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# OPERATIONAL RISK & REGULATORY CHANGE MANAGEMENT

# Speaker: Ed Sattar

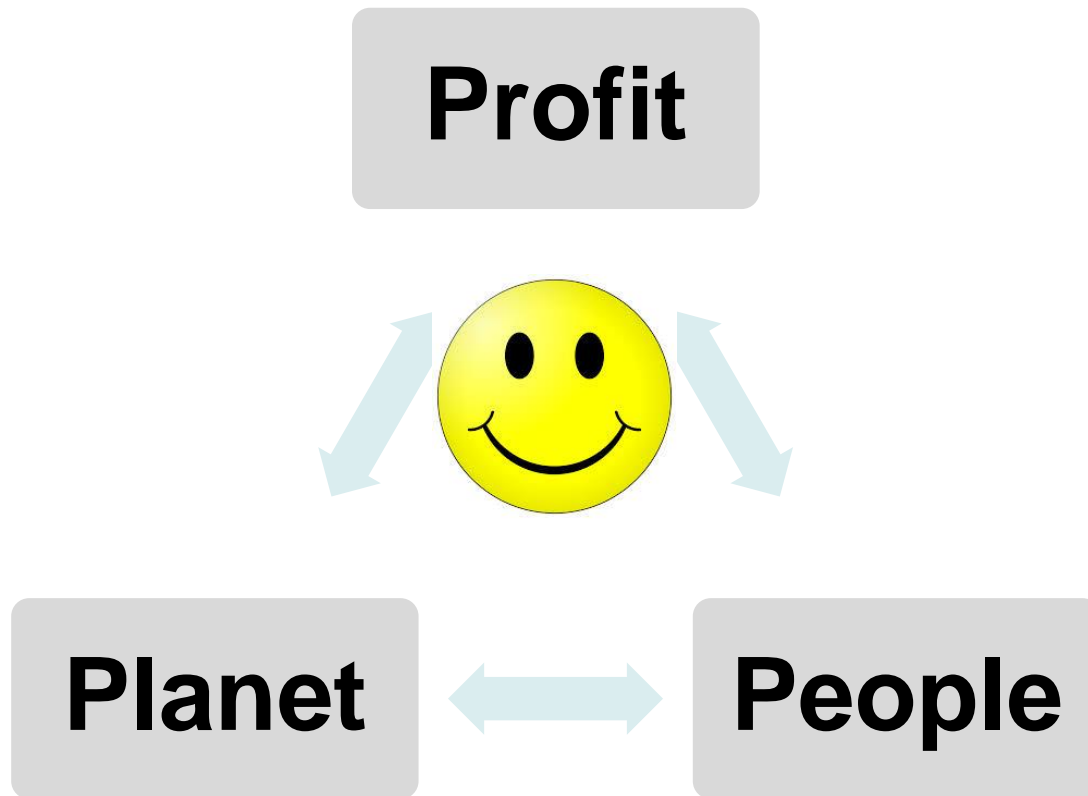


Ed Sattar is the CEO of 360training and founder of 360factors, an operational risk and compliance management software company. For more than a decade, Ed has made significant professional contributions to the regulatory compliance space across multiple industries. His experiences include extensive research and consulting for regulatory compliance consulting firms and training providers as well as state and federal regulatory agencies. During his tenure in the risk and regulatory compliance workflow automation and eTraining space, he has identified key criteria and compliance standards that are currently being published and implemented.

Ed Sattar has been nominated for the Ernst & Young Entrepreneur of the Year award three times and was among the top seven finalists in 2009. He has appeared on the Deloitte Fast 50 as the leader of the 6th fastest growing company in Texas and got the companies listed in Inc 5000 several times as one of the fastest growing companies under his leadership.

Ed studied Electrical Engineering and Finance at the University of Texas at Austin.

# Effective Operational Risk Management & Three P's





# Outline



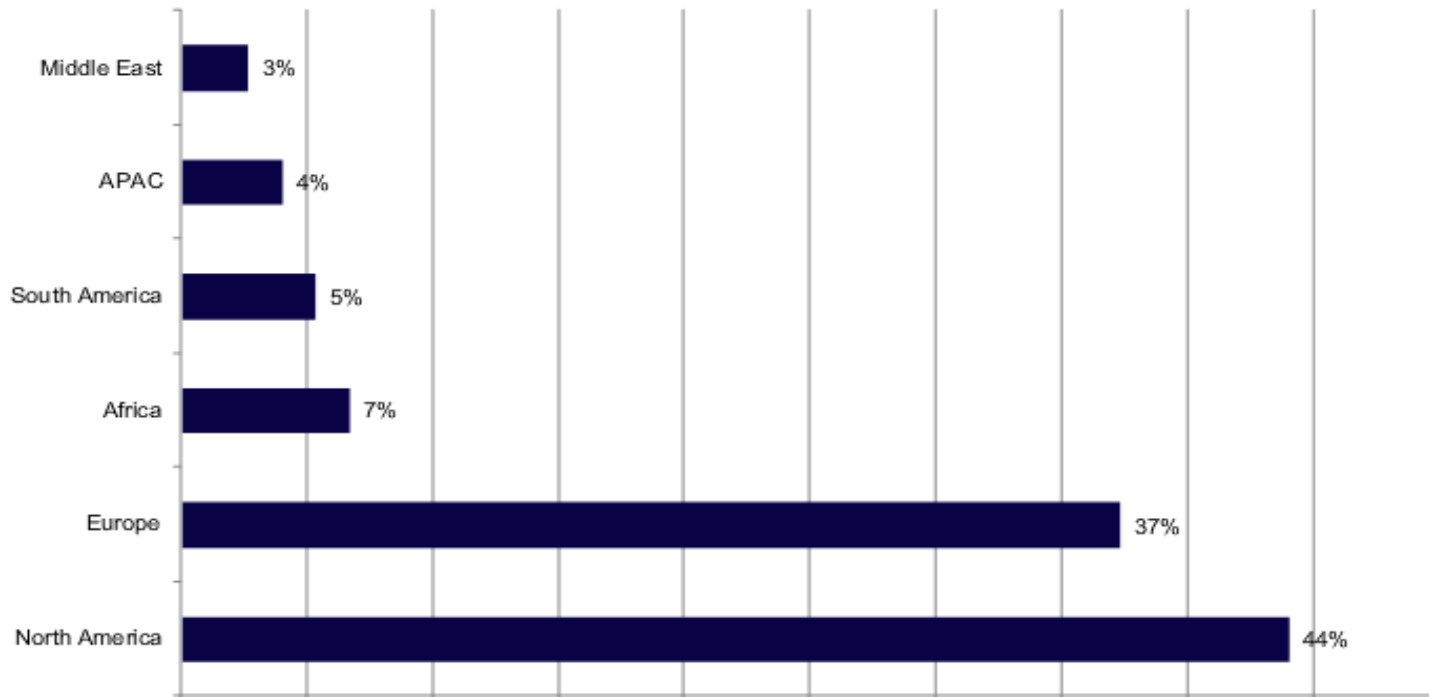
- Operational Risk & Regulatory Trends
- Why Automate an Operational Risk and Regulatory Change Management System
- Operational Risk and Compliance Management Model & Methodology
- How to Implement an Operational Risk and Compliance Management System
- Can Automation and Software Increase Operational Excellence and Reduce Risk & Cost?



