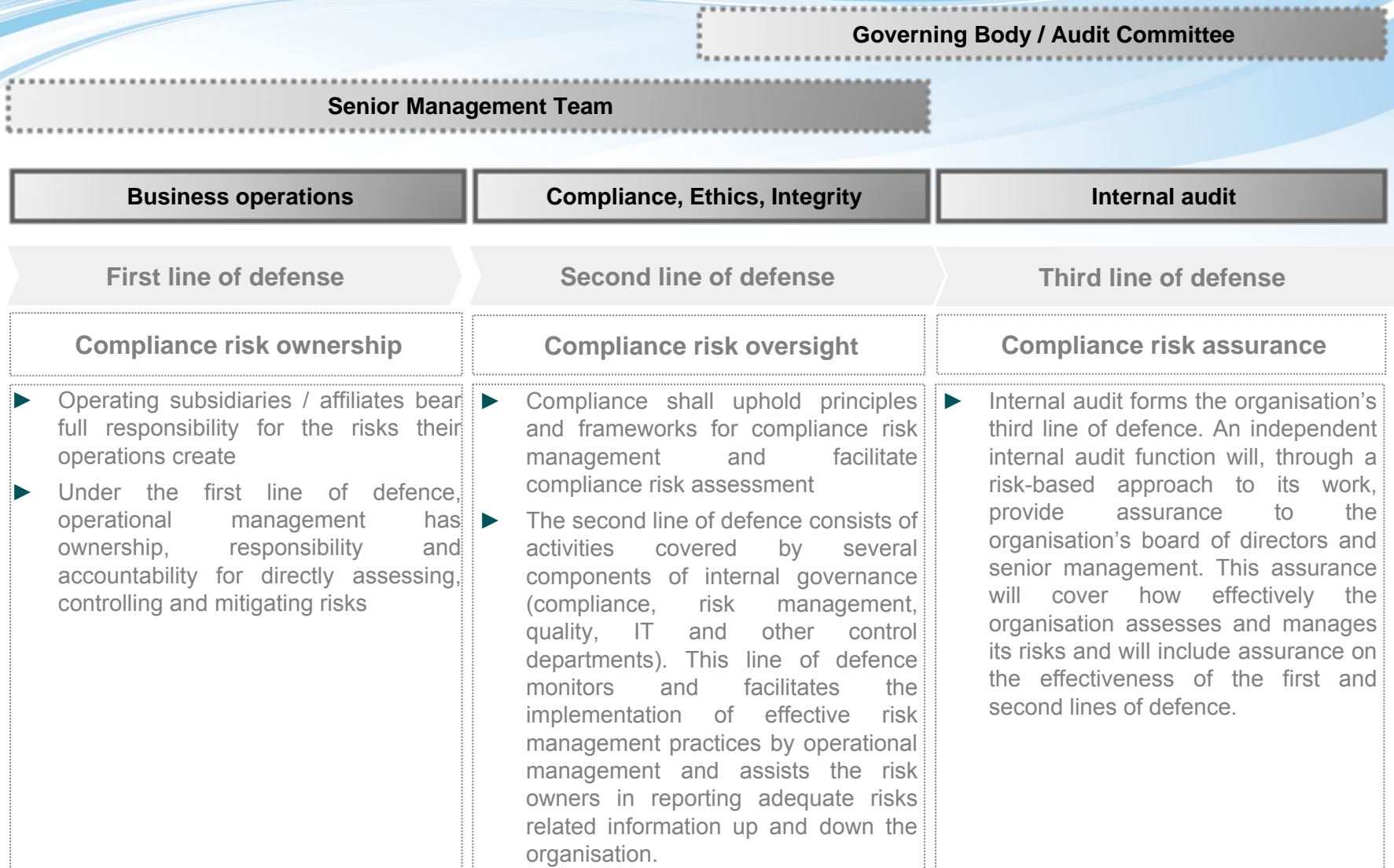
External criteria's/guidances (OECD, US DOJ, UK BA,...)	
Commitment from senior management and clearly articulated policy against key risk areas	<i>Often referred to as "Tone at the top", senior management and board directors alike are responsible for conveying a strong message that key risks will not be tolerated</i>
Code of Conduct and compliance policies and procedures	<i>Code of conduct provides ethical guidelines for those conducting business on the company's behalf. A company may also have specific policies and procedures that address its most significant risks and outline proper internal controls and monitoring procedures</i>
Oversight, autonomy and resources	<i>Responsibility for the compliance program should be assigned to an appropriate senior individual or group to provide the authority and autonomy to oversee the program and report to the company's governing bodies</i>
Risk Assessment	<i>Program should be designed around and commensurate with its unique risk profile, taking into account factors such as its size, structure, industry, geography, interactions with foreign officials and involvement of business partners. A thorough risk assessment adds efficiency and credibility to compliance efforts</i>
Training and Continuing Advice	<i>Company should take steps to ensure all employees are aware of the policies and procedures, which is often accomplished through periodic training. Certain key roles, such as management, sales, finance and business development personnel may receive enhanced training</i>
Incentives and Disciplinary Actions	<i>To avoid the appearance of a "paper program", corporate compliance program must be enforced unequivocally throughout the organization with clear disciplinary procedures for violators applied timely and consistently. Also positive incentives (financial or merit-based rewards) may reinforce a culture of compliance</i>
Third-Party Due Diligence and Payments	<i>Risk-based due diligence approach identifies and devotes attention to third-parties posing the greatest corruption risk. The guidance highlights three area's to govern dealings with third parties from pre-contractual due diligence efforts to payment terms and on-going monitoring of third-party relationships</i>
Confidential Reporting and internal Investigations	<i>Employees and third-parties should be encouraged to share tips or suspected violations in a secure and confidential manner</i>
Continuous Improvement: periodic testing and review	<i>Companies may perform periodic testing or audits to monitor compliance with the various elements and controls of the program and to uncover existence of potential violations and red flags signaling new corrupt risks</i>
Pre-Acquisition Due Diligence – Post-Acquisition integration	<i>An acquirer is responsible for conducting thorough due diligence of a potential target company, which extends to evaluating potential corrupt activity by the target</i>

# Effective Compliance Program

## Corruption Hallmarks



# Traditional 3 lines of defence





**THANK YOU for the lively exchange!!!**

**Ann, George, Isaure, Dominique & Ariadna**