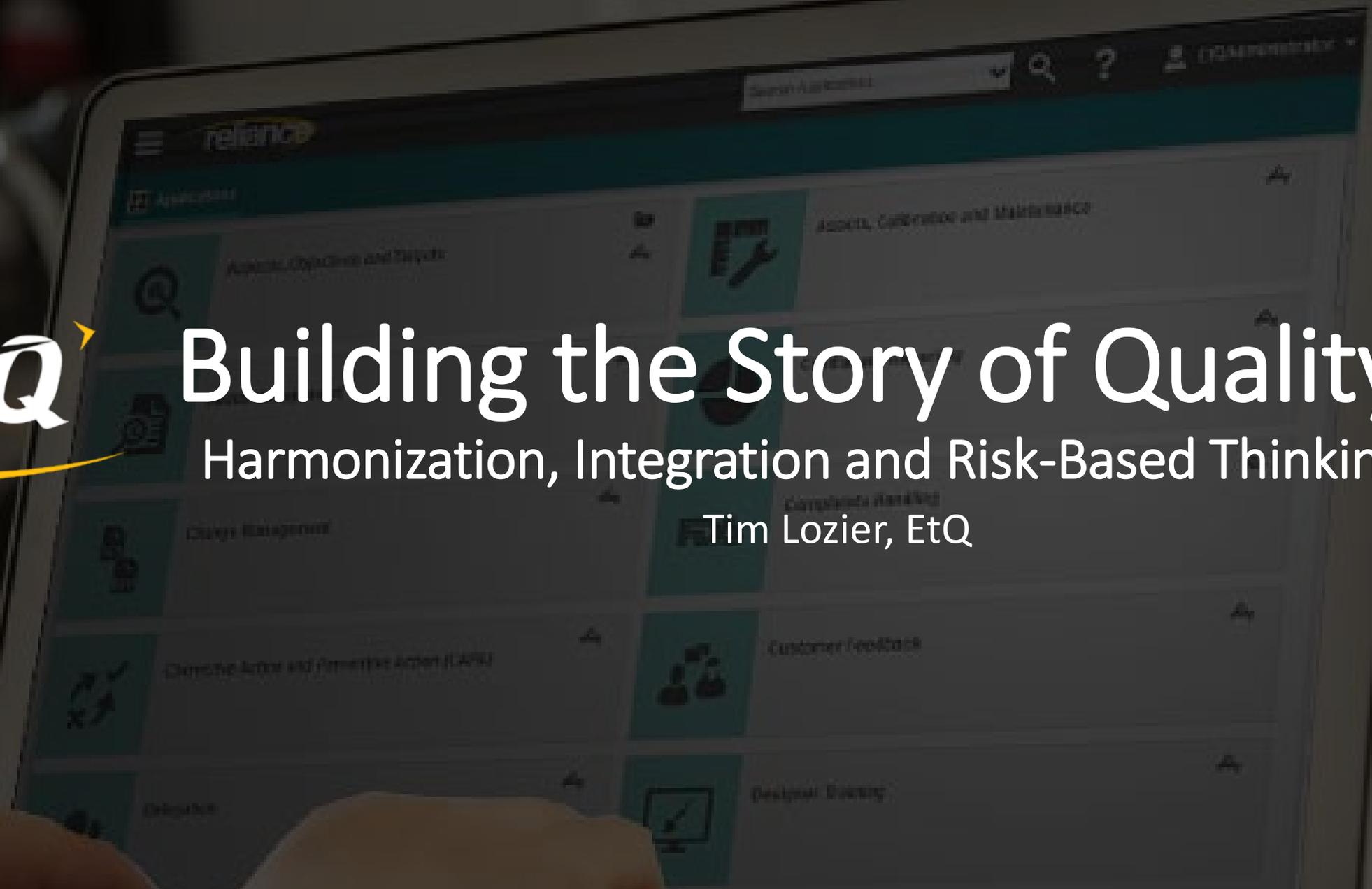




Building the Story of Quality:

Harmonization, Integration and Risk-Based Thinking

Tim Lozier, EtQ

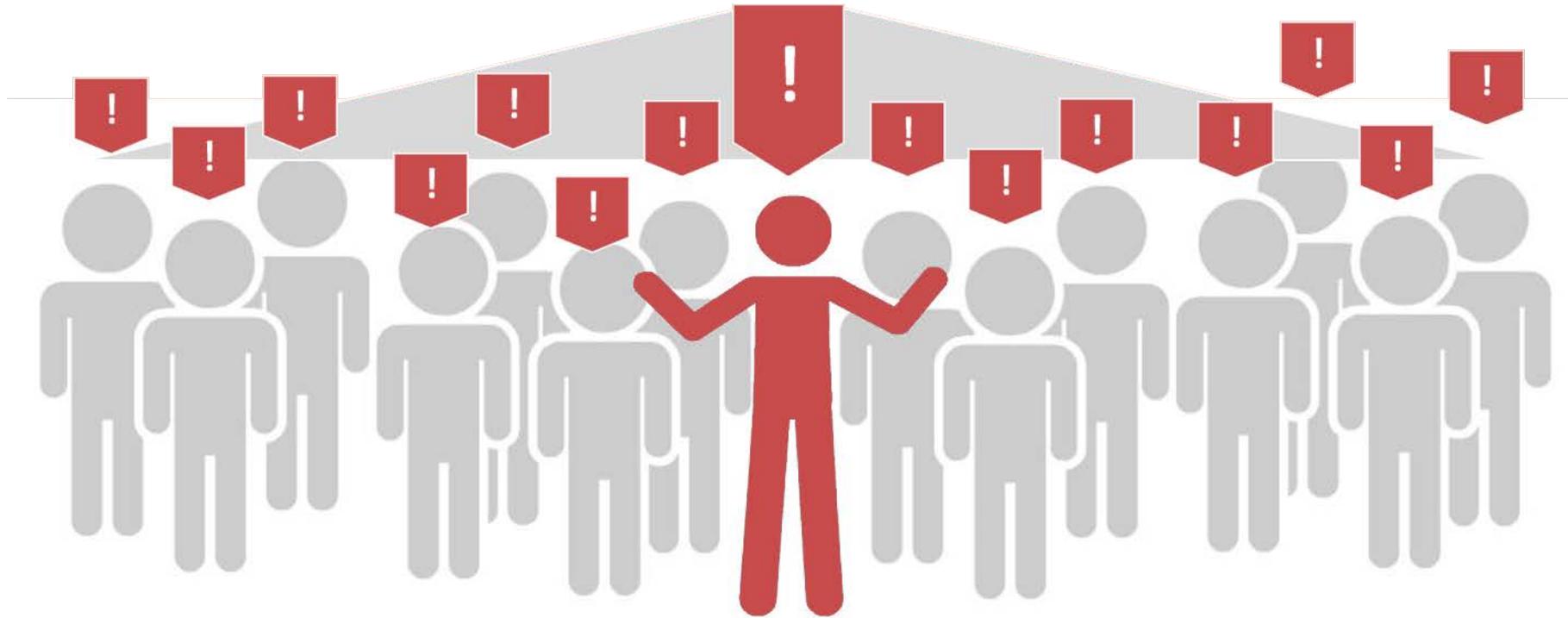


Agenda

- Understanding the dynamic of the Quality mindset today
- What are the challenges around enrolling more people into the Quality Story?
- Key areas that can lead to a seamless story of Quality:
 - Harmonization of Processes across the company
 - Integration of Systems to Quality
 - Leverage Risk-Based Thinking to Level the Playing Field

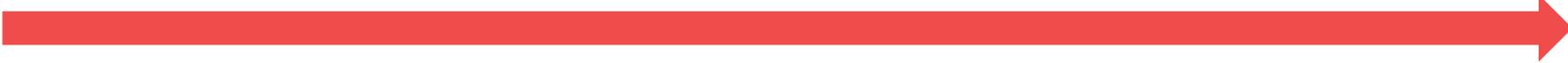
It's Not Just Requirements

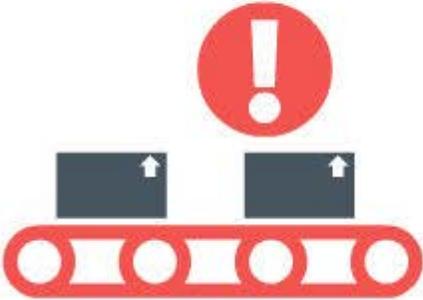
It's a company mindshare of Quality.