# Operational Risk & Regulatory Trends

# Rising Regulations and Cost

## Location of organization



# Regulatory Change is Significantly Impacting Operational Risk

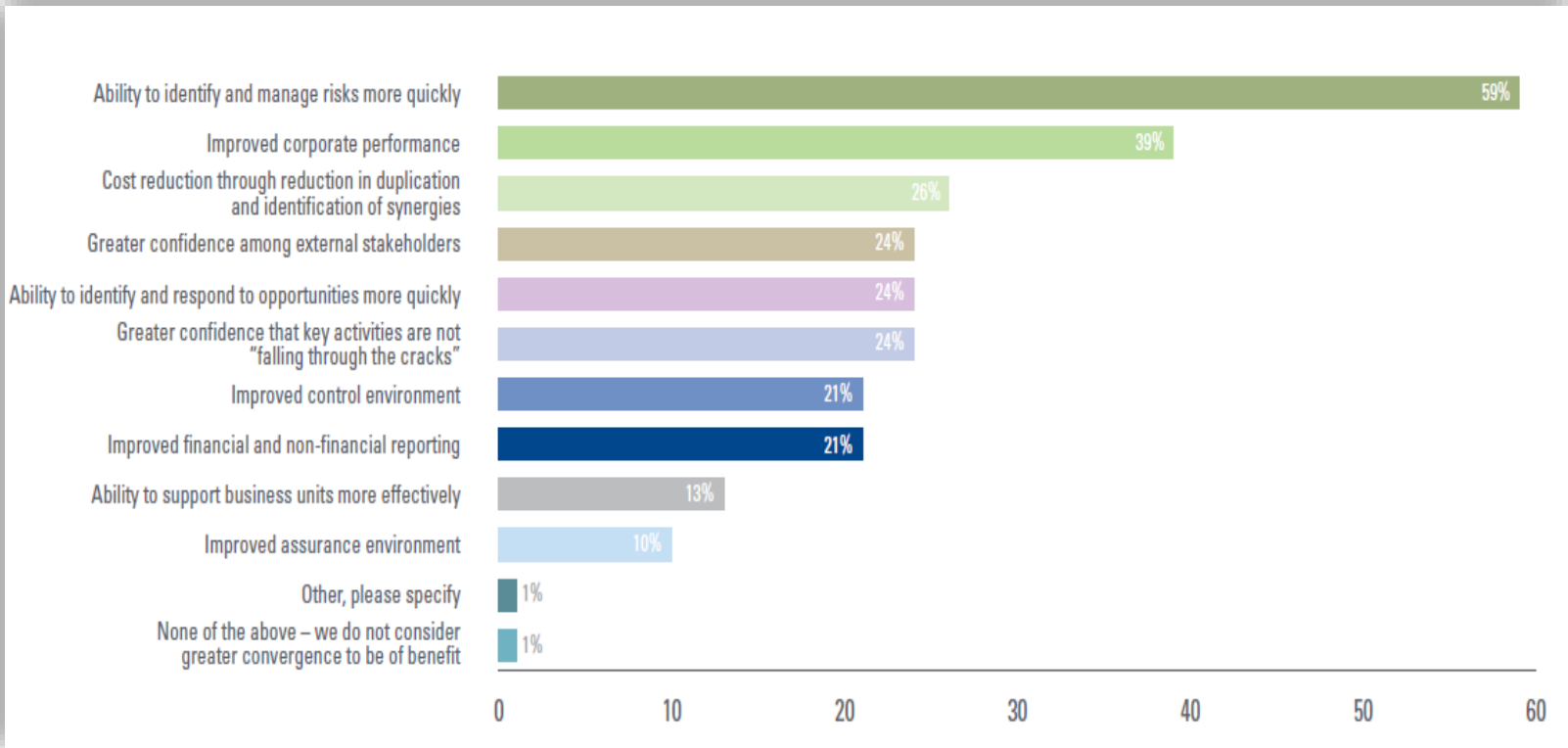




# Automate Regulatory Compliance Through Software



## BENEFITS OF AN INTEGRATED MANAGEMENT SYSTEM



# Operational risk Trends

Top Operational Risk Trends	
Changes in Legislation and Regulations	27 %
Business Interruption (safety, environment, disruption, supply chain)	33%
Loss of Reputation & Brand	30%
Cyber Security	10%

Source: Davis, Alliance Global Corporate

# Managing Your Operations Seamlessly While Reducing Risk

# Why Automate an Operational Risk & Regulatory Change Management System

# Four Reasons to Automate Operational Risk & Regulatory Change Management



1. Regulatory and Asset Intensive Organization
2. Understanding Regulations- Either Over Complying or Under Complying
3. Lack of Automation in Streamlining Day-to-Day Compliance, Event and Incident Management with Respect to Regulatory Change Management
4. Ability to React Quickly- Tracking and Monitoring Non-Compliance Items Such as Events, Incidents, Audits & Investigations

