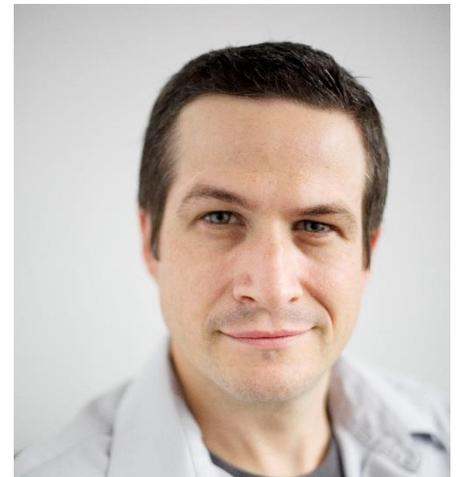


Achieving Operational Excellence:

How to Create a Culture of Quality for Desired Outcomes

**Tim Lozier, Director of Product
Strategy at Verse Solutions**



Tim Lozier
tlozier@versesolutions.com

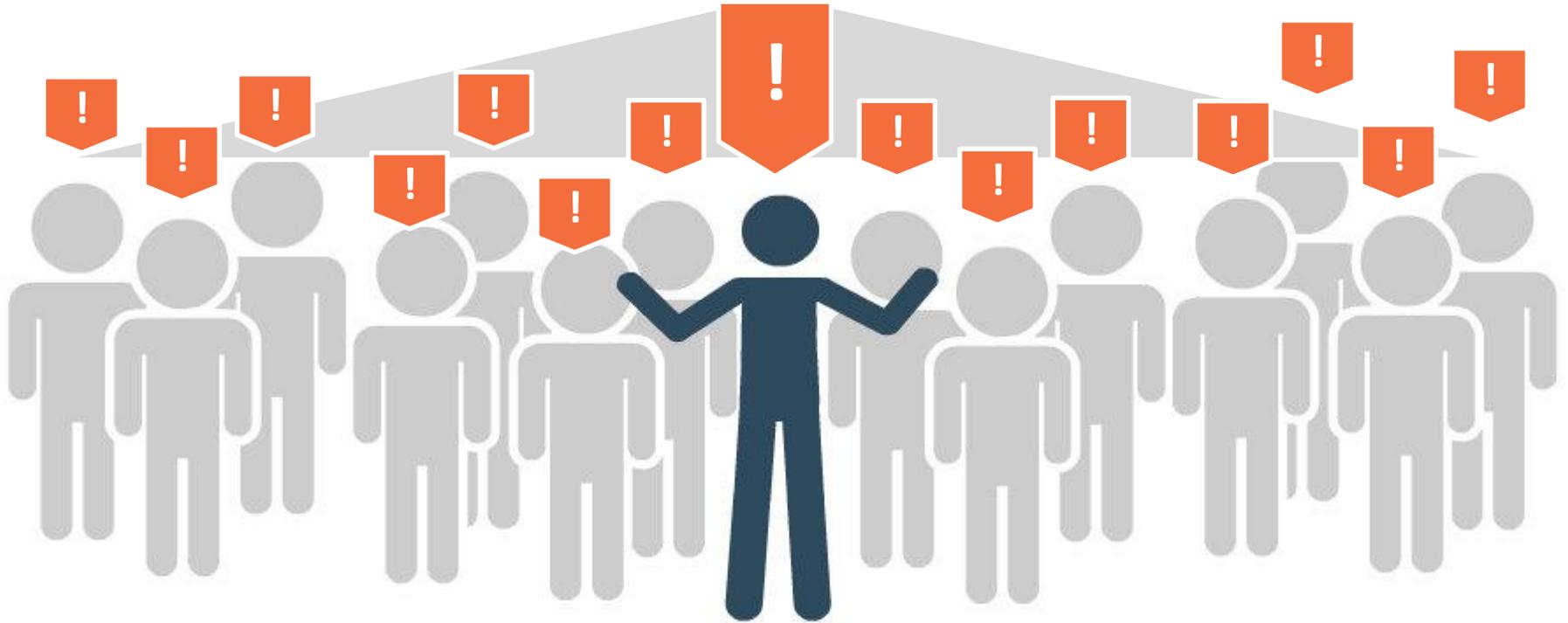
What we're covering today

- **What is Operational Excellence?**
- **What is the current state of the market?**
- **What are the key components to moving to an Operational Excellence mindset**



Not just about the requirements....

It's the mindset.



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



Not just about the requirements....

It's the mindset.



Quality for "external parties" (suppliers)



Quality for People within
your company

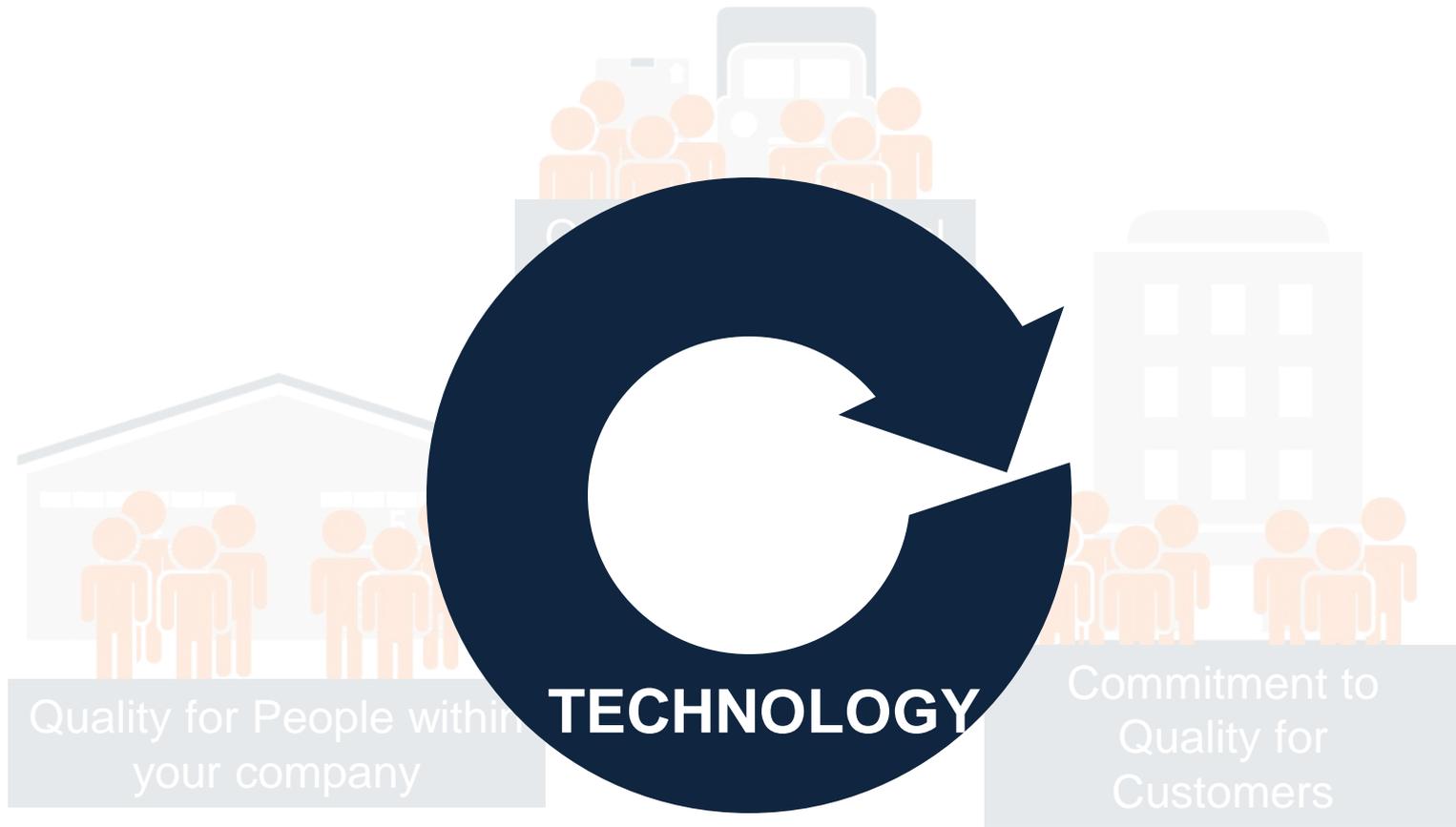


Commitment to
Quality for
Customers



Not just about the requirements....