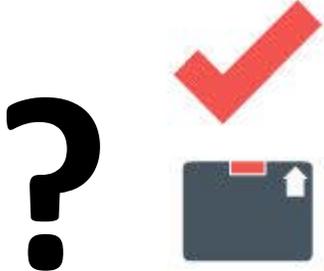
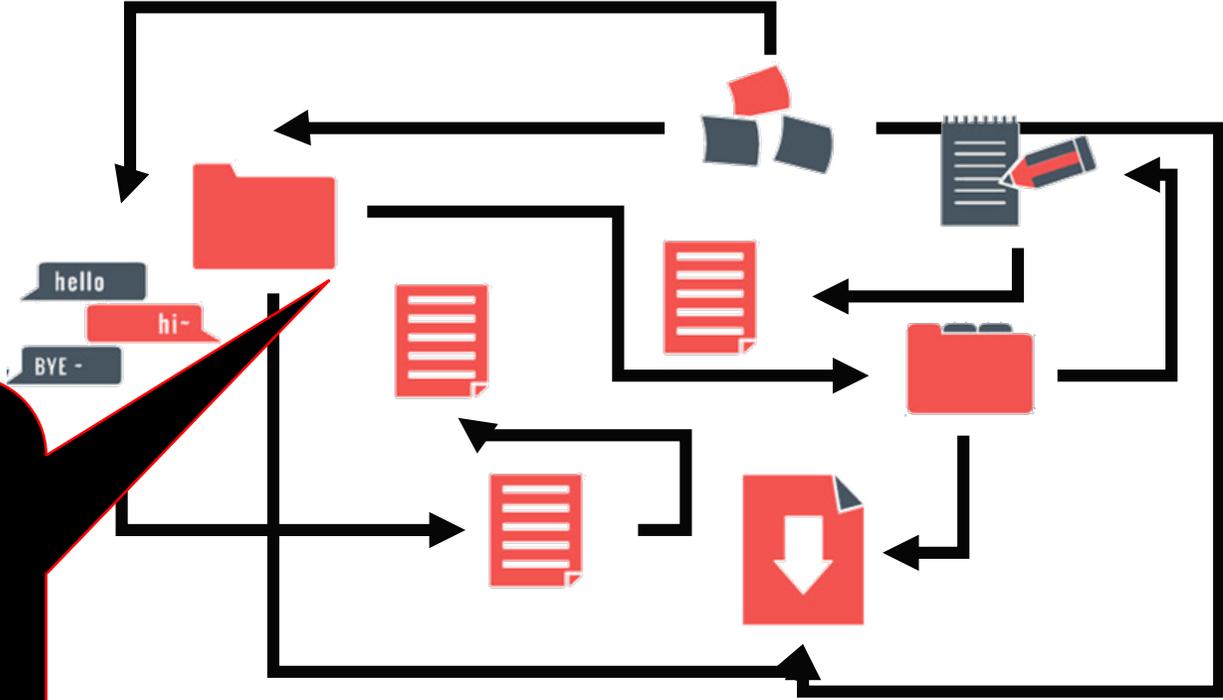
There should be a company-wide commitment/leadership around Quality

Are we making it too hard on ourselves when tracking Quality?

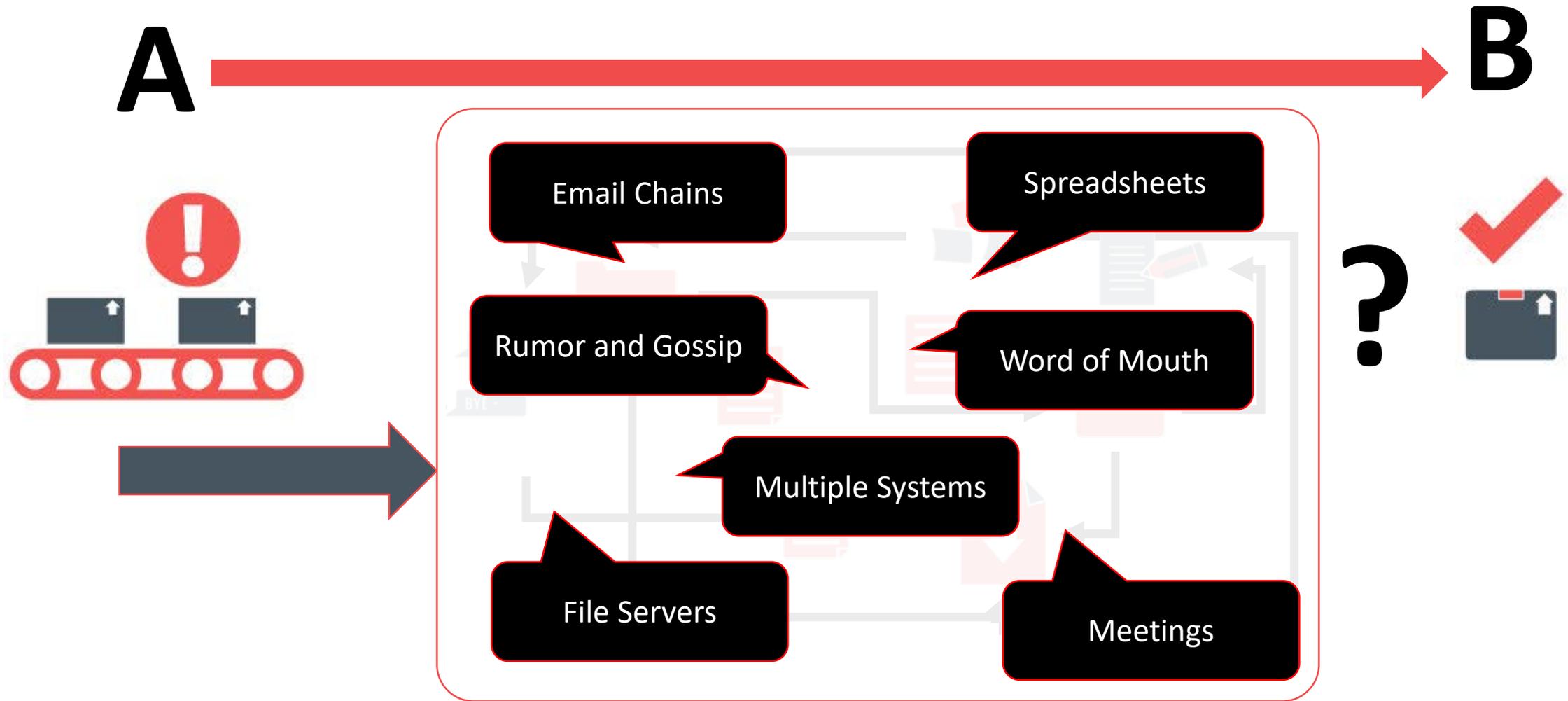
A  **B**



We consume about
34GB of
information a
day



Challenge: The Story of Quality can be disparate!