# Reasons to Automate Operational Risk & Regulatory Change Management



## Other Industry Pain Points

- Understanding Regulations
- Regulatory Change Management
- Regulatory Applicability
- Day-to-Day Compliance Tasking
- Event-Driven Compliance Tasking
- Incident Management and Root Cause Analysis
- Predictive Risk Analysis
- Corrective and Preventive Actions
- Policy and Procedure Management
- Audit Management
- Sustainability
- Training Management
- Multiple Tools to address Reg Compliance



# Operational Risk and Compliance Management Model

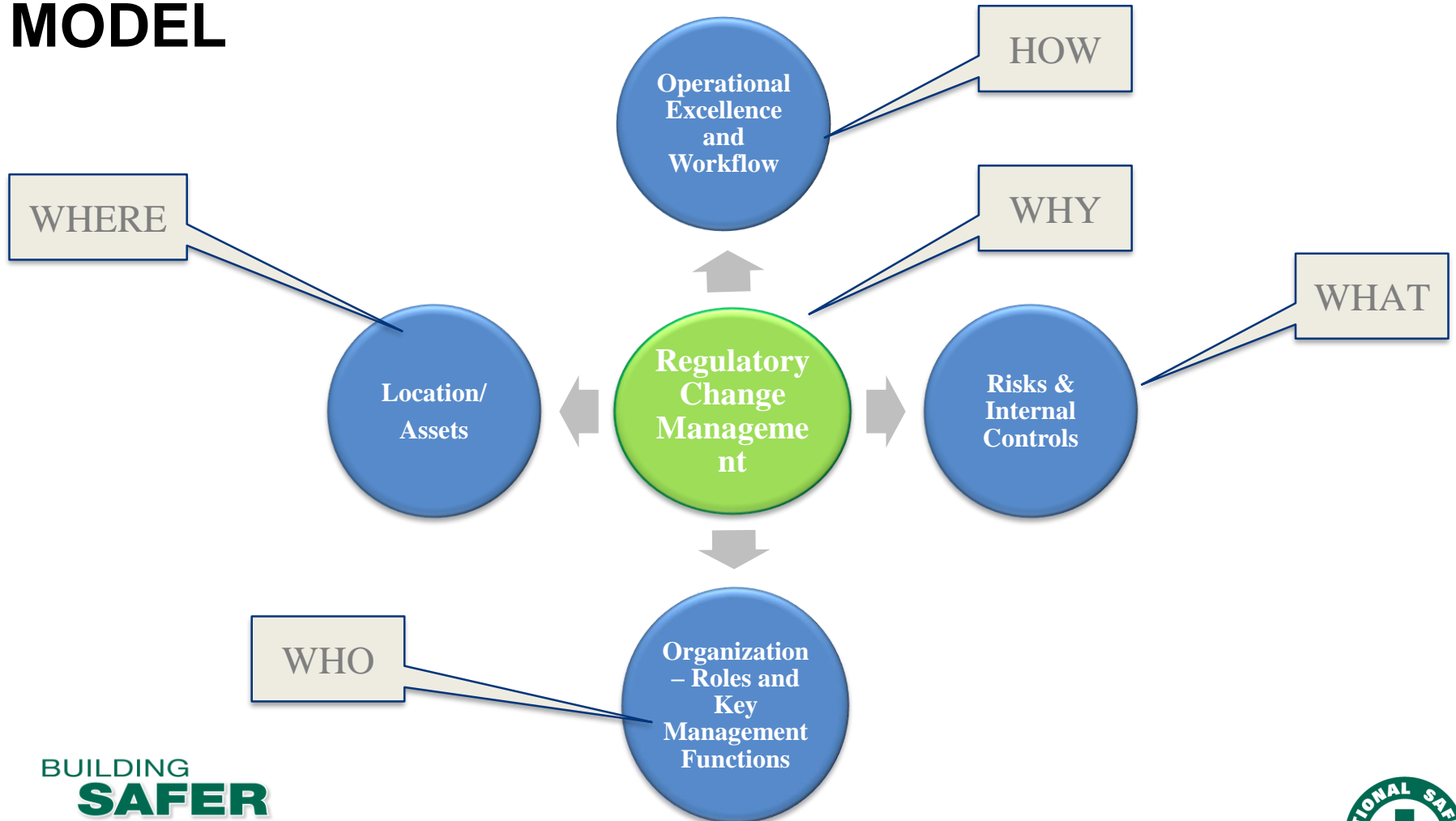
# Operational Risk and Compliance Management Model – Five Steps



1. WHY = Regulatory change management
2. WHAT = Risk and internal controls
3. HOW = Operational excellence and processes
4. WHERE = Location / assets
5. WHO = Defining & mapping roles / key management functions to metrics & P&L