It's the mindset.



Compliance Management

- **Compliance is:**

Quality

Operations

Safety

Governance

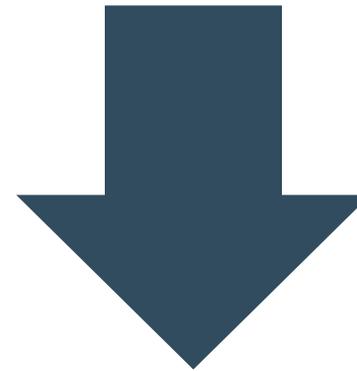
Risk

Regulatory

Financial

Sustainability

It's **BROAD.**



[It's also only a component of a larger theme]



Relationship of Compliance and Operational Excellence

- **Compliance**

- Adherence to Guidelines
- Specifications created by a standards body
- Required in order to do business in certain industries
- Abiding by both industry regulations and government legislation

- **Operation Excellence**

- Adherence to company strategy
- Specifications created to the sustainable improvement of key performance metrics.
- Abiding by process to foster long-term change in organizational culture, not just remain in “compliance”

What's Required

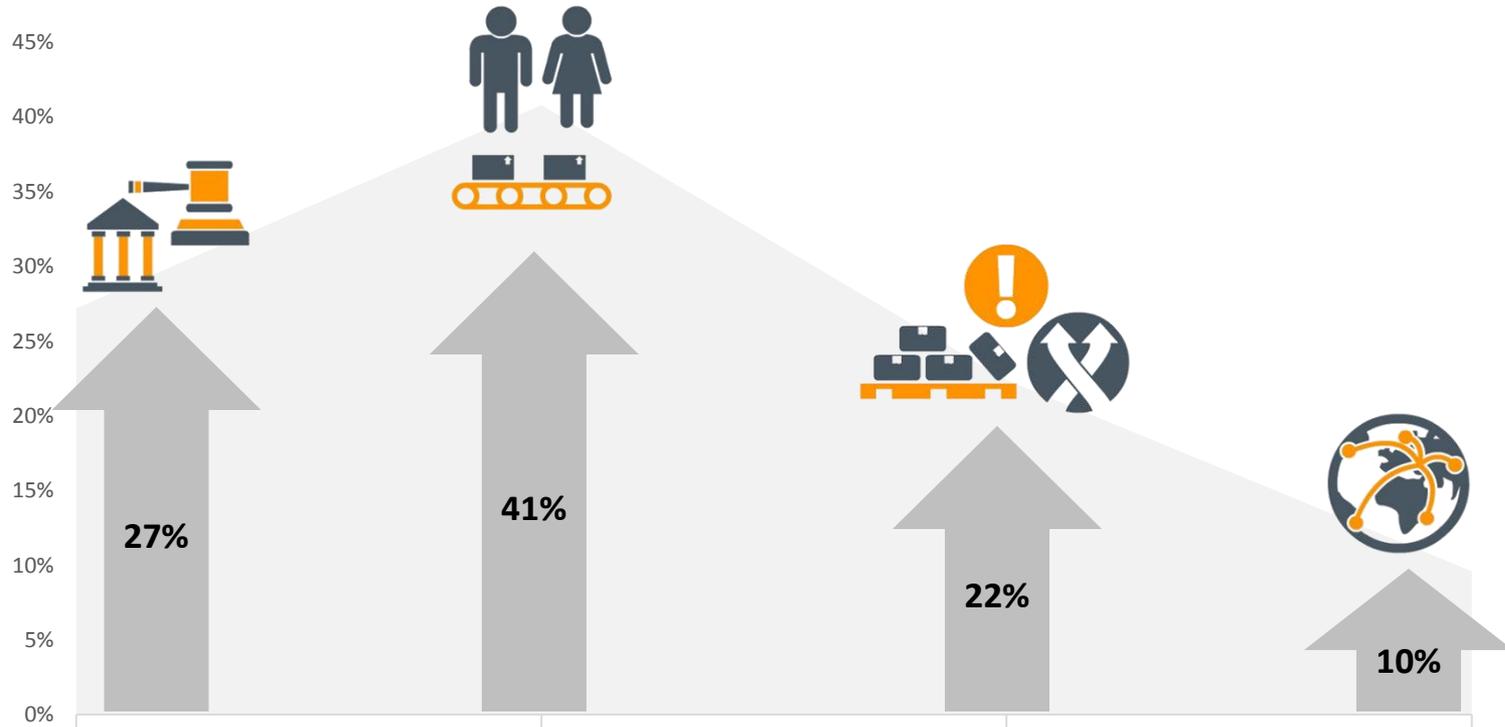
What's Desired

Mindset Shift.



What's Driving Quality Management?

Where is your current focus in Quality



Registration to ISO and similar international standards

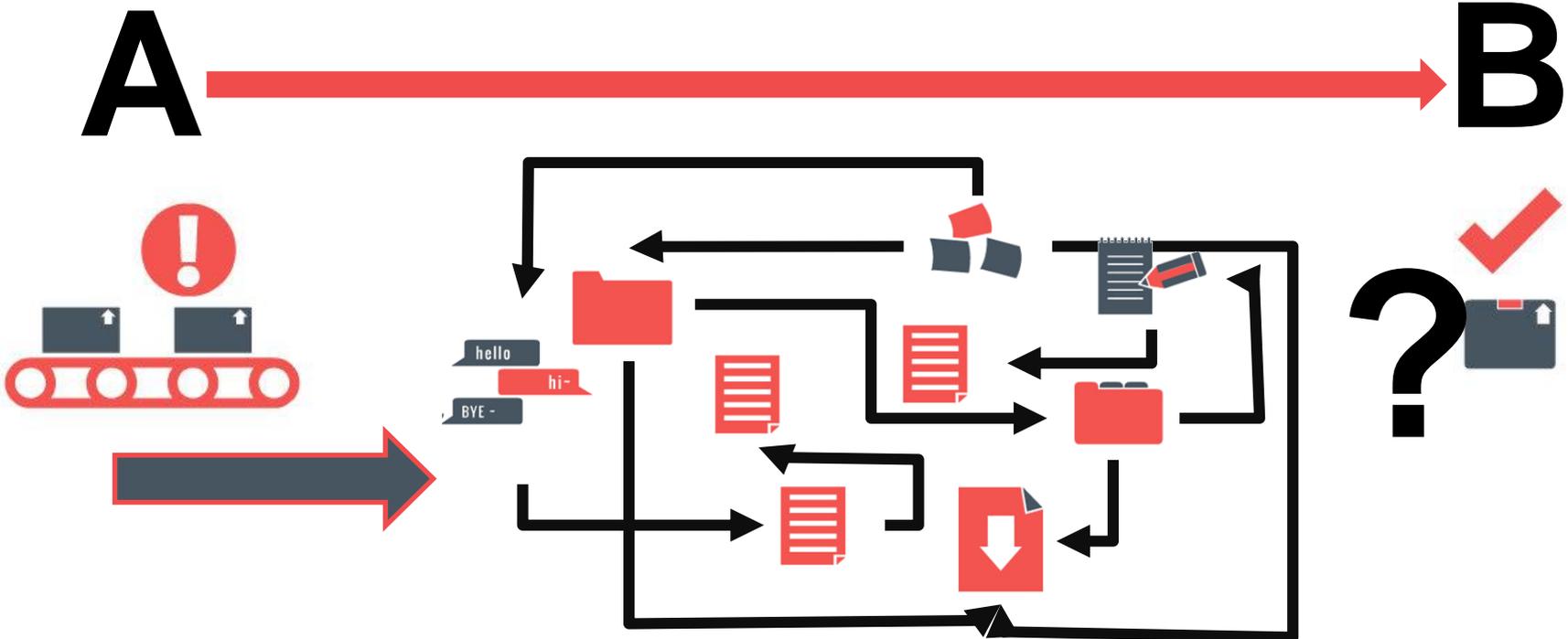
Meeting customer and product regulatory requirements

