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**18<sup>th</sup> Annual Pharmaceutical and Medical Device  
Compliance Congress  
Chief Compliance Officer Round Table**

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# Panel Introductions



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# Today's Topics

Risks in an Era of New Business Models

Globalization & Regulatory Trends

The Future of Ethics & Compliance

# Market Dynamics

- Market Access and Reimbursement
- New Drugs and Devices Hitting the Market
- Mergers/Acquisitions/Joint Ventures
- Quickly-Changing Technology



# Empowerment of Compliance

Comprehensive compliance

Compliance integration

Lack of compliance focus



## Reactive

### Defensive compliance

- Remediation focused
- Limited resource
- Prescriptive processes
- Inadequate ownership
- Minimal training

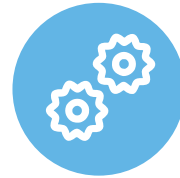
Emerging



## Passive

### Superficial compliance:

- Enforcement culture
- Fragmented resources
- Misalignment of local and global objectives
- Compliance consulted at end of decision



## Operational

### Transactional compliance:

- Simplistic training
- Remediation distracts from proactive approach
- Providing adequate processes of compliance
- Ineffective compliance incentives

Evolving



## Strategic

### Embedded compliance:

- Compliance technology enhances daily business activities
- Local affiliates input to global process design
- Advanced training programs
- Tone at middle relays consistent messaging



## Holistic

### Fully integrated compliance:

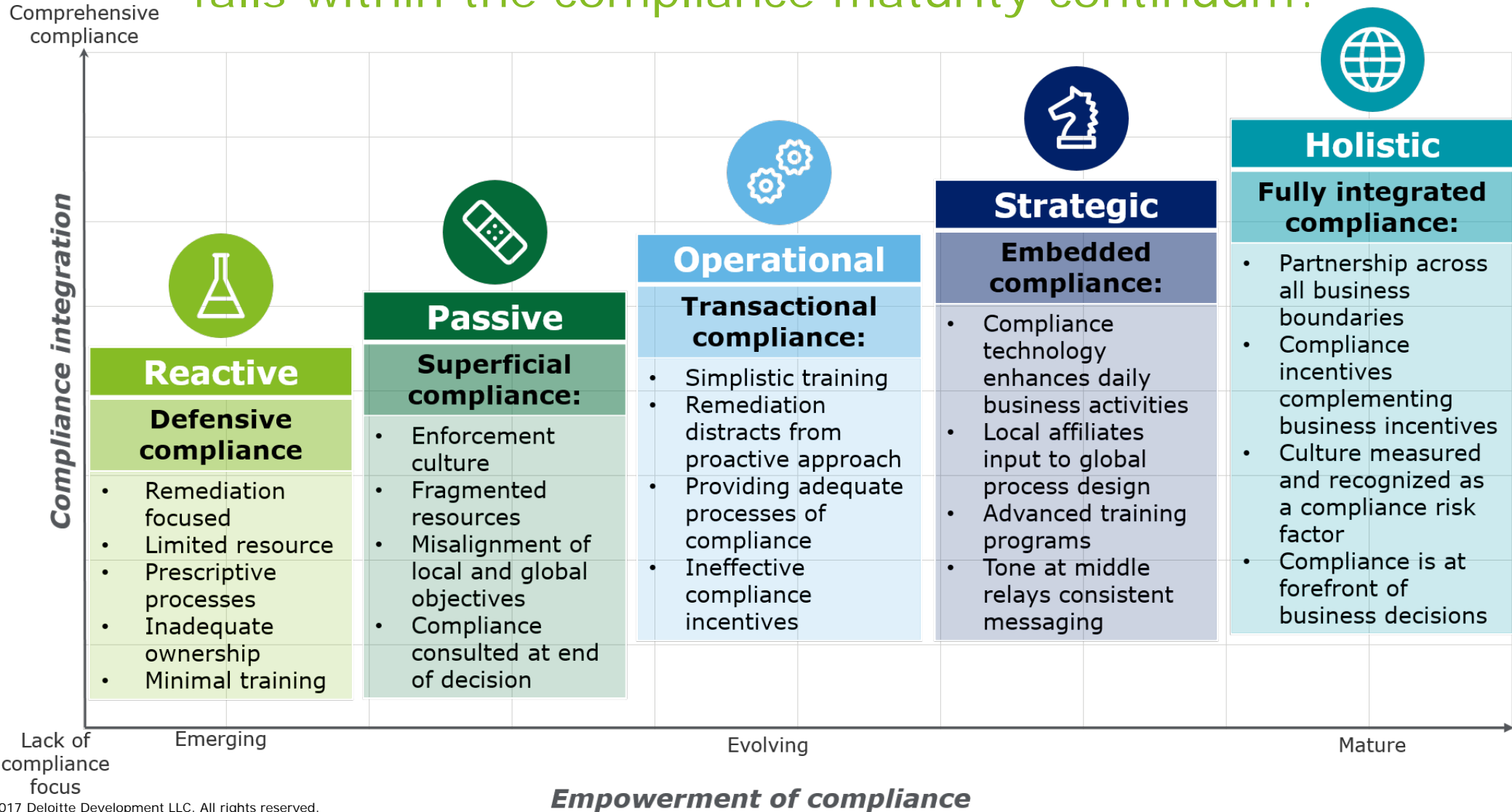
- Partnership across all business boundaries
- Compliance incentives complementing business incentives
- Culture measured and recognized as a compliance risk factor
- Compliance is at forefront of business decisions