# OPERATIONAL RISK & COMPLIANCE MANAGEMENT MODEL



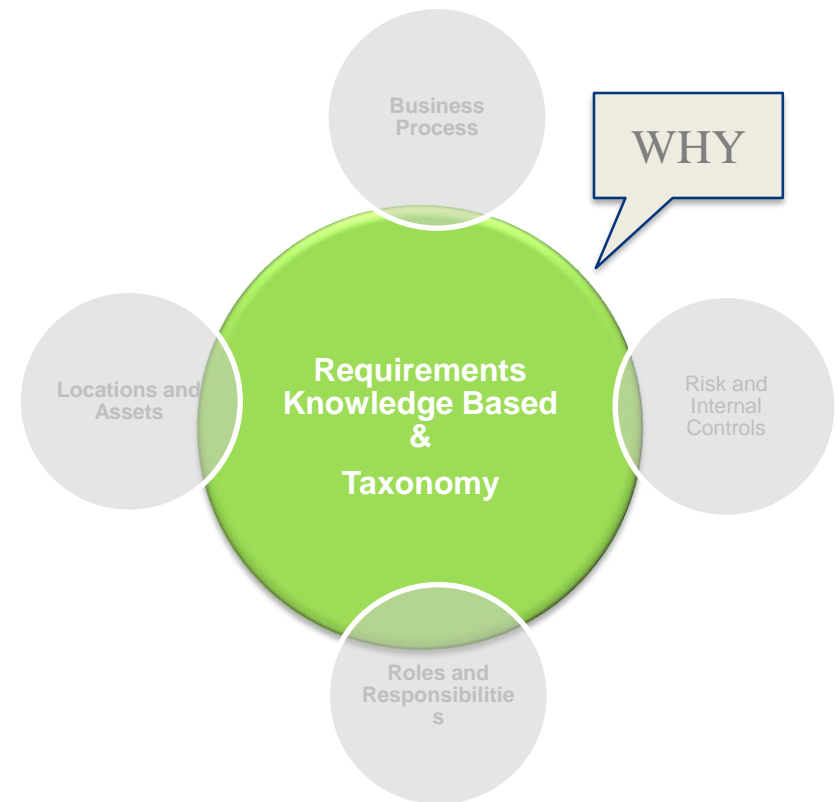


# How to Implement an Operational Risk and Compliance Management System

# Step 1- Requirements Knowledge Base & Taxonomy

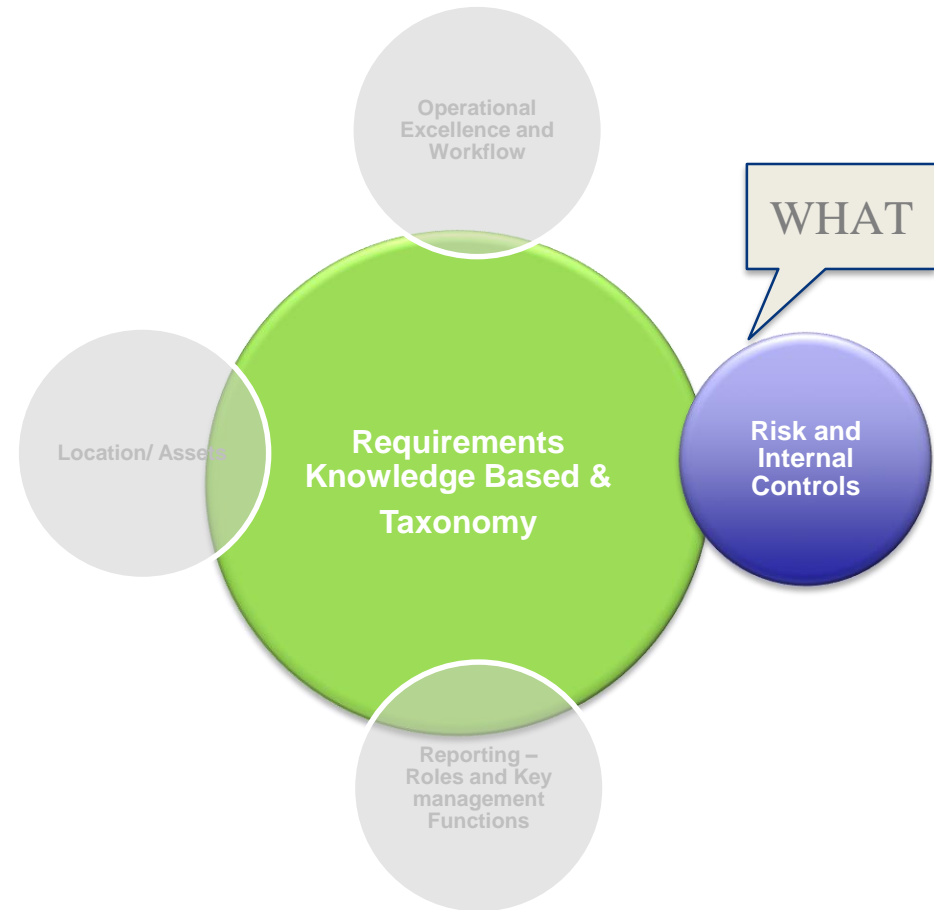
## COMPONENTS OF REQUIREMENTS KNOWLEDGE BASE

1. Library - Regulations, standards, requirements and objectives
2. Translate regulatory requirements into action, evidence, subject, and frequency
3. Monitor regulatory change
4. Regulations in effect to proposed
5. Mapping- regulatory requirements mapped to CAPA , policy procedures and evidence, risks and audits
6. Regulation applicability