Product and process improvement driven by quality (e.g. reduce risks and variations)

Strategic directives for operational efficiency (e.g. reduce costs and product defects)

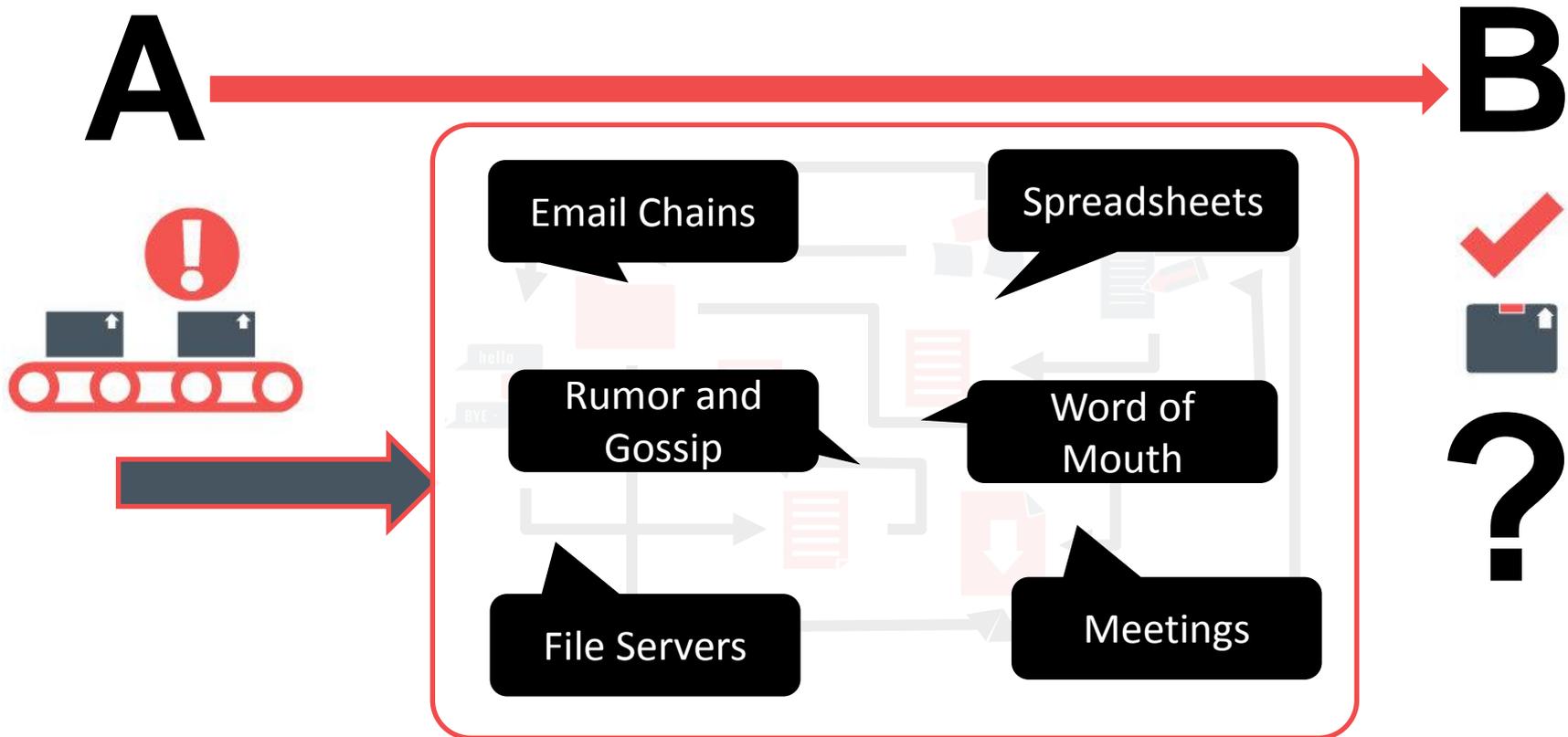


Operational Excellence: Starts with People



Operational Excellence: Starts with People

Challenge: Conversations around Quality are disparate? How can we create a single "Story of Quality" and tap into companywide, tribal knowledge?



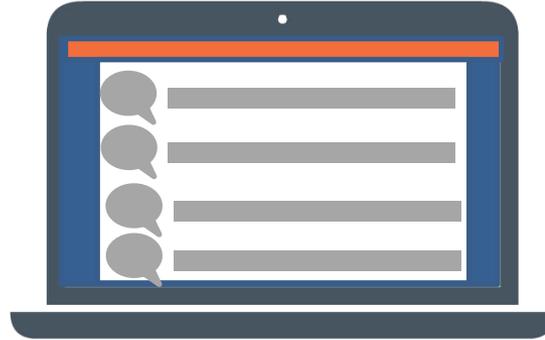
Operational Excellence: Starts with People

OpEx brings people to a central place



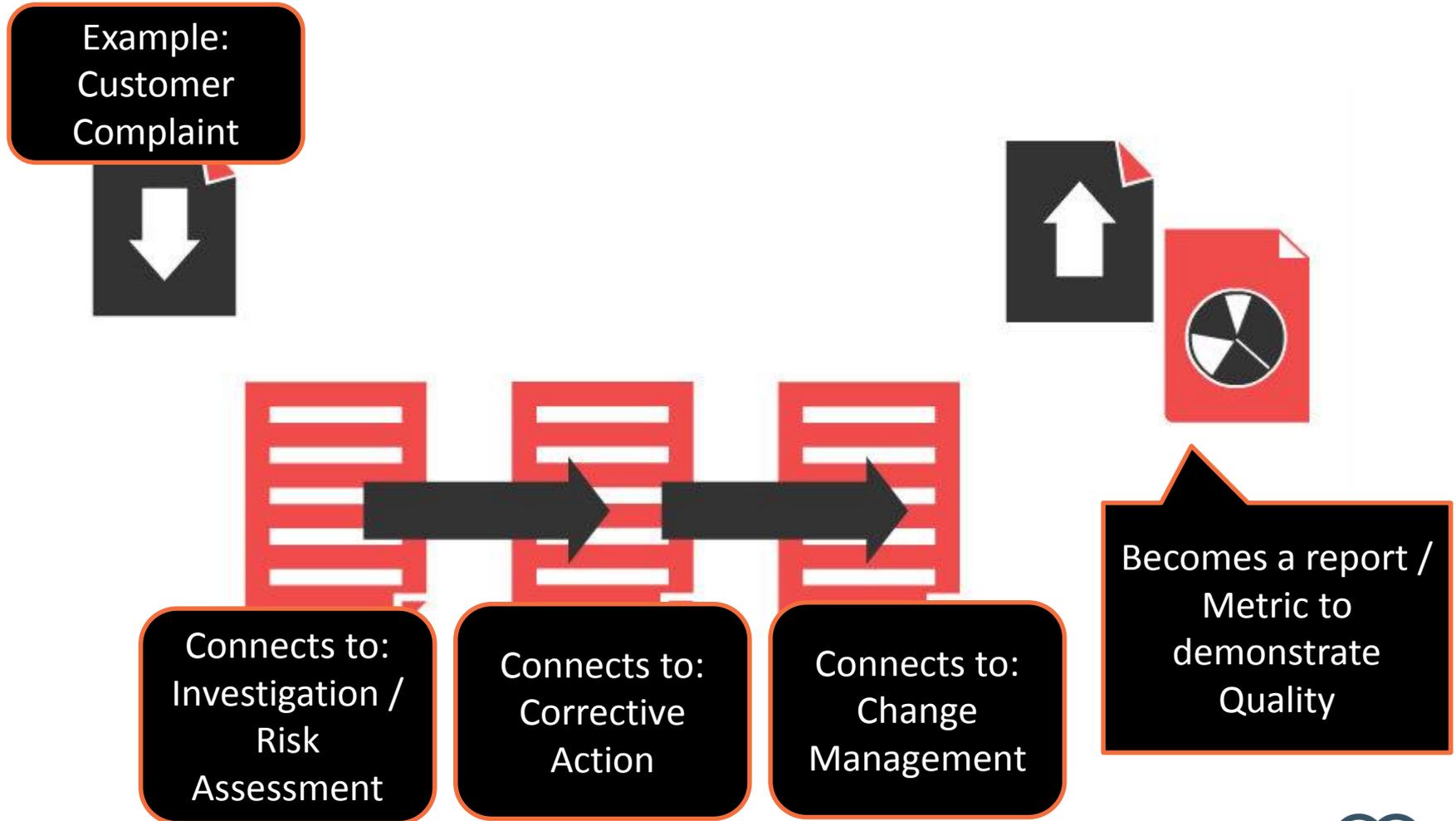
Operational Excellence: Starts with People