Mature

*Empowerment of compliance*

# Audience Polling

“In relation to this chart, where do you feel your organization falls within the compliance maturity continuum?”



# Topic 1: Risks in an Era of New Business Models

With new business models, there is a need to “share” risk.

What are some recommendations for navigating the potential compliance risks when partnering with third parties to conduct business?

# Audience Polling

“As companies look at new business models, how likely is your organization to pursue a collaboration in the next two years to commercialize a product (merger, acquisition, licensing, joint venture, etc.)?”

- A. Unlikely
- B. Already collaborating with other partners
- C. Very likely
- D. Both B & C





# Topic 1: Risks in an Era of New Business Models

We are no longer simply selling products but “healthcare solutions.”

The industry has moved from selling products to “healthcare solutions.” How has this shift impacted your approach to risk management and compliance?

# Topic 2: Globalization & Regulatory Trends

## Managing risk across markets

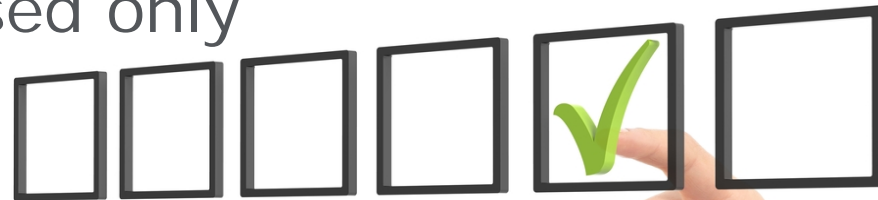
What are the global risks in the industry?

How are risks managed in a global environment?

# Audience Polling

“How integrated is your compliance program?”

- A. Compliance is centrally managed and fully standardized across the globe.
- B. Compliance is driven by local/regional compliance teams.
- C. Our compliance function is centralized but not yet standardized into other regions.
- D. N/A – US-based only



# Topic 2: Globalization & Regulatory Trends

Regulations continue to evolve and become even more region-specific.

What types of challenges have you encountered when implementing a global compliance program?

# The Future of Ethics & Compliance

## Audience Polling

“Which business area below do you believe is the biggest compliance challenge your company will deal with over the next couple of years?” (choose one)



- Distribution channels
- Global markets
- New promotional activities (i.e., digital, co-marketing)
- Market access
- Integrating compliance requirements in business systems
- Other

# Topic 3: The Future of Ethics & Compliance

Do you expect investments in compliance infrastructure to increase in the future or will compliance leaders be expected to do more with less?

In your opinion, what can enable greater efficiencies?

# Topic 3: The Future of Ethics & Compliance

What changes do you foresee for those who pursue a career path in compliance?

What will advancement look like and what skills will be required to be successful in the future?



Final  
thoughts  
from  
our  
panel

Thank you!





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