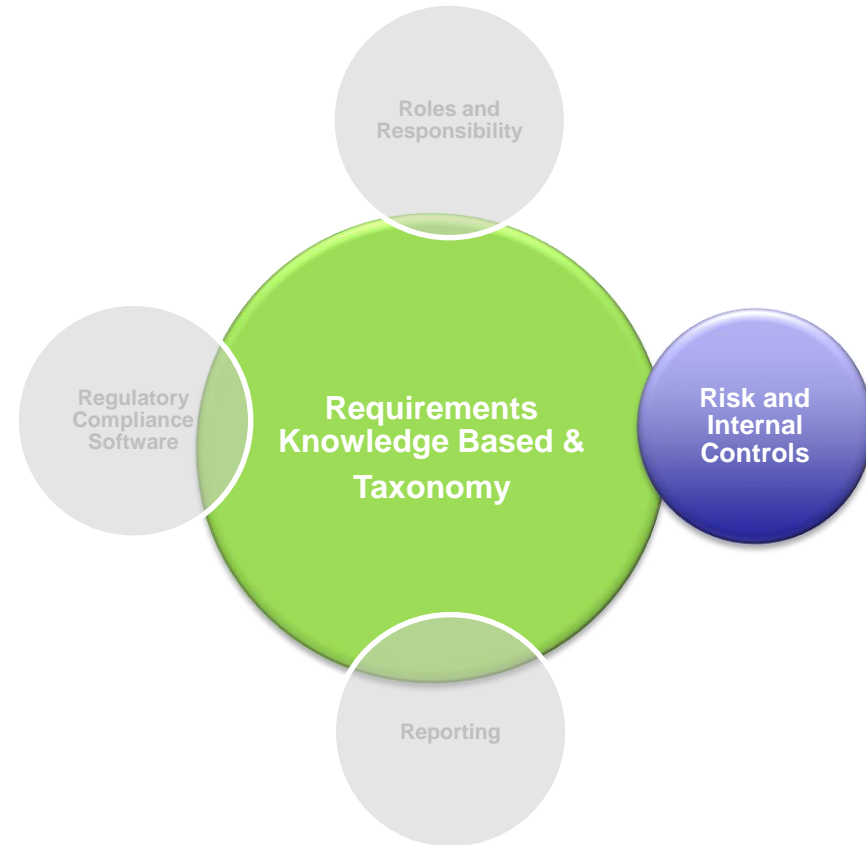
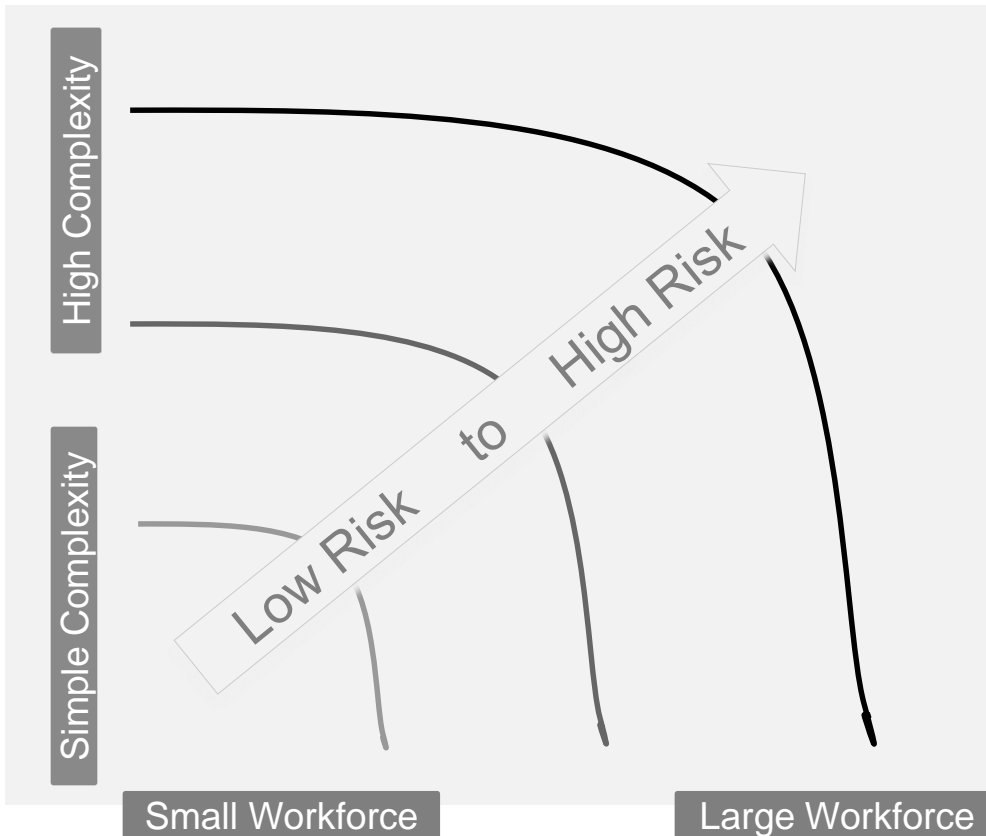


# Step 2- Risk & Internal Controls

1. What is impacted?
  - ✓ Environmental Risk
  - ✓ Financial Risk
  - ✓ Legal Risk
  - ✓ Reputational Risk
  - ✓ Operational Risk
2. Define risk levels
  - ✓ Which details are impacting factors?
  - ✓ Is it based on a systematic process allowing the organization to prioritize more efficiently?
  - ✓ Effectively assesses issues requiring immediate action.
3. Define internal controls
  - ✓ Process
  - ✓ Procedures
  - ✓ Risk Assessments
  - ✓ Tasks
  - ✓ Training