Central, Story of Quality.



Culture of Continuous Improvement

Harmonization

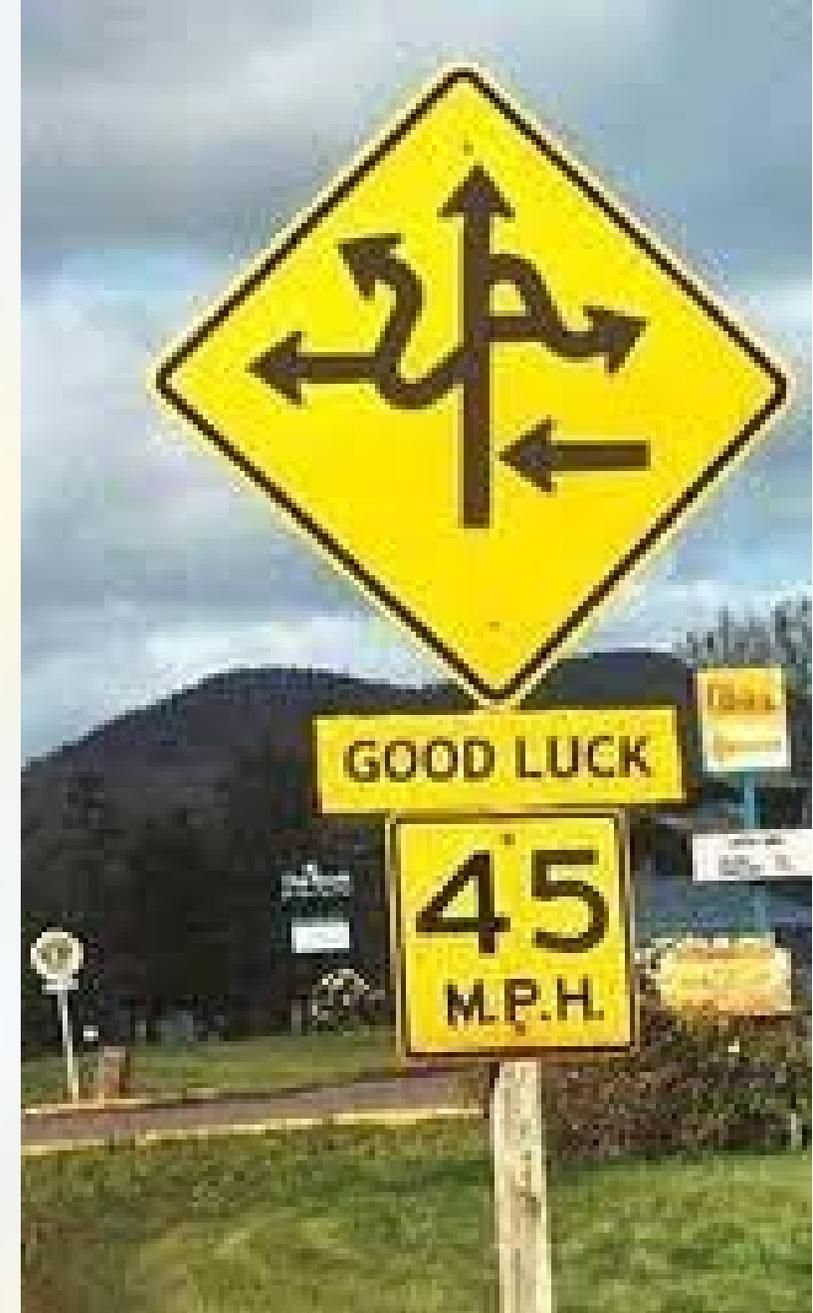
Integration

Risk-Based Thinking



The Need to Harmonize Affects Efficiency

- Constant Pressure to Diverge
 - Globalization introduces local differences
 - Product variety introduces technical differences
 - Mergers and acquisitions introduce cultural differences
- Drives Specialization of Business Systems
 - Customized or home-grown solutions
 - “Not invented here” syndrome
 - Political resistance to change from business and IT





The Road to Harmonize

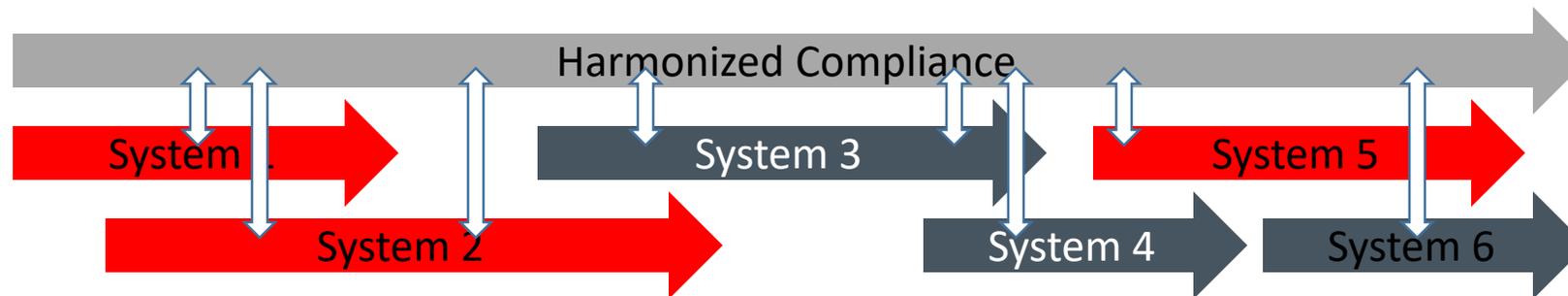
- Harmonization Can Help
 - Eliminate differences and inconsistencies across processes
 - Promote best practices while recognizing differences
 - Identify “shared data” to build enterprise view of compliance

Reasons to Harmonize

- The Road to Harmonization
 - Requires top-down commitment and enforcement
 - Powerful ROI justification in cost savings and better compliance
- Controls Complexity
 - Business systems need to “talk” (break down the information silos)
 - Exponential effect of interactions between systems
 - Cost of managing multiple systems
 - Opportunity cost of missing integrations
- Deliver Better Value
 - Faster response to change
 - Faster assimilation of new business
 - Consolidated view of compliance

