



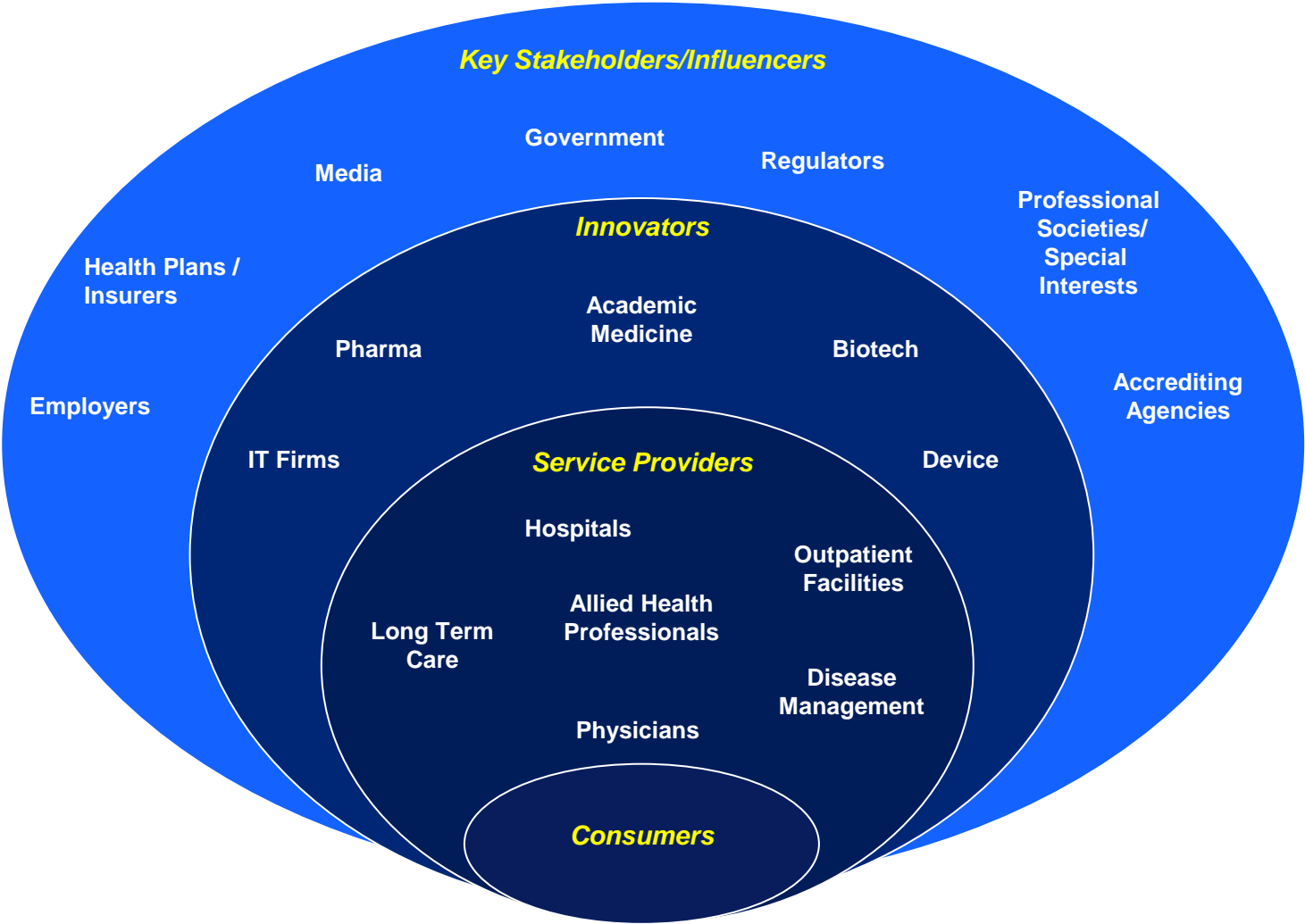
# Global regulatory trends

**David Hodgson, Deloitte & Touche LLP**

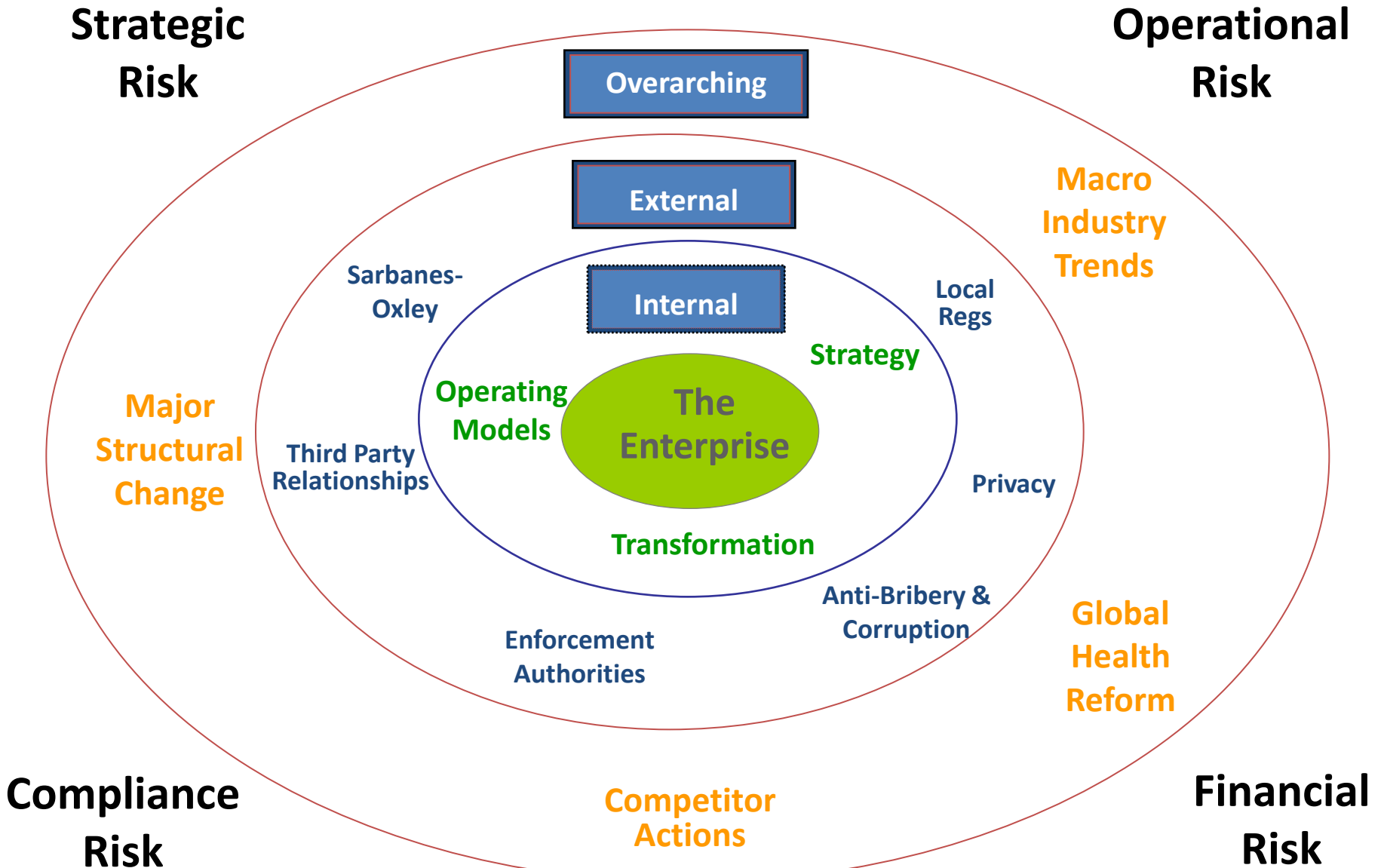
**Mexico City**

**May 2013**

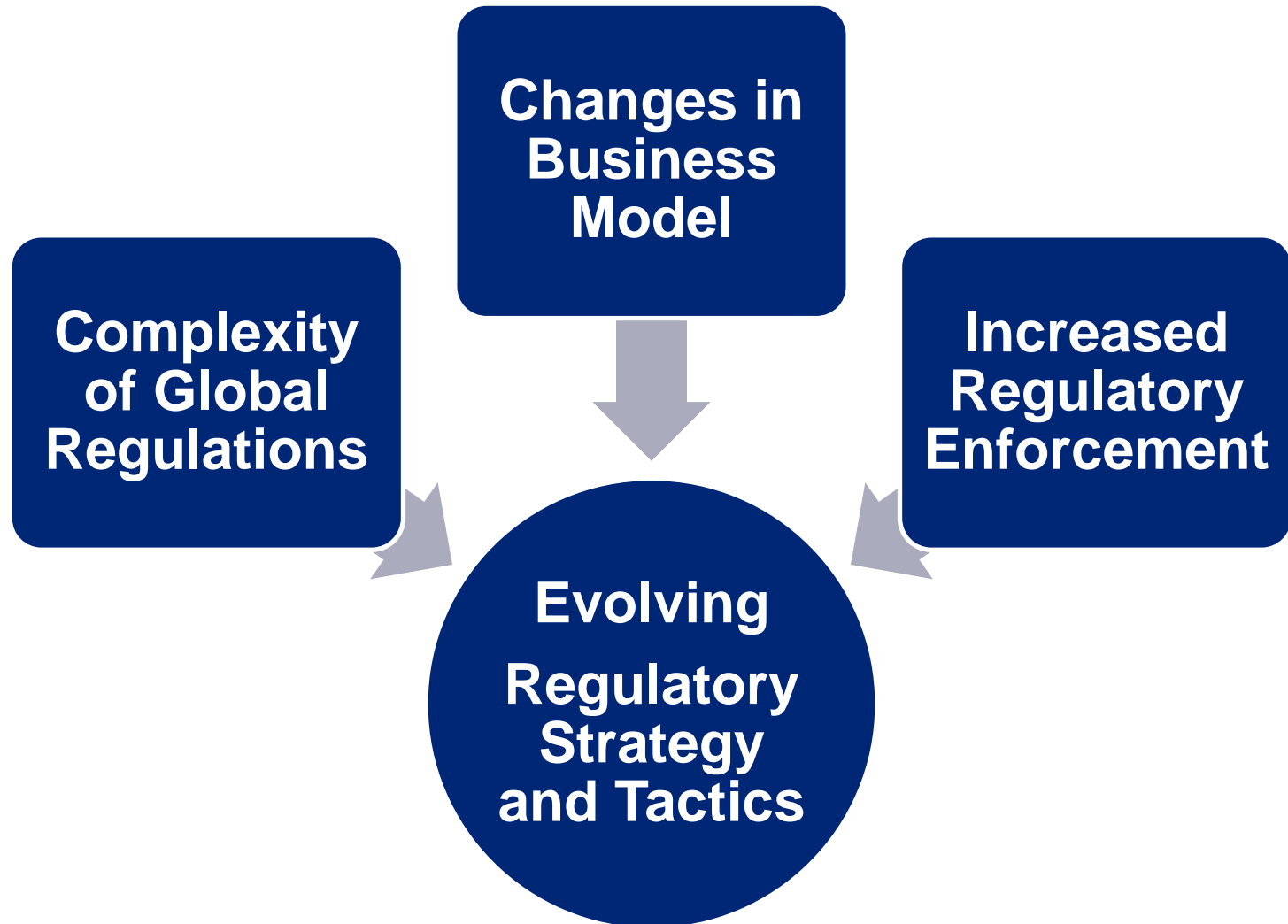
# The Life Sciences ecosystem



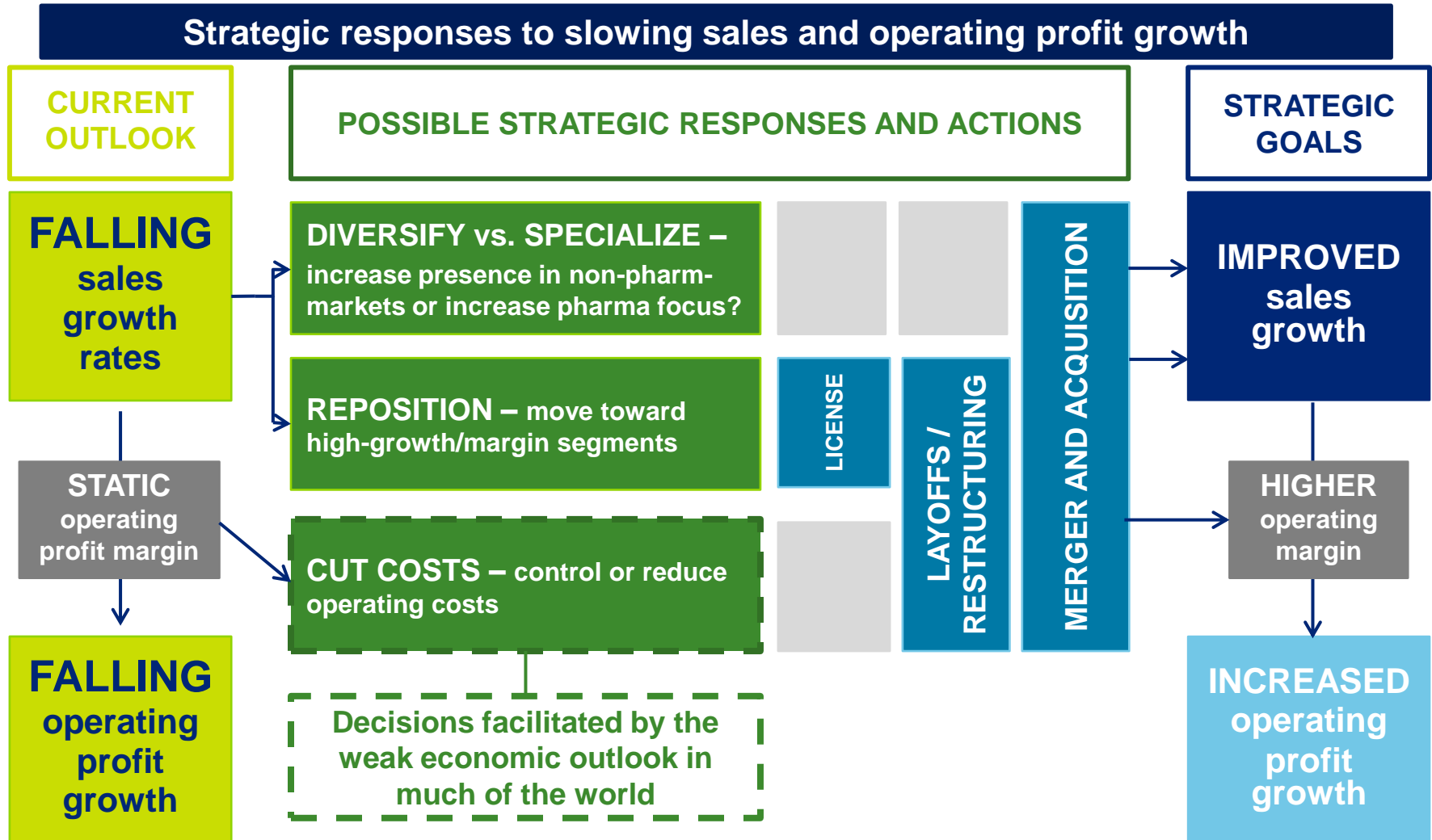
# Multiple drivers of risk



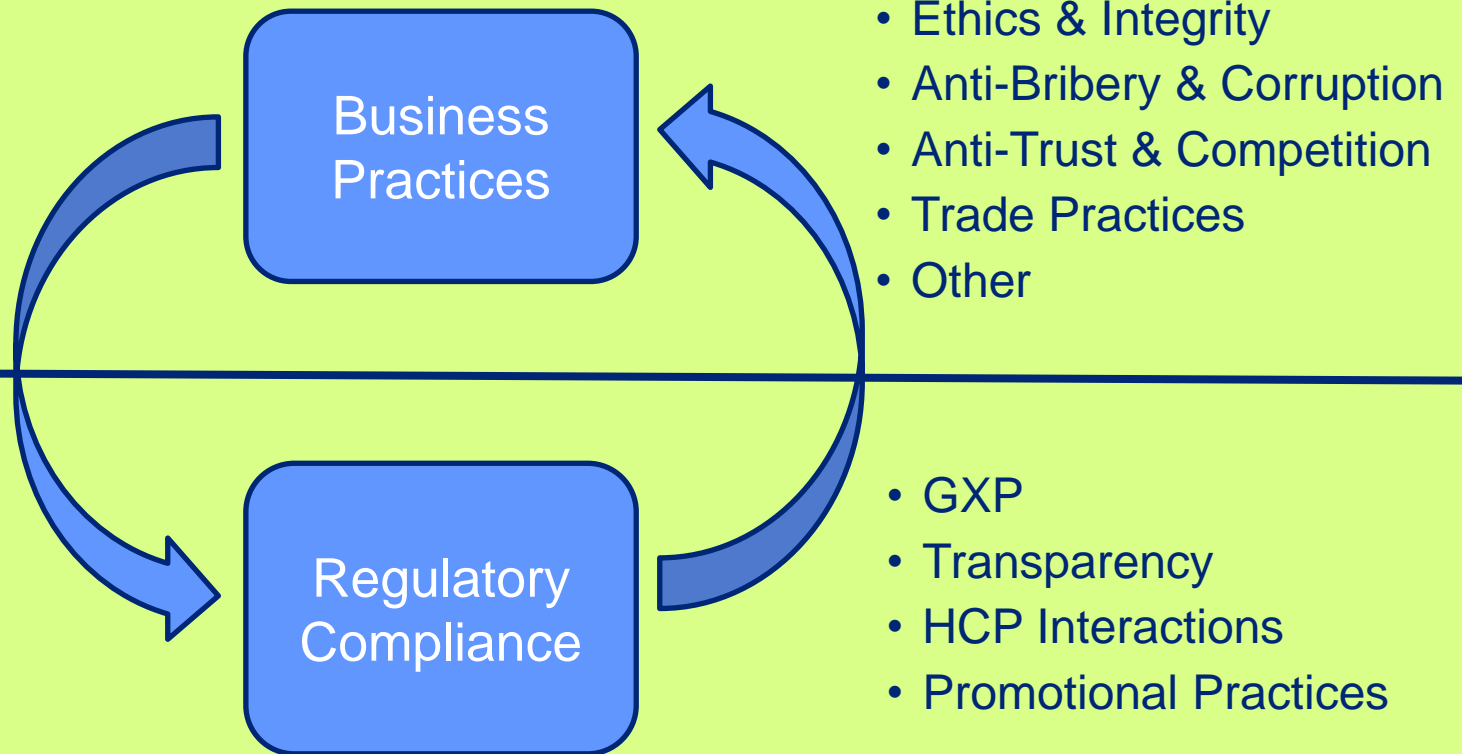
# Three factors impacting risks



# Structural industry change is well underway



# Industry regulation is