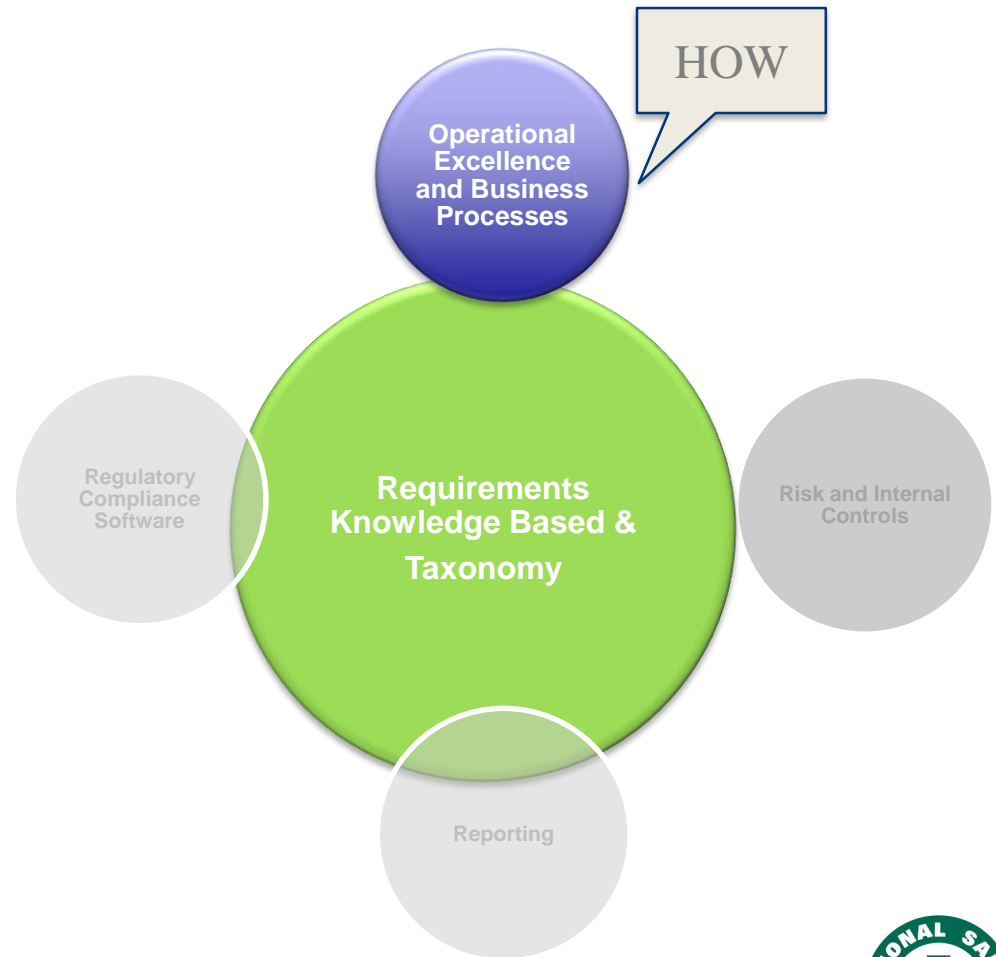


# Step 2- Risk & Internal Controls



# Step 3- Business Processes

1. How
2. Compliance routines process around sites, assets, and events into a coherent system
3. System enabled reports
4. Manual vs. automation analysis