Challenges to Harmonization

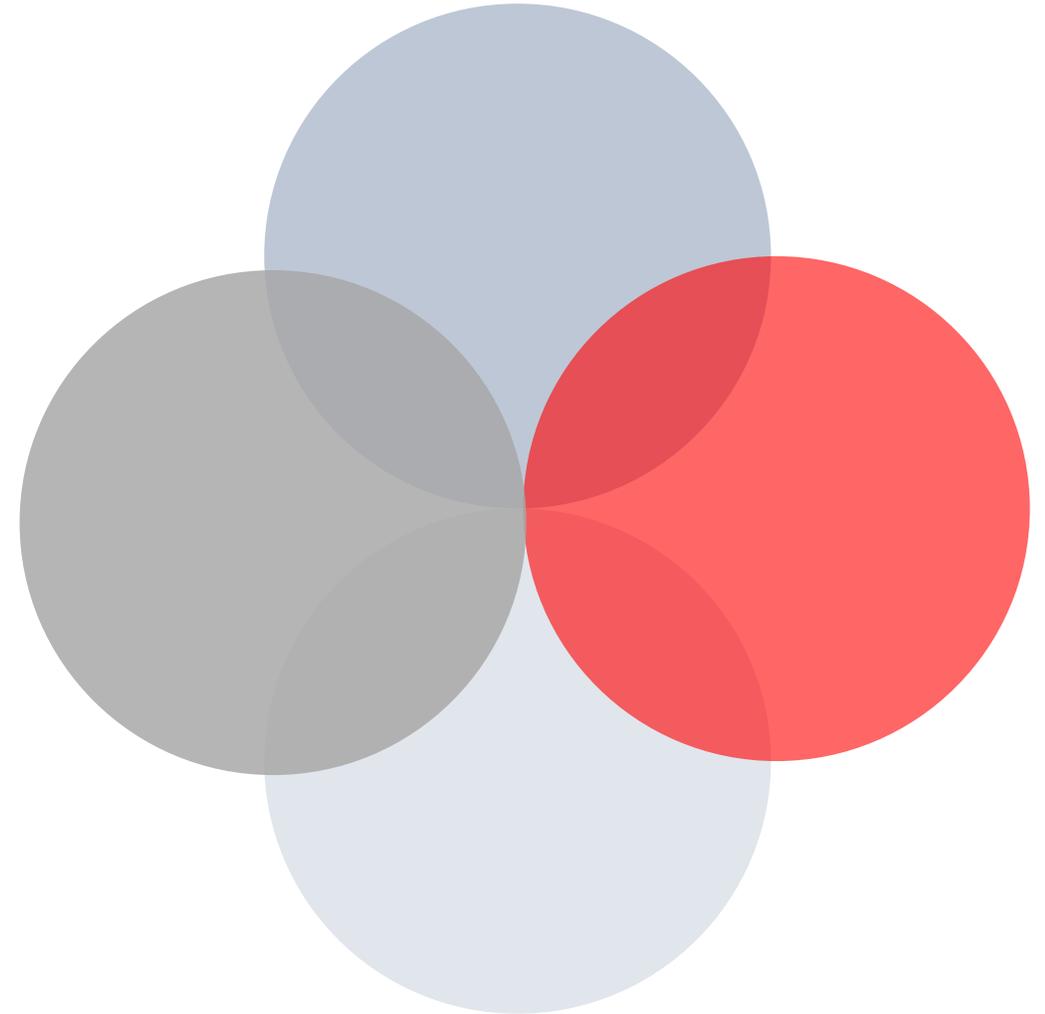
- How Different?
 - Business requirements not the same as compliance requirements
 - Unique, differentiated business processes = competitive advantage
 - Unique, differentiated compliance processes = non-compliance
 - Difficulty of unlinking business systems from compliance systems
- Integration with Other Systems
 - Harmonized compliance systems increases need for integration



- Reliability of Centralized IT Support
 - Administration bottleneck (always “in the queue”)
 - Provide consistent worldwide user experience

Benefits of Harmonization

- ↓ Reduce number of change requests
- ↓ Reduce cost of making changes
- ↓ Reduce cost of support
- ↓ Reduce cost of system administration
- ↑ Increase compliance with established processes
- ↑ Increase speed of rollout to new divisions
- ↑ Increase visibility across the enterprise
- ↑ Increase response time to changes
- ↑ Increase knowledge sharing



Integration

Automating Quality



Incremental Improvement

- Lower administration costs
- Reduce process times
- Improve compliance

Integrating Quality



Significant ROI

- Stop defects from going out the door accidentally
- Reduce inventory on hold
- Speed up complaint resolution
- Guarantee compliance

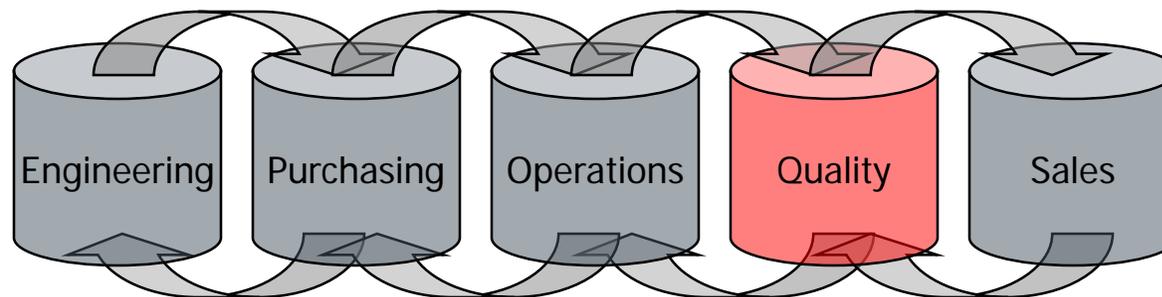
Why we have multiple Business Systems

- Business Systems Meet Departmental Needs
 - MRP, MES, SCM, CRM, PLM, LIMS, LMS, QMS, etc...
 - ERP deployed as department-specific modules
- Incompatible Systems Reinforce Silo Mentality
 - Departments have a narrow view of business performance
 - Business systems provide narrow view of business data
 - Enterprise-wide visibility is difficult



Information Silos

- Sharing Information is a Business Necessity
 - Departments need to communicate daily
- Information Silos Make the Process Inefficient
 - Print-and-carry information flow
 - Double-entry, with variable error checking
 - One-way transfer of information with no return status
 - Data needs to be “cleaned” before it can be used

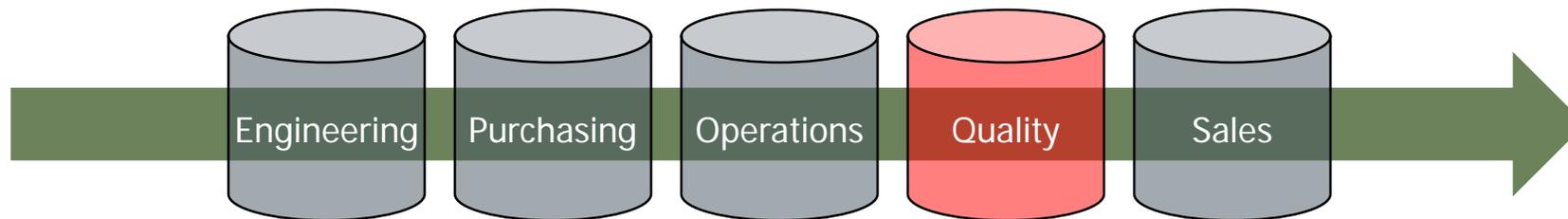


The Quality Silo

- A QMS Needs Data from Other Departments
 - Customer, supplier, product, equipment information
 - Inspection results for nonconformance reports
 - Customer service calls for complaint investigations
 - Production and shipment rates for performance reporting
- A QMS Contains Critical Business Data
 - What is the disposition status of defective product
 - What are the results of a complaint investigation
 - Which suppliers are the most reliable
 - When will a manufacturing change be completed
 - Who is qualified to perform critical jobs

Integrated QMS

- Real-Time Quality Status for Other Business Systems
 - Automatically release or dispose of defective product
 - Provide complaint investigation results to customer service
 - Up-to-the-minute approved vendors list (AVL)
 - Prevent unauthorized use of equipment or product
 - Prevent tasks from being performed by untrained employees