complex and wide-ranging



# Illustrative list of regulators around the world

Type	Agencies and Organizations
<b>Drug Regulatory Agencies</b>	<ul style="list-style-type: none"><li>• Food and Drug Administration (FDA)</li><li>• Center for Drug Evaluations and Research (CDER)</li><li>• Center for Biologics Evaluation and Research (CBER)</li><li>• Center for Devices and Radiological Health (CDRH)</li><li>• European Medicines Agency (EMA)</li><li>• Japanese Ministry of Health, Labor and Welfare (JMHLW)</li><li>• China State Food and Drug Administration (SFDA)</li><li>• International Committee on Harmonization (ICH)</li></ul>
<b>Other Regulatory Agencies</b>	<ul style="list-style-type: none"><li>• US Securities and Exchange Commission (SEC)</li><li>• US Environmental Protection Agency (EPA)</li></ul>
<b>Government Organizations</b>	<ul style="list-style-type: none"><li>• Department of Health and Human Services (HHS)</li><li>• National Institutes of Health (NIH)</li><li>• Centers for Medicare and Medicaid Services (CMS)</li><li>• Centers for Disease Control (CDC)</li></ul>
<b>Oversight Boards</b>	<ul style="list-style-type: none"><li>• Financial Accounting Standards Board (FASB)</li><li>• Internal Revenue Service (IRS)</li><li>• Federal Trade Commission (FTC)</li><li>• Office of Inspector General (OIG)</li></ul>

# Some areas of focus

- **Commercial / sales practices**
  - Off-label promotion, labeling, interactions with physicians