OpEx brings people to a central place



Operational Excellence: Process Alignment

Aligning Processes to connect from one to the next – desired state is a true story from start to finish



Operational Excellence: Process Alignment

Aligning Processes to connect from one to the next – desired state is a true story from start to finish

Example:
Customer
Complaint

Desired State:
The Quality Report
Provides a full report on
the history of an
occurrence, from event
detection to event
correction.

Result:
an Audit /Inspection
ready state

Risk
Assessment

Connects to
Corrective
Action

Complaint Handling # COMP-00076

Created by Glenn Davis on: Mar 16, 2017 10:02:17 AM

Investigation

Complaint Information

Complaint Number: COMP-00076

Complaint Description: Patient described while in patient

Alert Date: Jun 11, 2017

Event Date: Jun 11, 2017

Product Information

Product Number: 89942

Product Line Affected: Jun 11, 2017

Sample Source: No Sample

Sample Status: In Use

Adjustment: No

Decommissioned: No

Date Returned: Jun 11, 2017

Additional Information

Initial Assessment required? Yes

18hr Decision Time required? Yes

API Decision Time required? Yes

Risk Assessment

Risk Assessment # RSM-00047 of Risk Item: Functional (Approved, due Mar 16, 2017 11:00:00 AM)

Related Complaints

Create Deviation

Deviation Link

Create EDO

is a report /
metric to
demonstrate
quality



Operational Excellence: Process Alignment

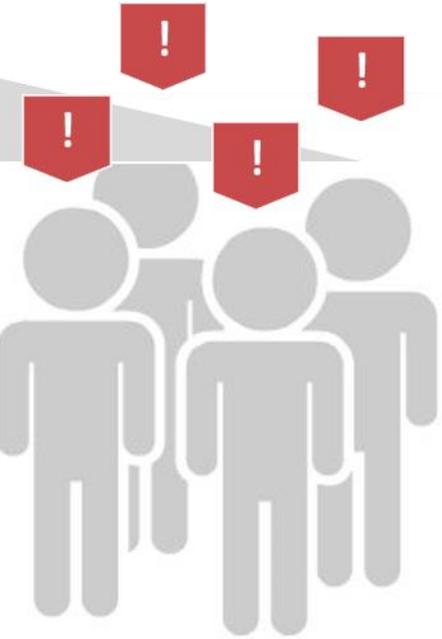
Aligning Processes, connecting from one place to the next ensures no information is lost, the story of Quality is constant, and gives you full traceability on the entire process.



Fostering traceability throughout the process....



Operational Excellence: Leverages Risk-Based Thinking



Section 5: Leadership

Provide leadership by encouraging a focus on quality

Promote the use of risk-based thinking.

Section 6: Planning

Consider risks and opportunities when you plan your QMS

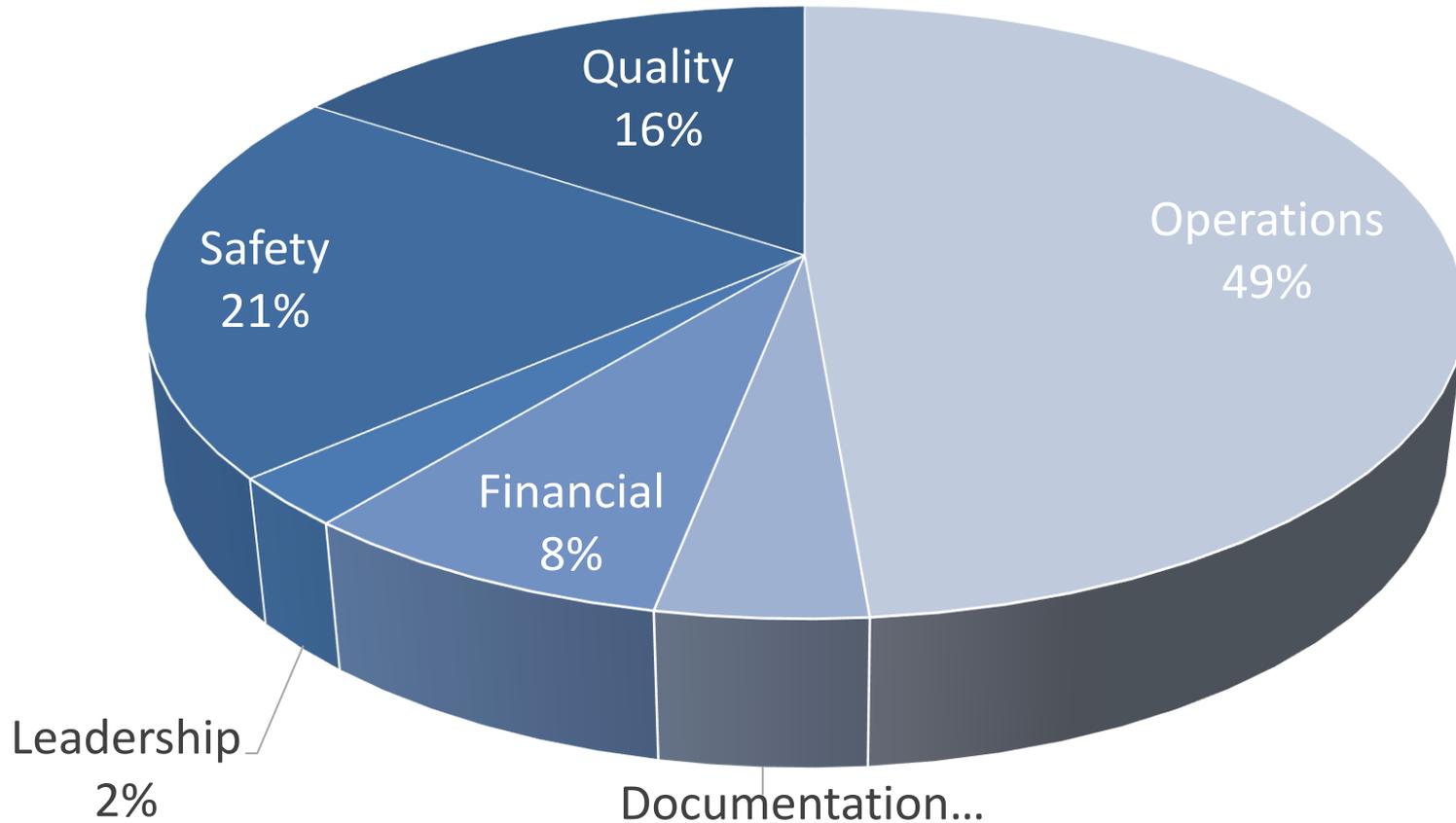
Plan how you're going to manage risks and opportunities

DISCLAIMER: The ISO view on risk is SIMPLY STATED. "Use Risk-based thinking" to manage and plan... But what does that really mean? Broad, and simple – lots of interpretation!