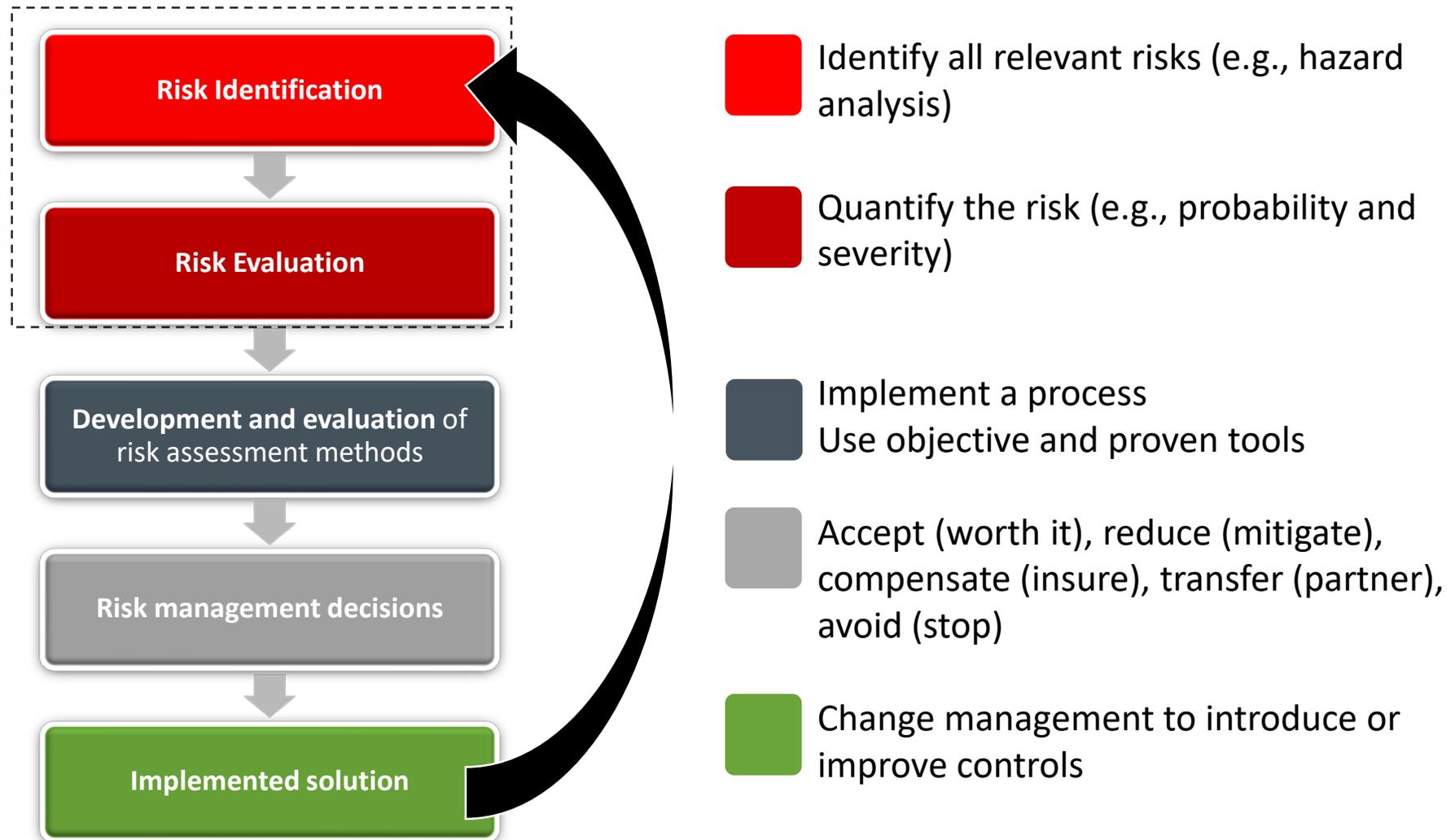


How to Integrate

- Many Options – Few Standards
 - By default, business systems cannot “talk” to each other
 - Also, keyword terms may not be consistent
 - Many technologies available to link systems together
- Point-to-Point Integration
 - Direct connection from one system to another
 - Requires compatible APIs (e.g., Java, .NET, Web Services)
 - Less expensive, but more affected by changes to business systems
- Middleware Integration
 - Business systems “talk” to a common broker
 - Use EAI tools or build custom tables
 - More expensive, but better monitoring

Risk Management: the Process

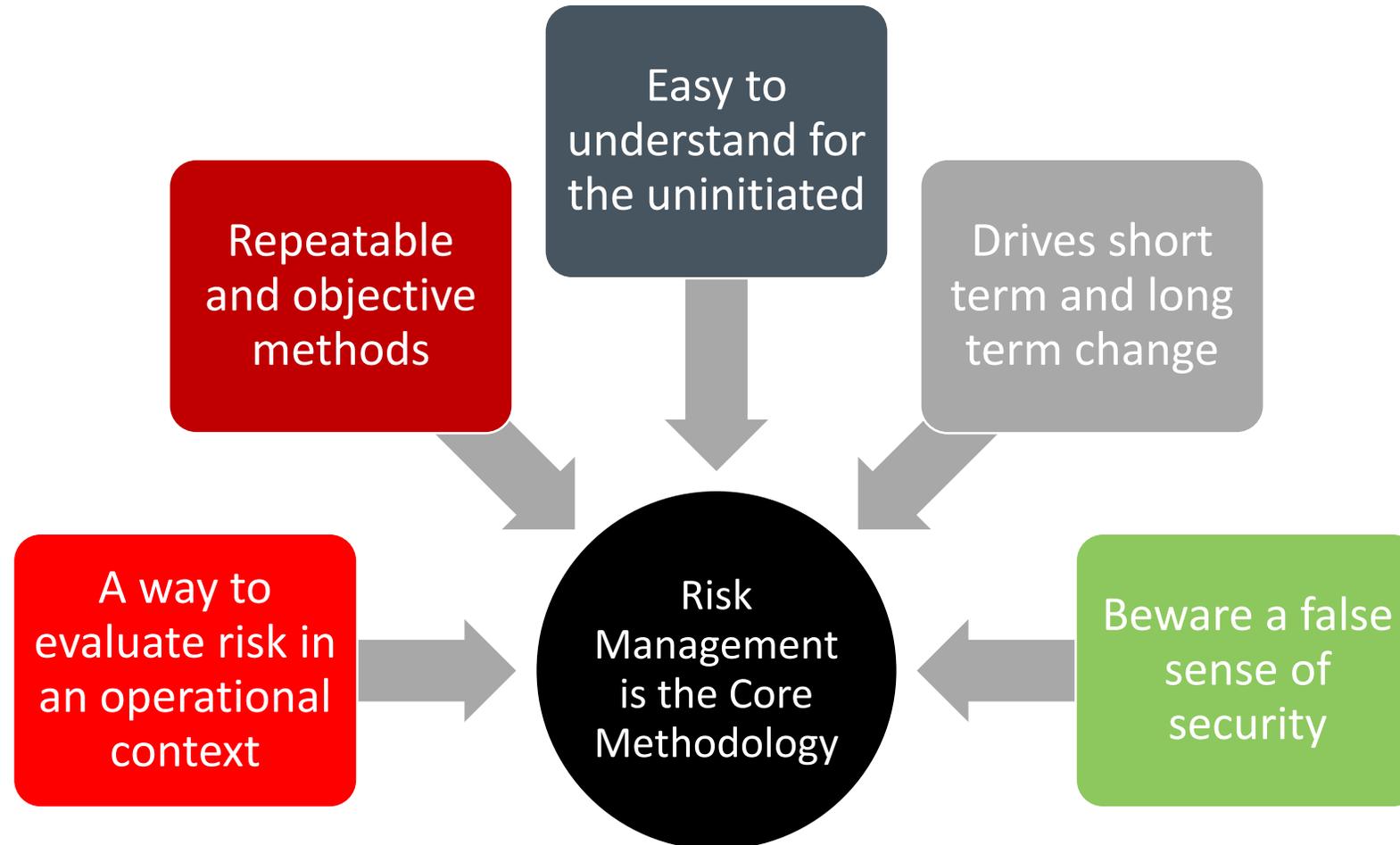
- Risk Management is a broad standard (ISO 31000)