  - Transparency
- **Anti-bribery and corruption**
  - Foreign Corrupt Practices Act – LS industry a focus
  - U.K. Anti-Bribery Act
- **Manufacturing quality**
  - Consumer as well as branded/generics
- **Emerging**
  - Medical devices
  - R&D
  - Social media
  - Comparative effectiveness



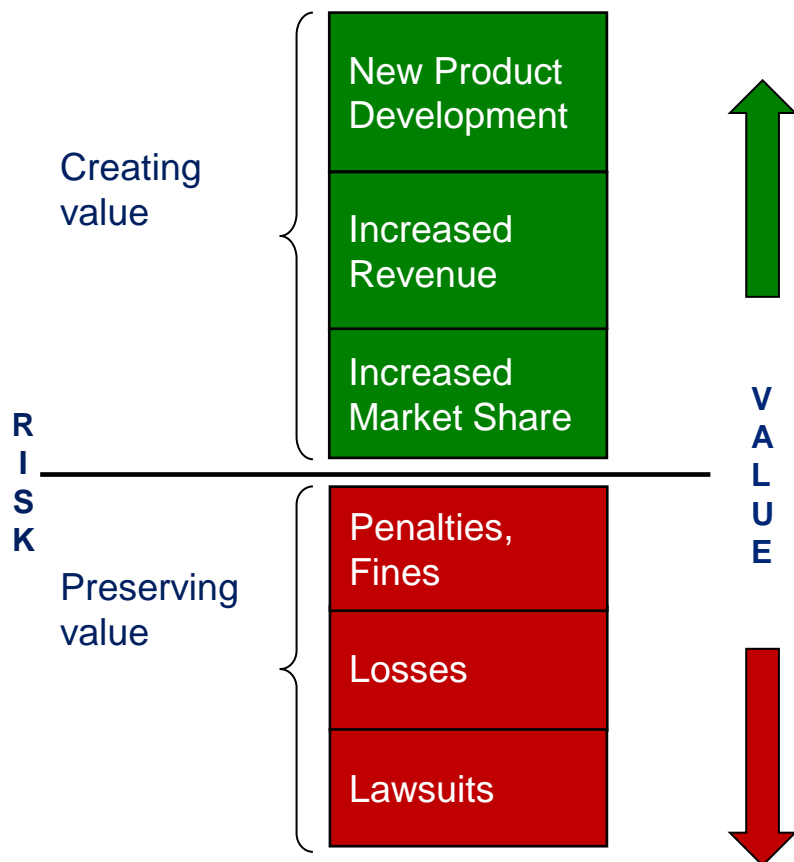
# New risk management/assurance models are needed

## Preserving value

- Board and executive accountability
- Fines and penalties
- Cost of risk management