# Step 3- Business Processes

## PROCESSES THAT CAN BE AUTOMATED

Corrective Action to Increase Speed,  
Eliminate Waste and Cut Costs

Scheduling, Tasking and Tracking

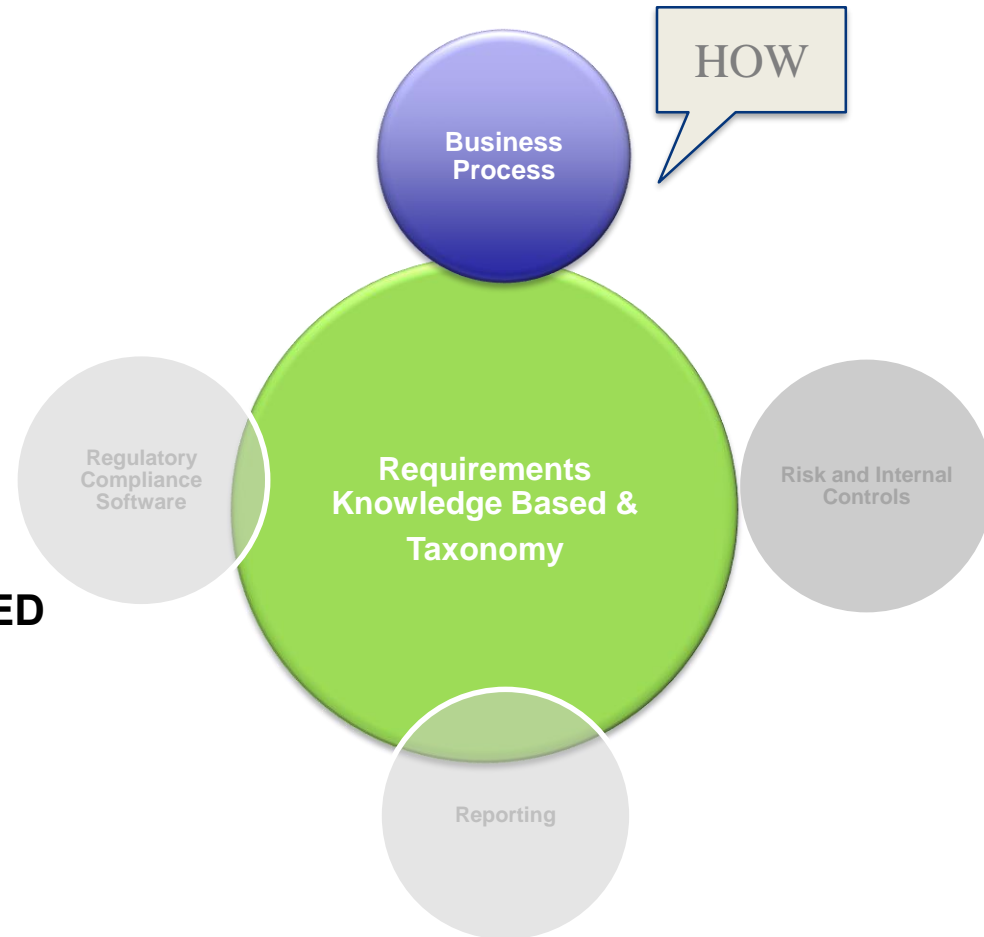
Embed Transparency and Accountability

Management of Change

## PROCESSES THAT CAN'T BE AUTOMATED

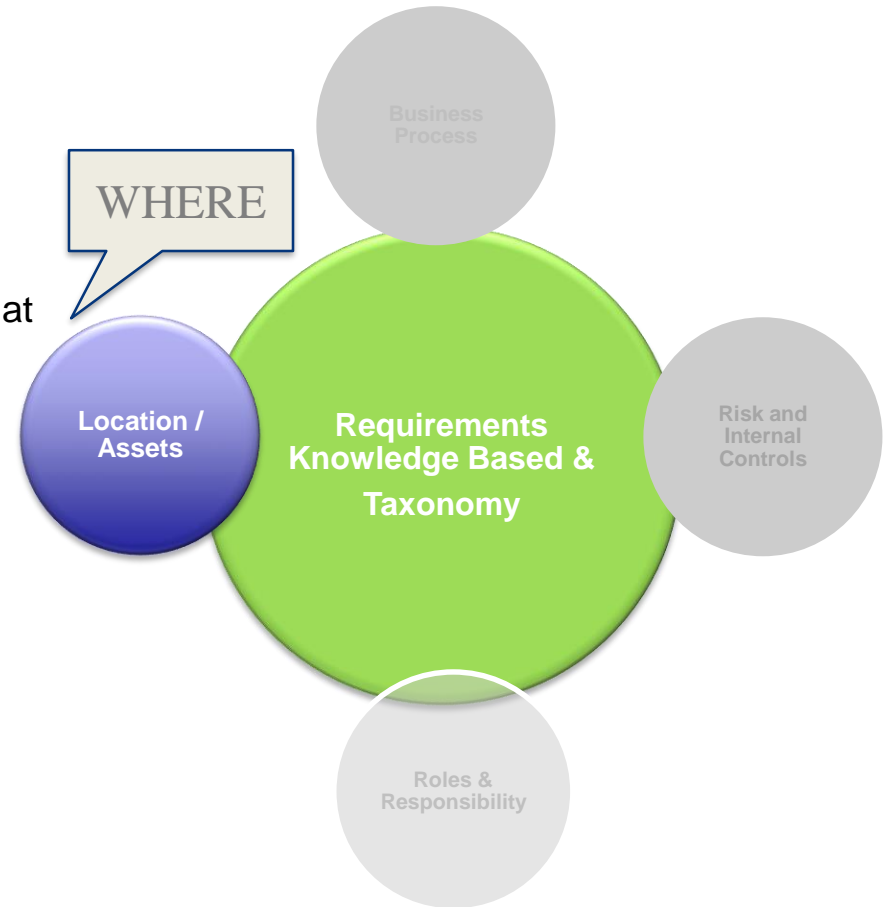
Translation of Requirements

Subject Matter Expertise



# Step 4. Location & Assets

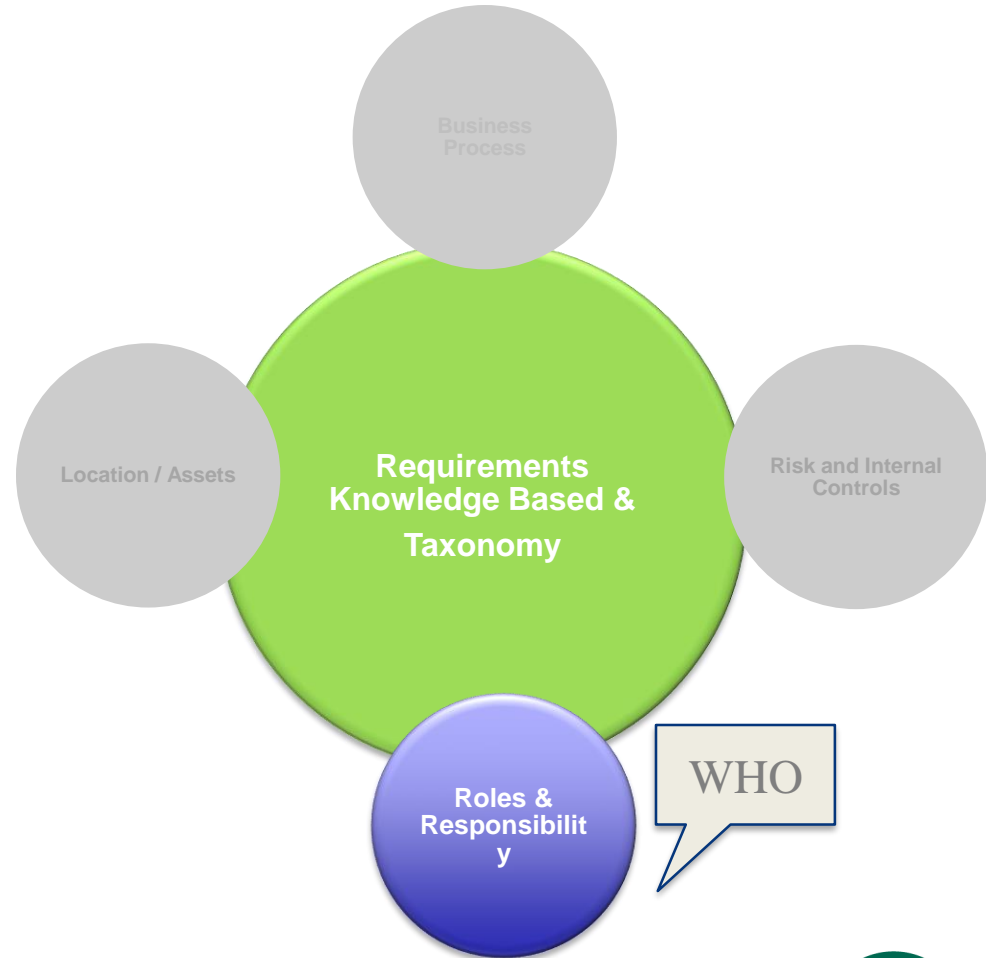
1. Where is compliance done.
2. Compliance done at the site and asset level
3. Ability to determine which regulations are applicable at a location/site





# Step 5. Roles & Responsibility

1. EHS Regulatory Compliance Governance Structure - Clarify roles, responsibilities and functions
- 2 Clarify resource capabilities and escalation procedures, as well as the information and reporting systems.
3. This last step ties in all four steps of the model.
4. Is there a specific role and responsibility structure or can it vary by organization and industry?