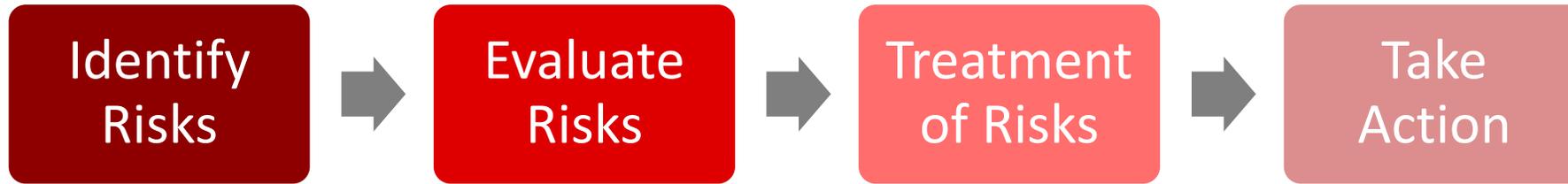
Risk Management: Areas of Coverage



Risk Management: Rationale for Risk

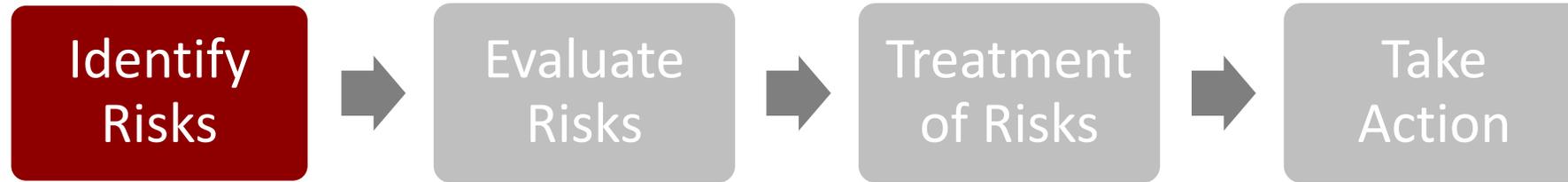


Planning Your QMS with Risk in Mind

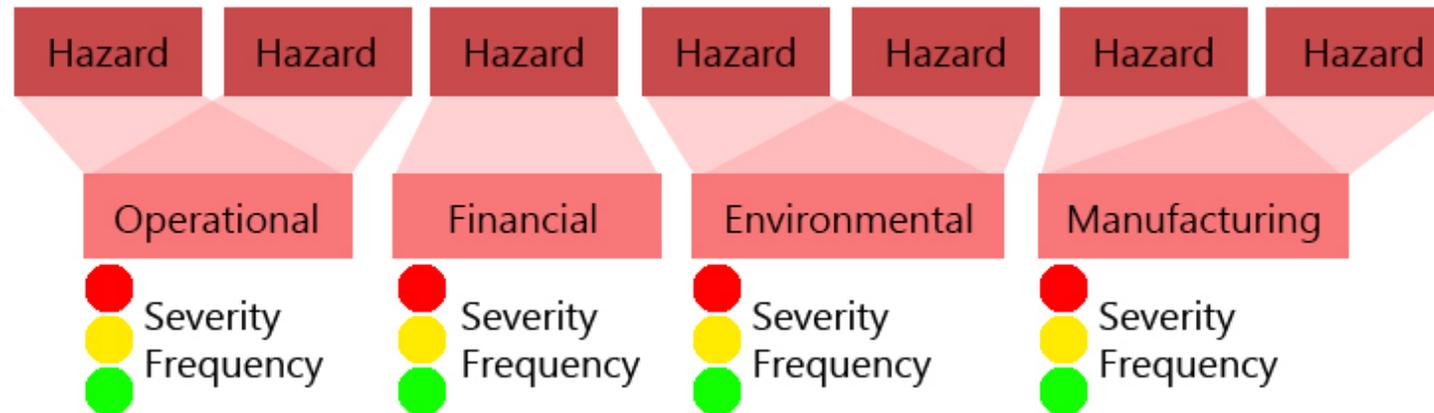


- Identify risks and opportunities to influence QMS performance
- Determine how you're going to measure those risks
- Build risk treatment options
- Define actions to address these risks

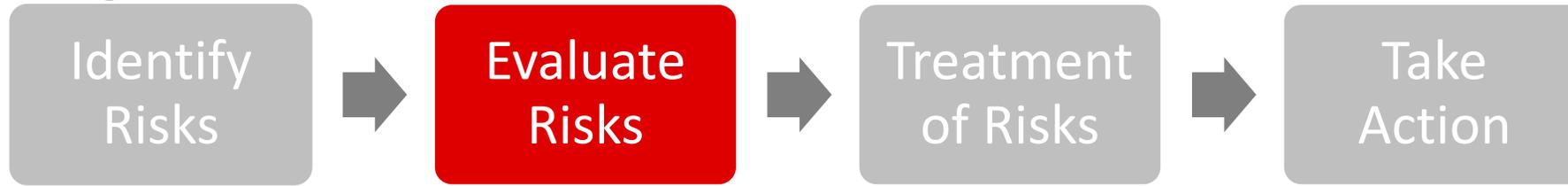
Planning Your QMS with Risk in Mind



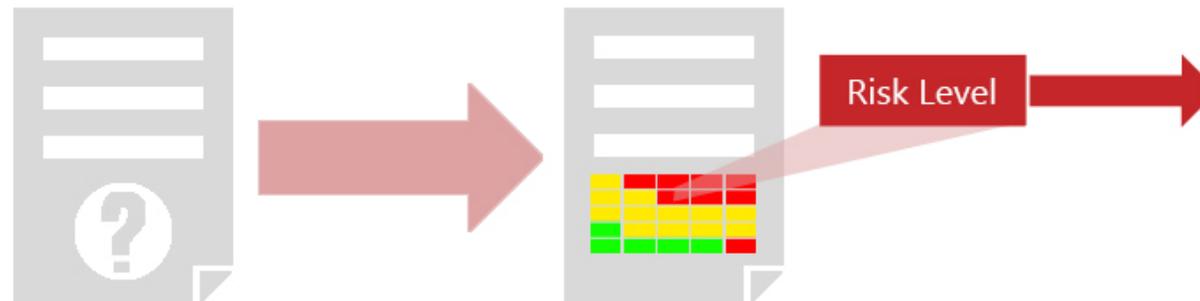
- How to start Identifying risks?
 - Survey your operations
 - Audit, Survey, collect, analyze