## Creating value

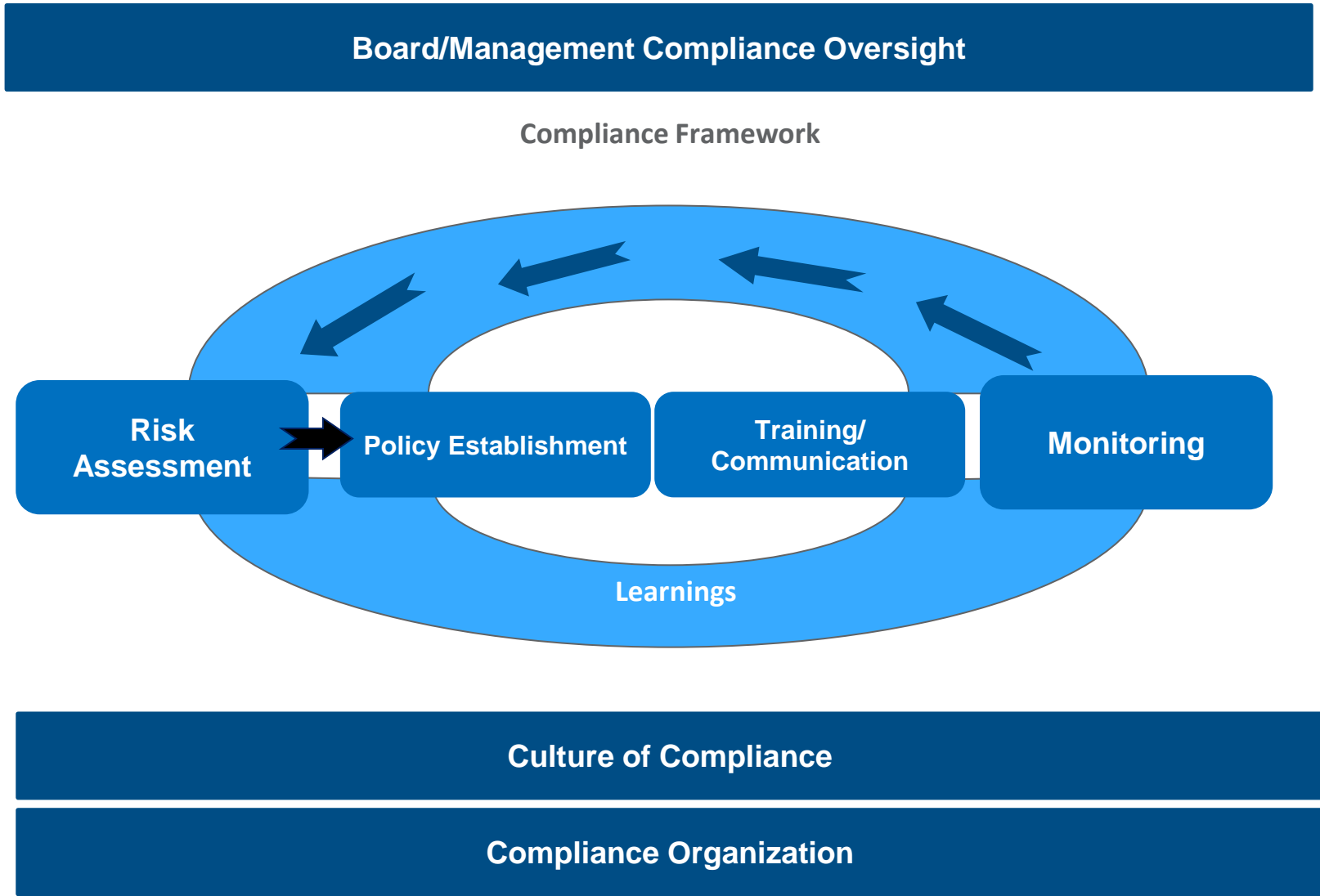
- Effective risk management/assurance provides a sound platform for growth
- Increased focus on timely and clear communications on how risks are being managed



## Regulatory landscape

- Global regulations are increasing in volume and complexity
- Increased focus on enforcement in some markets
- Increasing sophistication of regulatory agencies in emerging markets