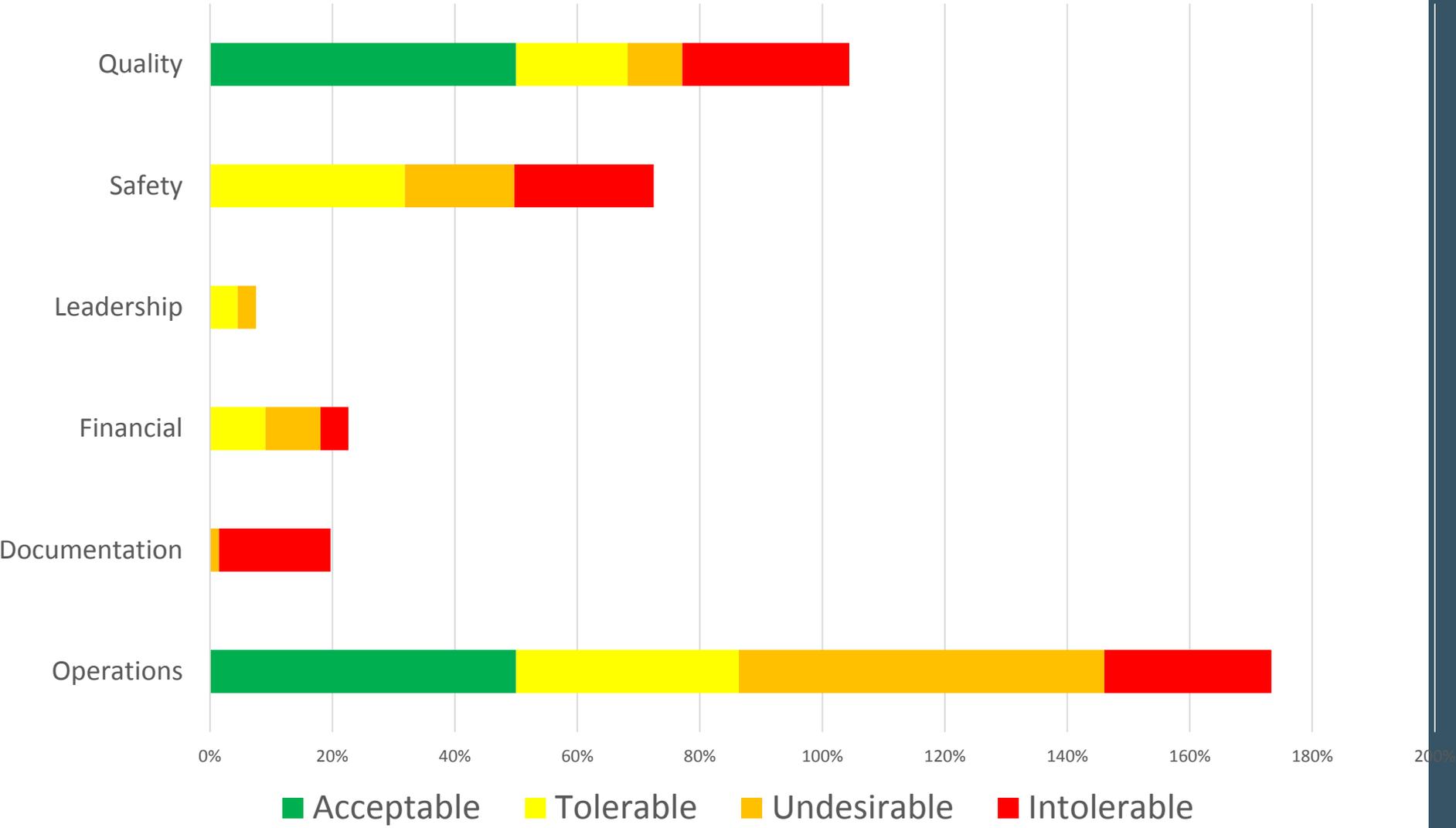


What does the market view as risk?

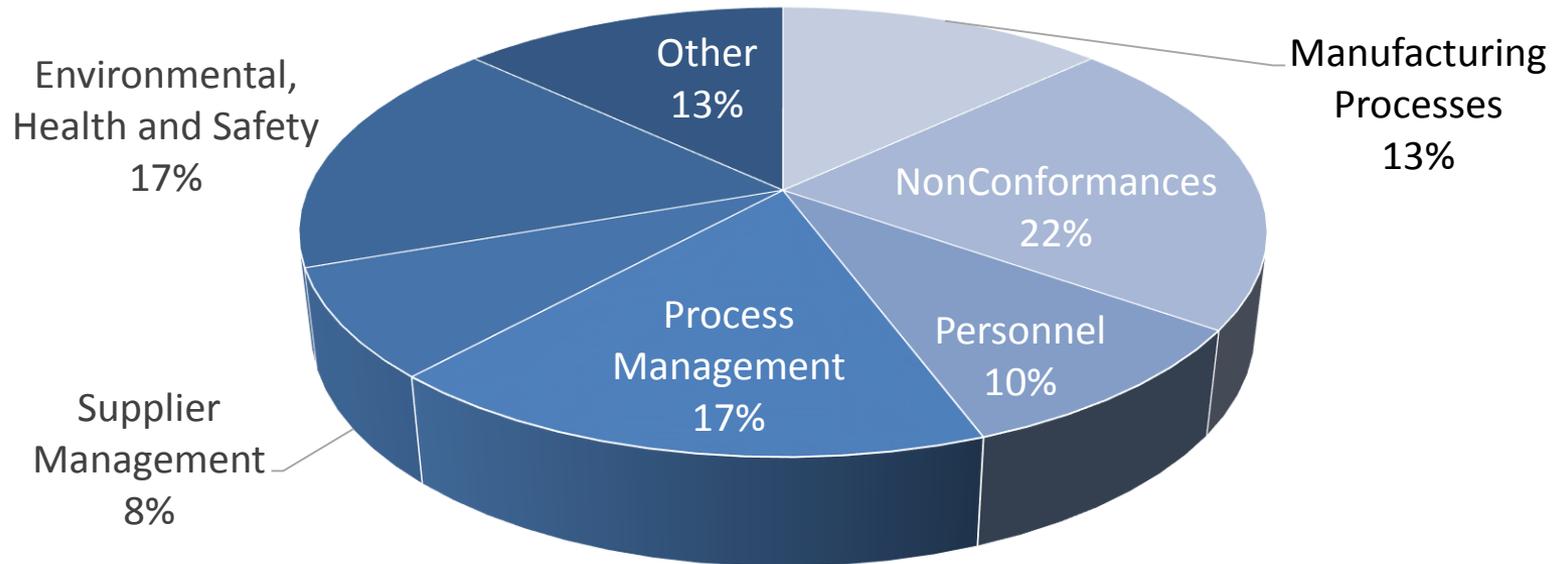
Most Common Risk Areas



Risk Levels by Risk Area



Reasons for Assessing Risk



Manufacturing Processes: inconsistencies in the manufacturing process poses risk

NonConformances: Defects in products leading to risk

Personnel: Improper Training and Resource planning poses a risk

Process Management: Processes are not well-defined and could lead to high risk events