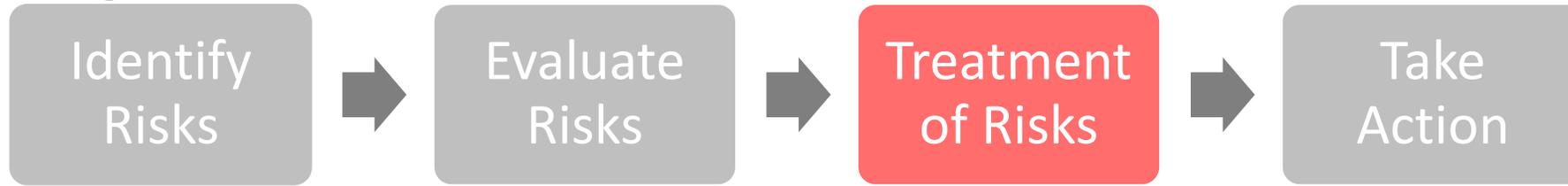
Planning Your QMS with Risk in Mind



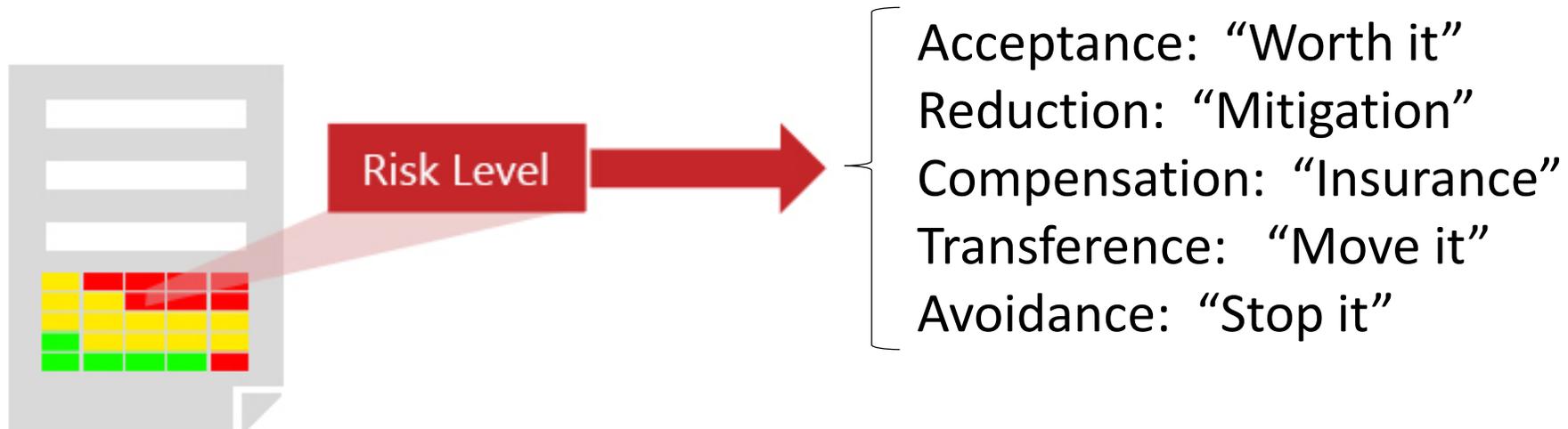
- Evaluate How to handle the risk
- Risk Assessment
 - Should be repeatable, objective
 - Should be backed by REAL-WORLD DATA
- Quantitative means to build a risk assessment



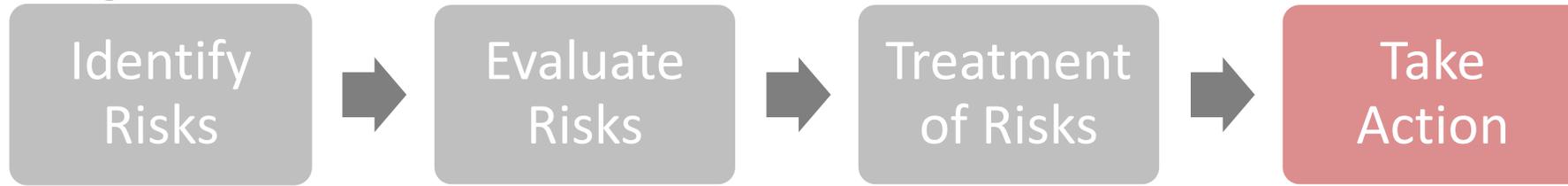
Planning Your QMS with Risk in Mind



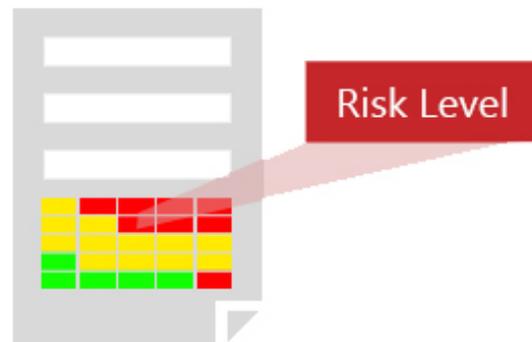
- We know the risk....how do we handle it?