# Risk-based compliance continuum



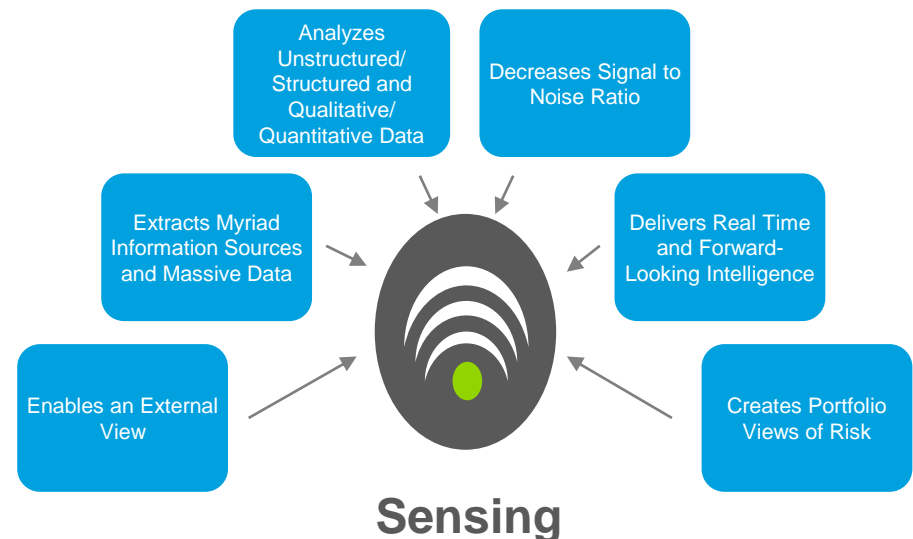
# Risk sensing

**Risk Sensing** is the capability to extend and enhance forward and peripheral vision

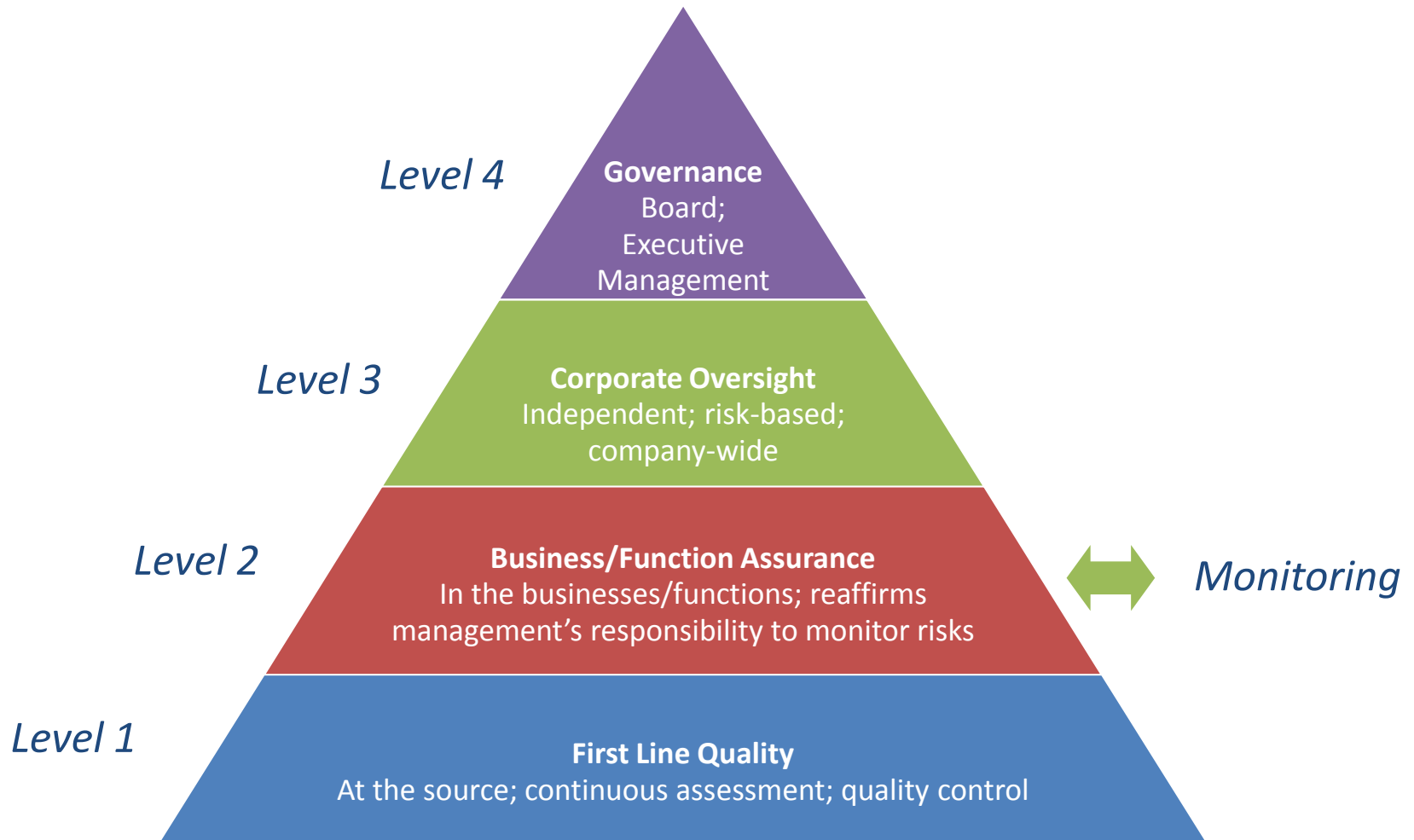
- Traditional Risk Management programs can be reactive, slow, and, due to the persistent problem of “information overload”, some important data may not be tapped
- Few organizations are equipped to detect and understand how new and unforeseen risks are emerging
- Today, organizations have access to larger varieties of information in higher volumes, communicated at higher velocities than ever before