Supplier Management: Risks associated with Supplier non-compliance

Environmental, Health and Safety: Risks to the environment, health and safety within the organization

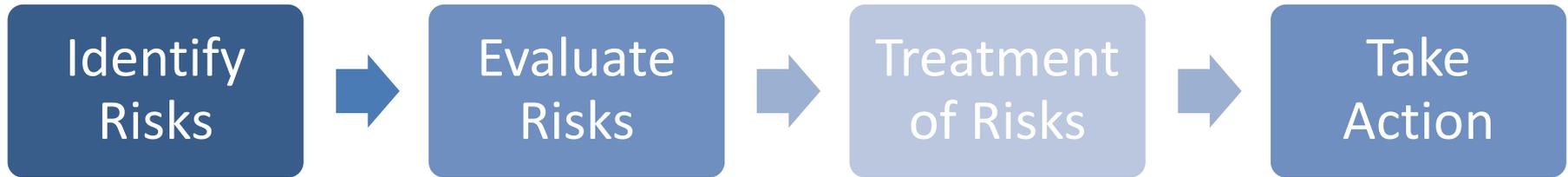
Other: Risks associated with other items

Yeah but...

How do I start my risk management journey?



Planning your QMS with risk in mind...



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



Planning your QMS with risk mind...

Identify
Risks



Evaluate
Risks



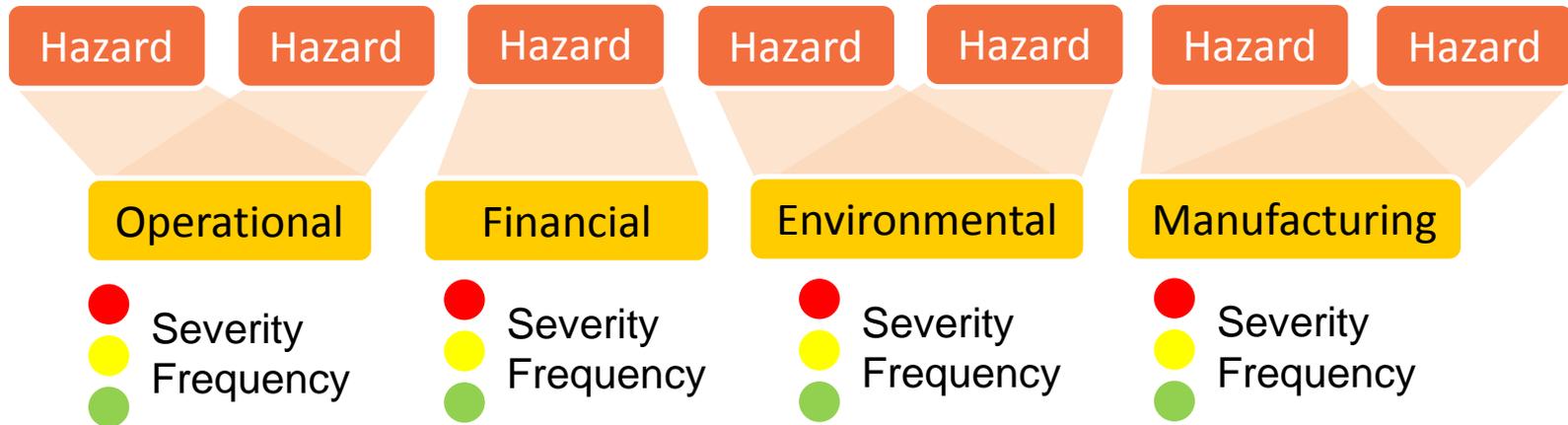
Treatment
of Risks



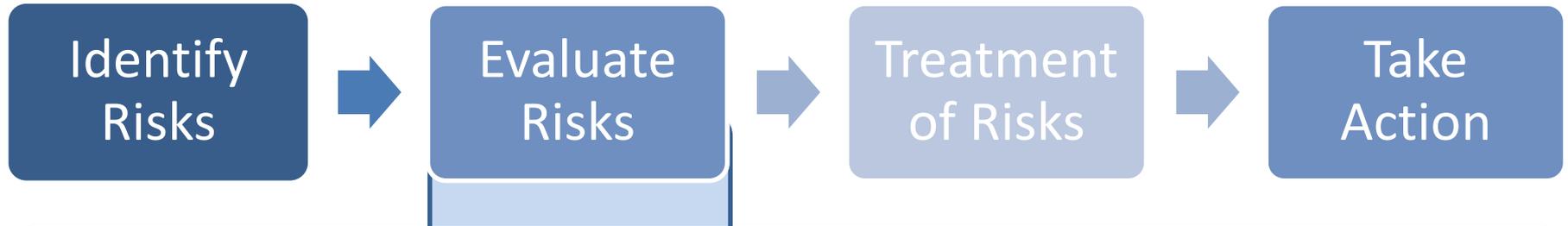
Take
Action

- **How to start Identifying risks?**

- Survey your operations
- Audit, Survey, collect, analyze



Planning your QMS with risk in mind...



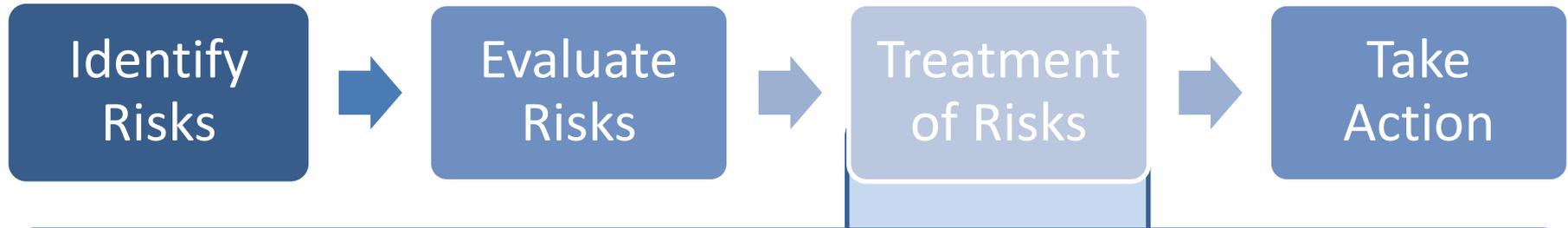
- **Evaluate How to handle the risk**
- **Risk Assessment**
 - Should be repeatable, objective
 - Should be backed by REAL-WORLD DATA
- **Quantitative means to build a risk assessment**



RISK LEVEL



Planning your QMS with risk in mind...



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



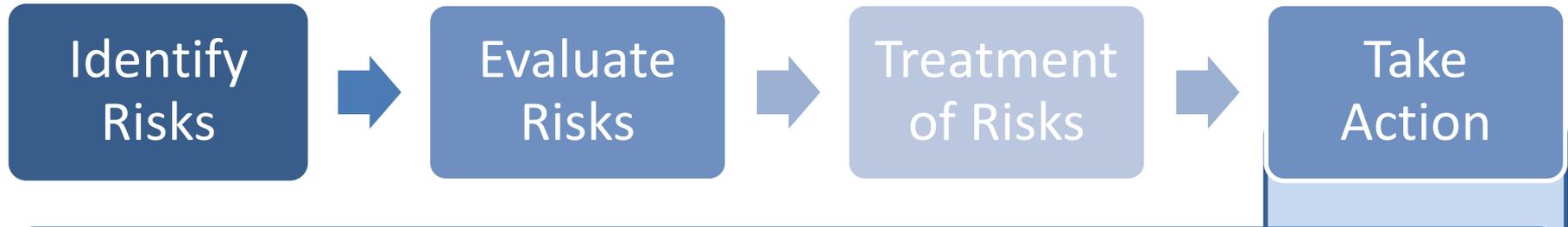
RISK LEVEL



Acceptance: “Worth it”
Reduction: “Mitigation”
Compensation: “Insurance”
Transference: “Move it”
Avoidance: “Stop it”



Planning your QMS with risk in mind...