Planning Your QMS with Risk in Mind



- Take Action: Create Visibility and Control the Risk



Corrective/Preventive Action

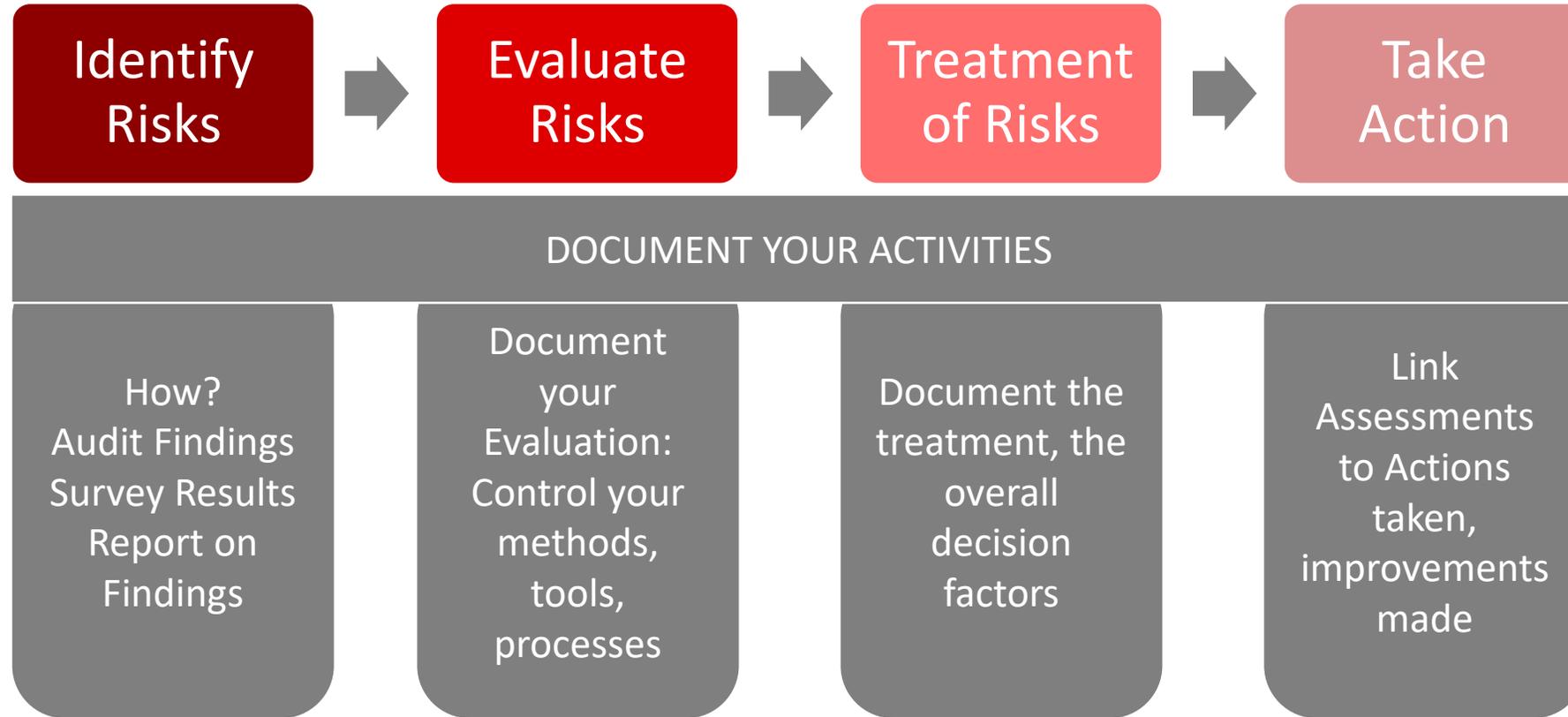


Controls/Action Plans



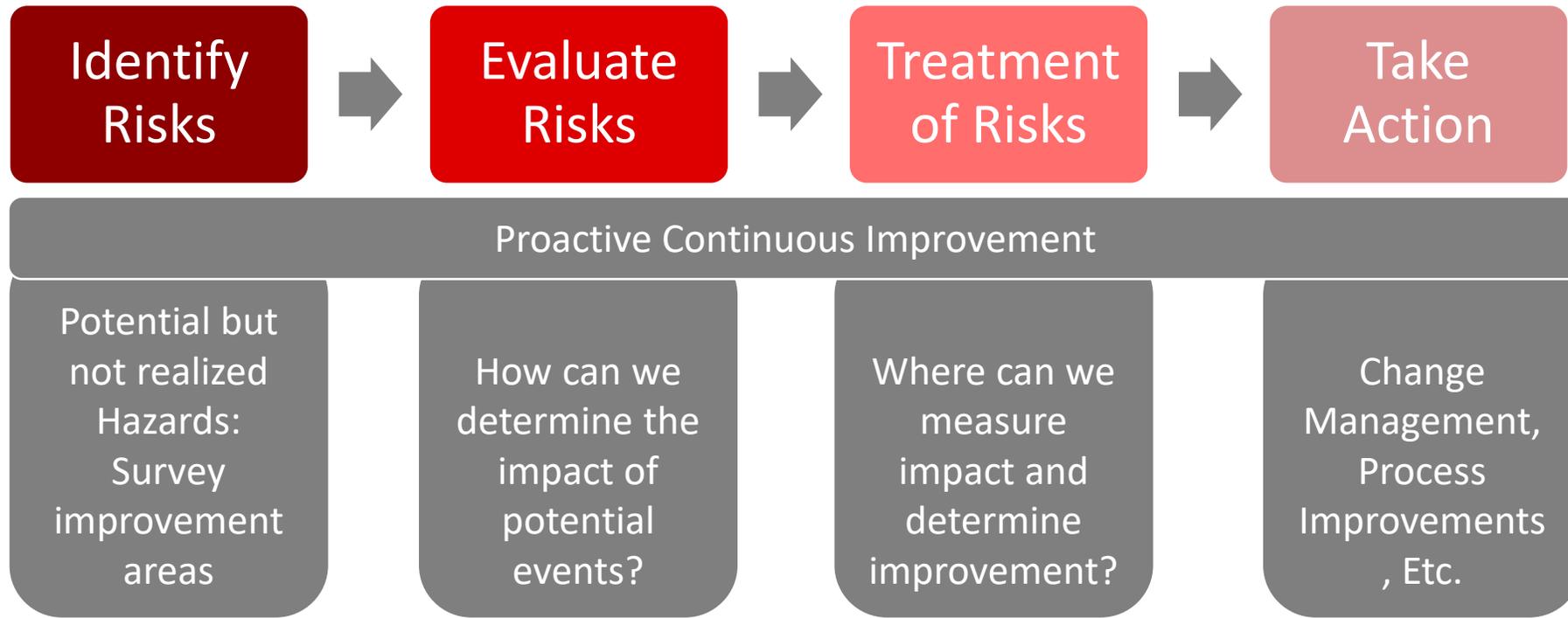
Reporting/Trending

Planning Your QMS with Risk in Mind



- Document the process in order to have traceability.

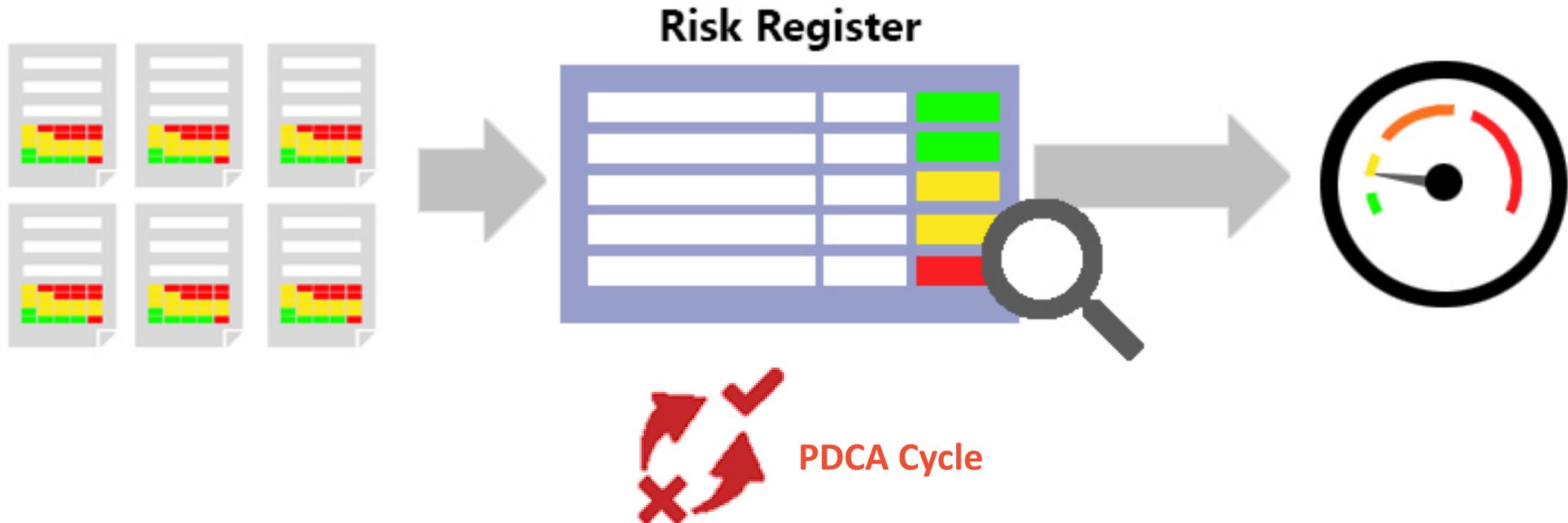
Planning Your QMS with Risk in Mind



- It's not all for just the Risks! Identify Opportunities too!

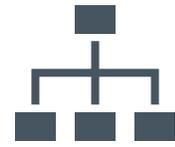
Risk Register

- Monitors risk levels over time
 - Library of hazards (typically known for each industry)
 - Collects risk assessment data from many processes
 - Provides visibility into critical events and data for trend reporting



Summary

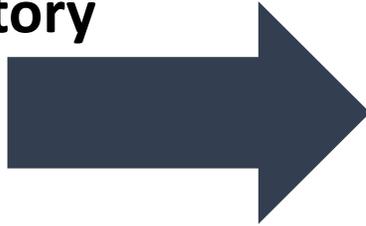
- The Story of Quality is driven by these points:



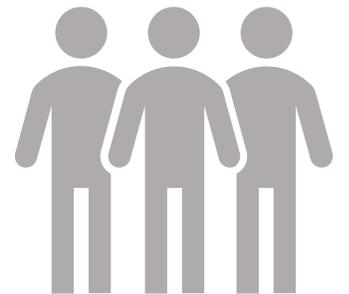
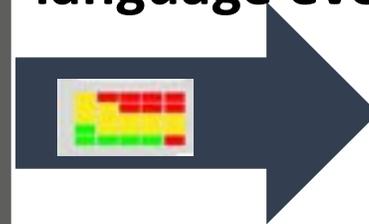
Harmonization: Get on the Same Page



Integration: Add more content to your story



Risk: Put the Story into a universal language everyone can read





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