## One Approach is *Risk Sensing*:

- Allows businesses to **identify and act on emerging risks**
- **Provides forward-looking insights** into risks by continuously scanning and analyzing a wide array of structured and unstructured information
- Enables **prioritization across a portfolio of risks** with the ability to drill down into risks, risk indicators, and data sources
- Monitors and assesses **continuously evolving risks and opportunities**
- Collects and analyzes key stakeholder inputs to **inform and validate** leadership’s view of risk

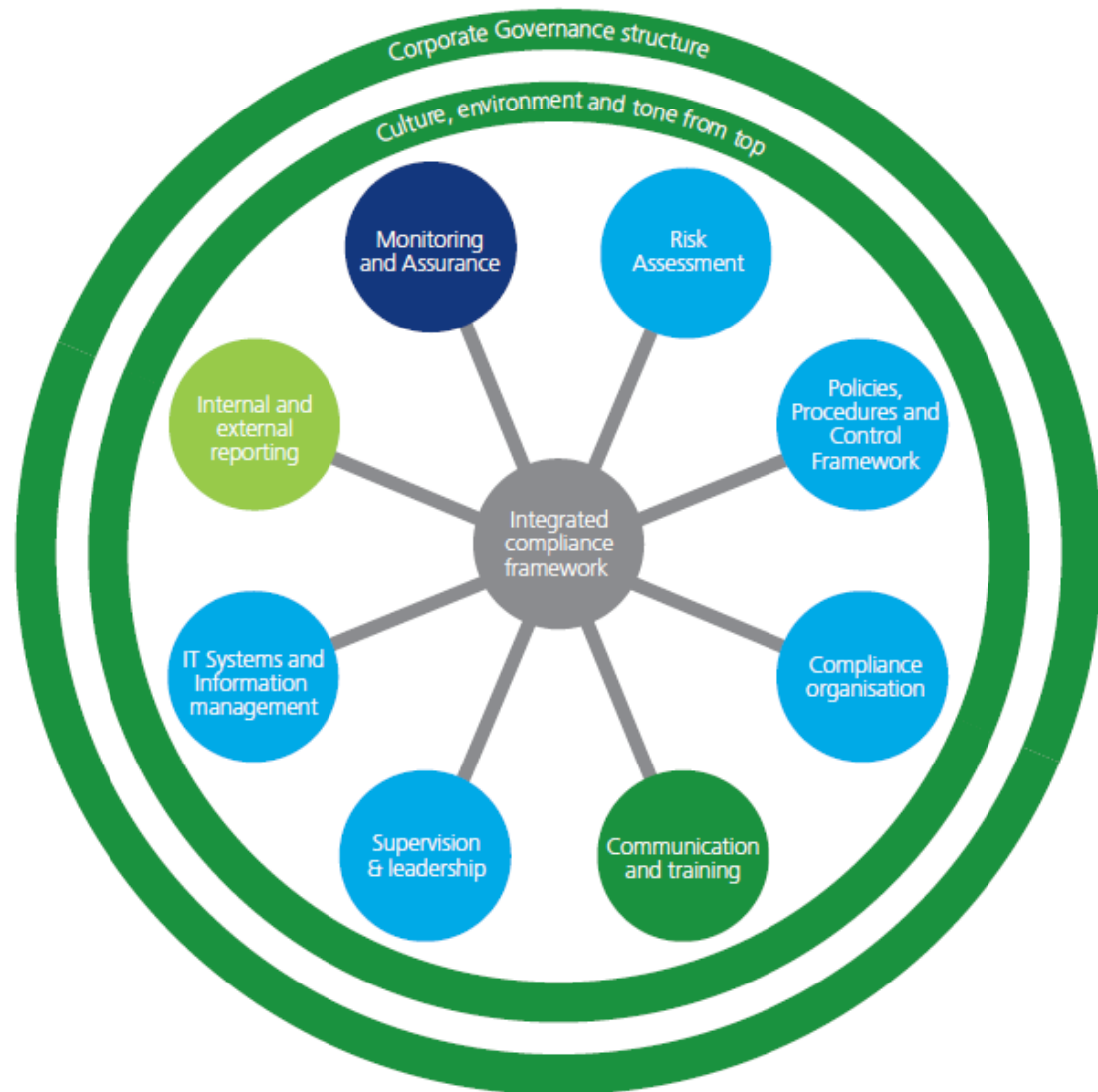


# Integrated assurance model



# Leading Practice Compliance Framework and Elements

1. A clear **articulation of the organization's requirements** (policies, procedures, requirements)
2. A **risk-based** approach (doing the right things well – not everything!)
3. A **clear line of sight** on accountabilities and responsibilities
4. An alignment between **performance objectives** and governance objectives
5. The framework for **assuring compliance**



# Key takeaways

- **Adopt a culture of compliance**
- **Take a fresh look at monitoring**
- **Treat third party distributors as an integral part of your supply chain**
- **Understand and benchmark your “cost of compliance”**
- **Help set the regulatory agenda**



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