- **Take Action: Create Visibility and Control the Risk**



RISK LEVEL



Corrective / Preventive Action



Controls / Action Plans



Operational



Financial



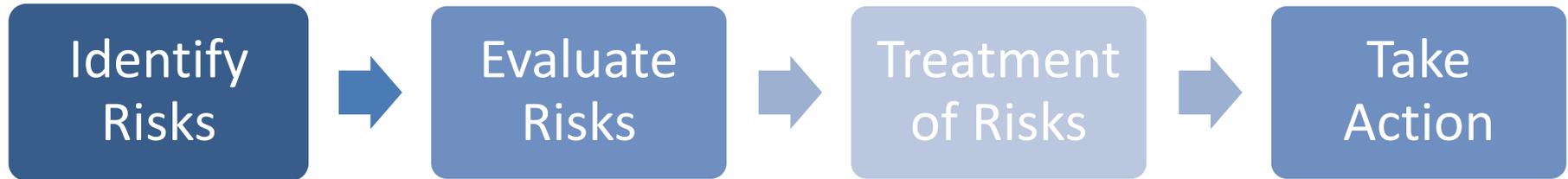
Manufacturing



Reporting / Trending



Planning your QMS with risk in mind



DOCUMENT YOUR ACTIVITIES

How?
Audit Findings
Survey Results
Report on Findings

Document your Evaluation:
Control your methods, tools, processes

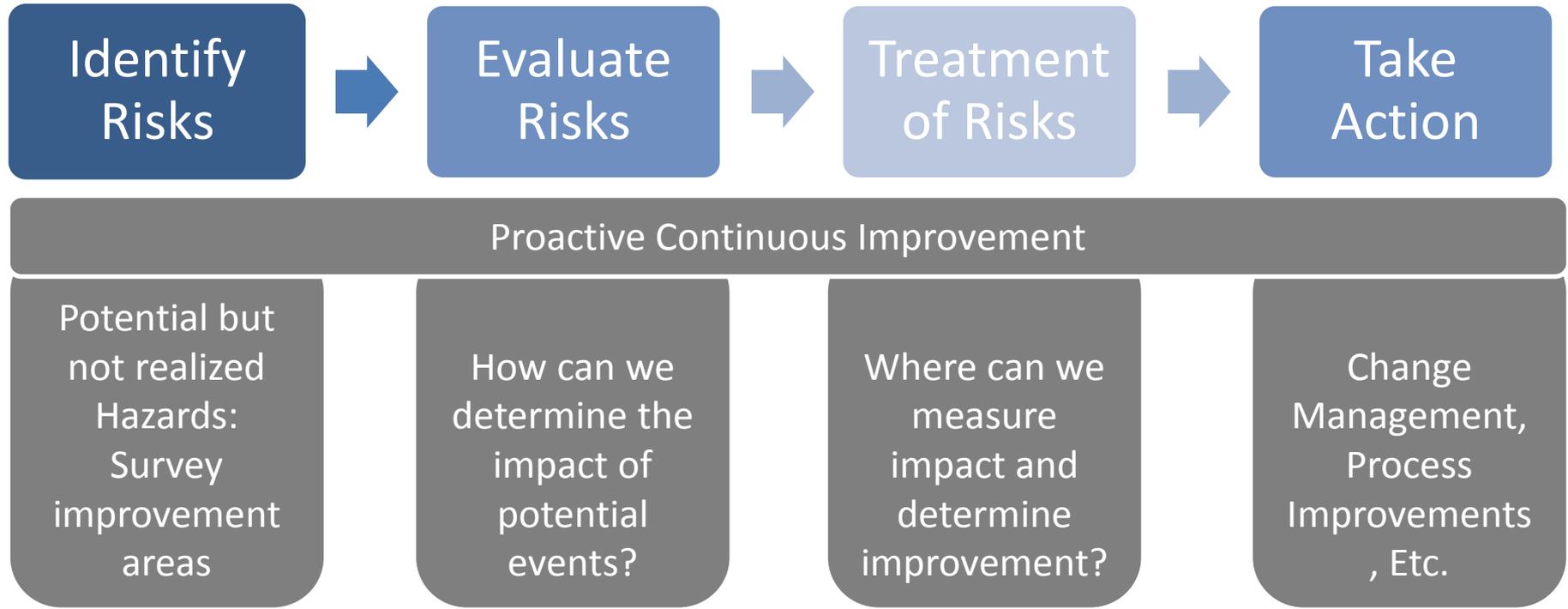
Document the treatment, the overall decision factors

Link Assessments to Actions taken, improvements made

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!



Planning your QMS with risk in mind



Operational Excellences leverages risk to EXPAND the story of Quality to others in the organization.

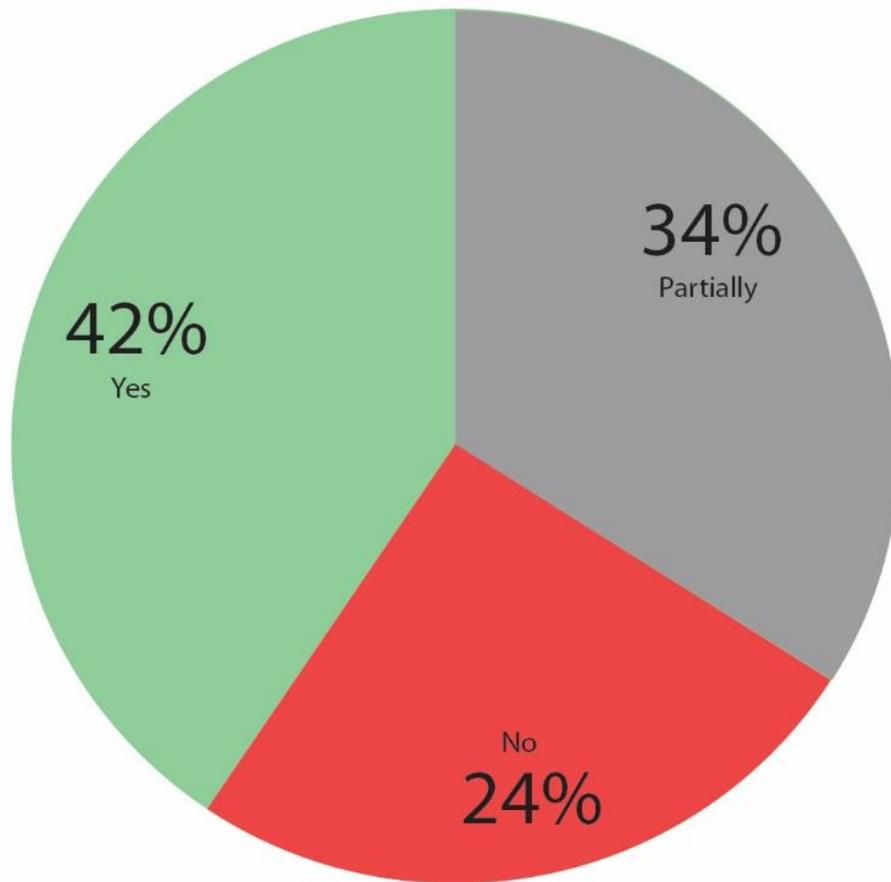
They may not all “speak” quality, but they certainly will speak RISK

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



Operational Excellence: Relies on meaningful reporting

Reporting: Have the ability to produce metrics on problem areas and their causes



The Takeaway:

We're doing what's "required"
Are we doing what's "desired"?

Operational Excellence drives for deeper look into Key Performance indicators to achieving improvement.