# Step 5. Roles & Responsibility

## COMPONENTS OF ROLES AND RESPONSIBILITIES

### 1. Key Roles and Structure

Example- EHS Mgrs, Owners

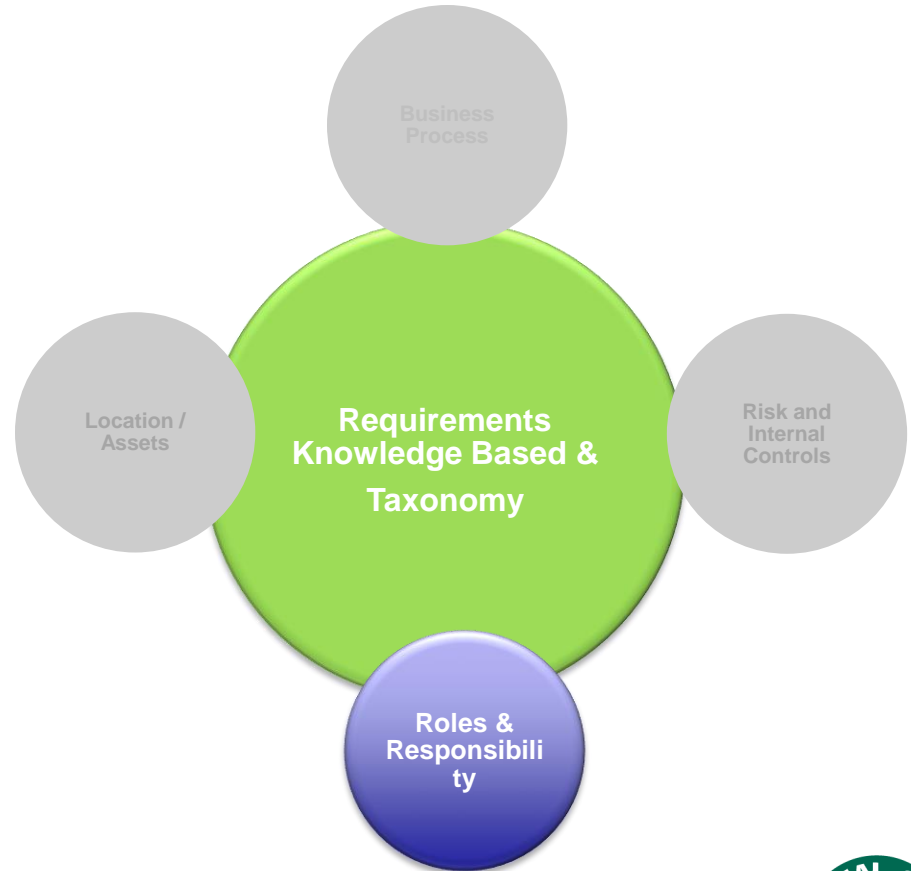
### 2. Key Functions

Example- EHS, OSHA, NERC compliance

### 3. Key Actions

Example: Compliance, Quality, Sustainability

### 4. Outcome / Results



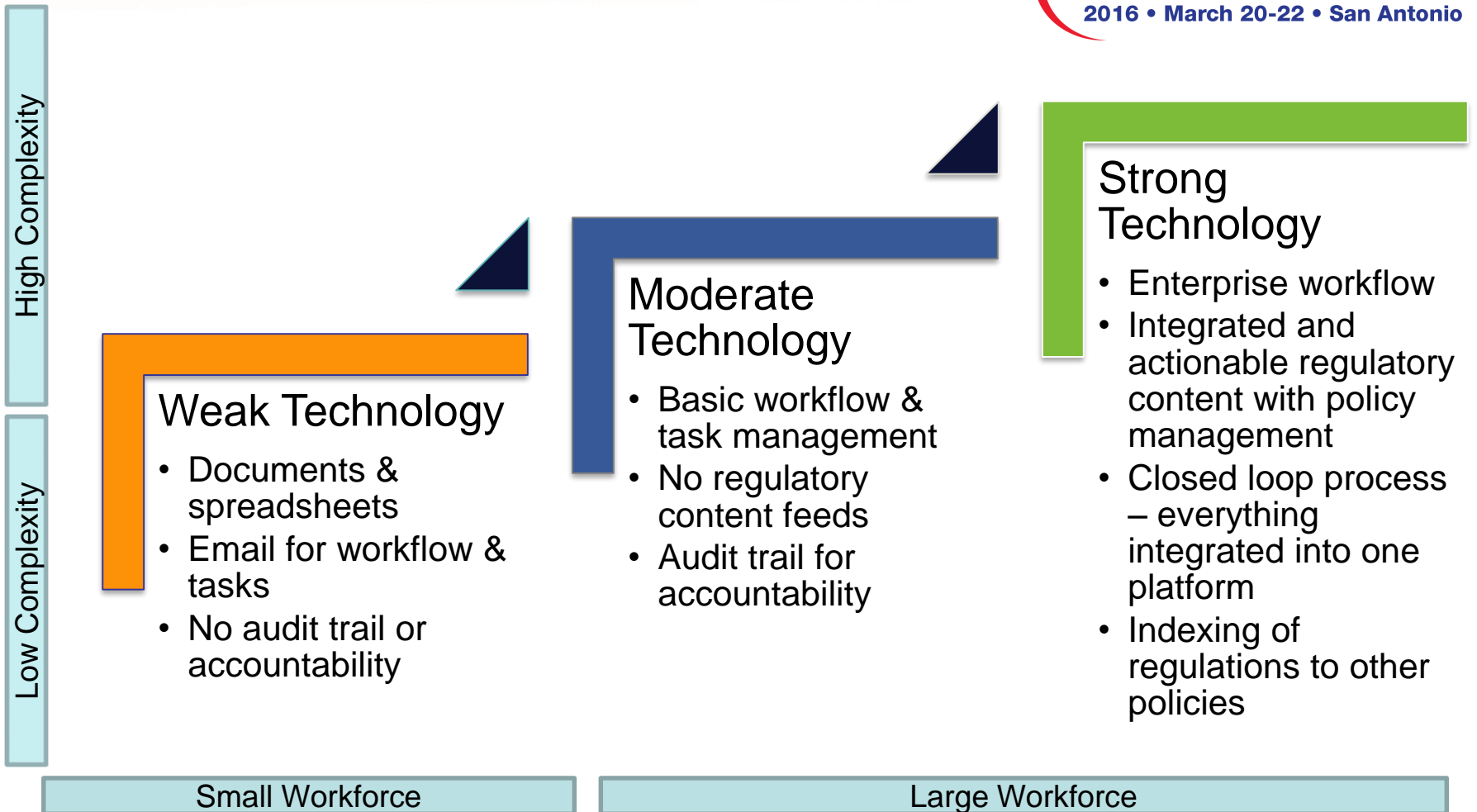
# Can Automation and Software Increase Operational Excellence and Reduce Risks and Overall Cost?

# Automate Regulatory Compliance Through Software

1. Is technology perceived as a catalyst for growth and performance?
2. Are people or technology barriers to Regulatory Compliance Automation?



# Step 2 - Risk & Internal Controls



# Predict360 REGULATORY COMPLIANCE ARCHITECTURE



# People, Planet and Profit



Pharrell Williams - Happy (Official Music Video)

# RECAP



1. **Regulations are growing at an increasing rate, causing the cost to go up**
2. **Enterprise risk and regulatory change management model**
3. **This model drives operational excellence across all functional departments**
4. **Complex vs. non-complex organization – risk increases**
5. **Automation and technology drives operational excellence**
6. **Profit, people and planet are happy**





# Q & A