24% are not doing this, and **34%** are partially doing this.

Majority is not getting the desired effect!



Operational Excellence: Relies on meaningful reporting

We may be reporting, but are we getting the whole story?
What is the “single source of the truth”?



Operational Excellence: Relies on meaningful reporting

Centralization of the data brings in people, processes and technology into a single source – more data, but organized in a meaningful way!



Operational Excellence: Manages change effectively

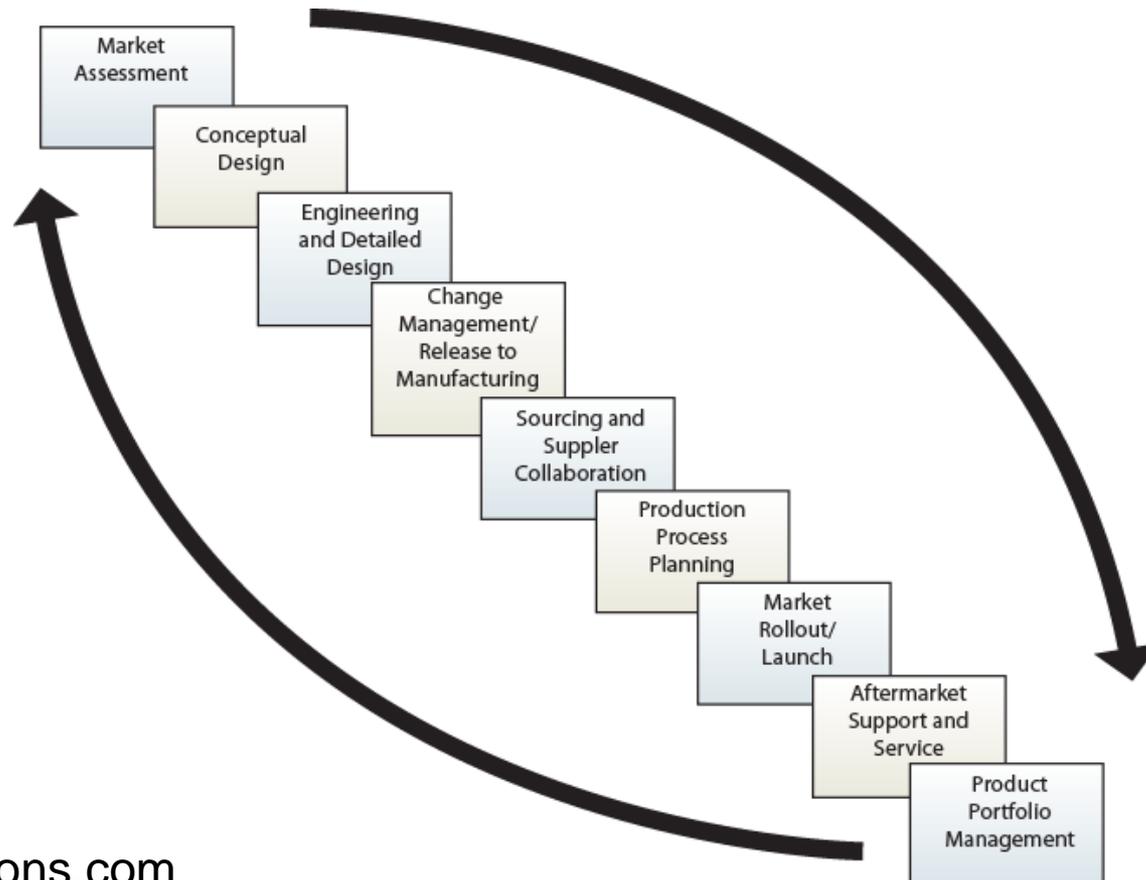
Culture of Continuous Improvement



Operational Excellence: Manages change effectively

Culture of Continuous Improvement

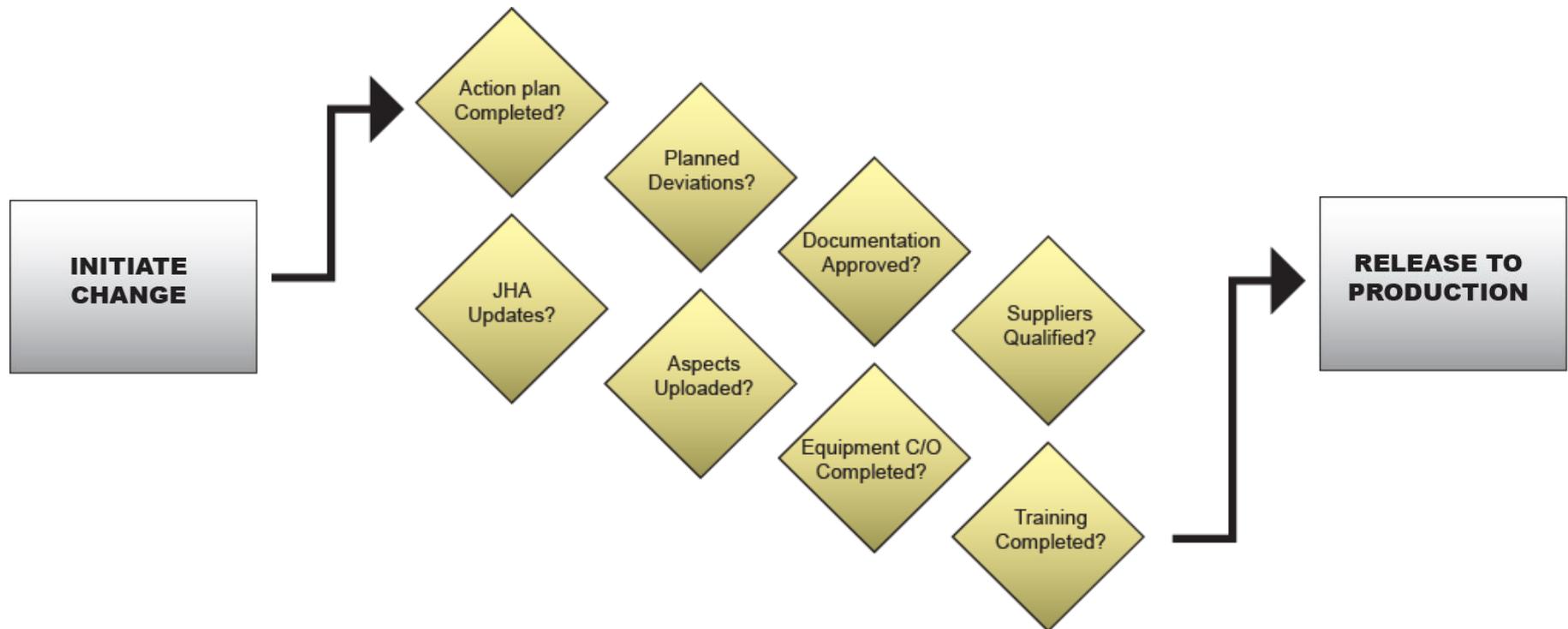
Change Management is a process that impacts all areas of the business



Operational Excellence: Manages change effectively

Culture of Continuous Improvement

By incorporating the same connected process to our change, we can manage more efficiently



Summary

- **Operational Excellence assumes we've controlled the required, and are ready to move to desired outcomes**
- **Operational Excellence revolves around**
 - People: Having a centralized way to consume company-wide knowledge
 - Processes: Having a process that provides a connected way from event detection to event correction
 - Factors in Risk: leverages risk-based thinking to “level the playing field”
 - Builds meaningful, actionable reports: A “Single Source of the Truth”
 - Drives Change management: Treats as a process that is efficient and repeatable
- **Move from just Required, to Desired – impact the business on a strategic level**



Thank you! Questions?



Designed for small workgroups in Quality, EHS and Compliance looking to track events, issue action items and launch corrective actions.

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