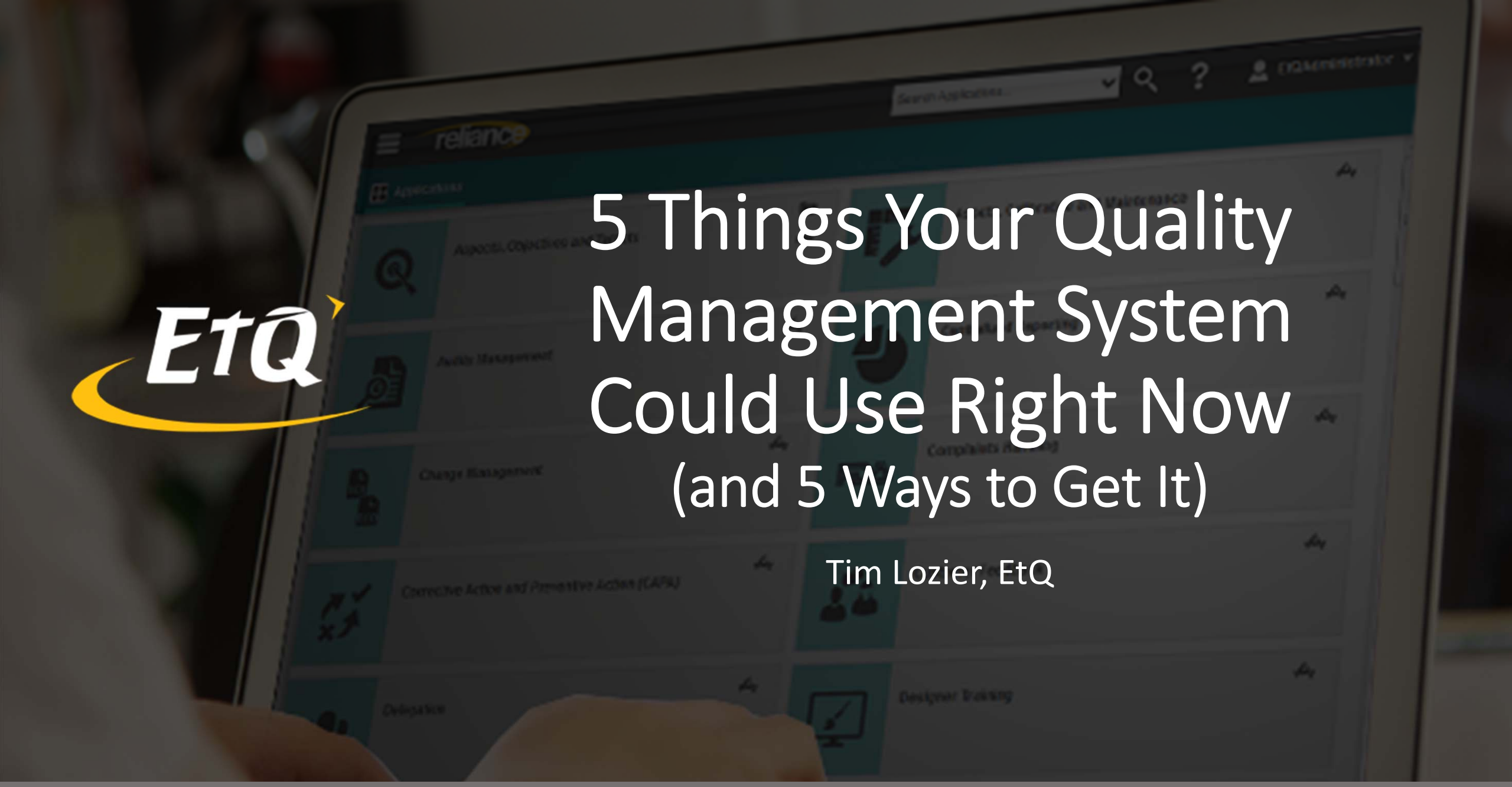


5 Things Your Quality Management System Could Use Right Now

(and 5 Ways to Get It)

Tim Lozier, EtQ

Agenda

- The Quality Management Market: Drivers, preferences and scope
- 5 things to look for in a QMS
  - Flexibility
  - Traceability
  - Risk-Based Thinking
  - Integration
  - Reporting
- Recommendations in QMS Selection

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

What did we do?

….We asked the market about their mindset on Quality Management…

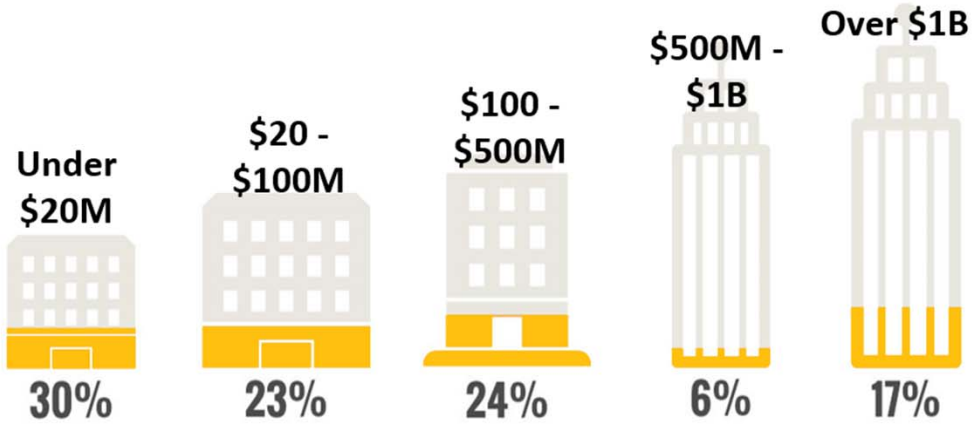
…specifically around who they are,

what drives them, and…

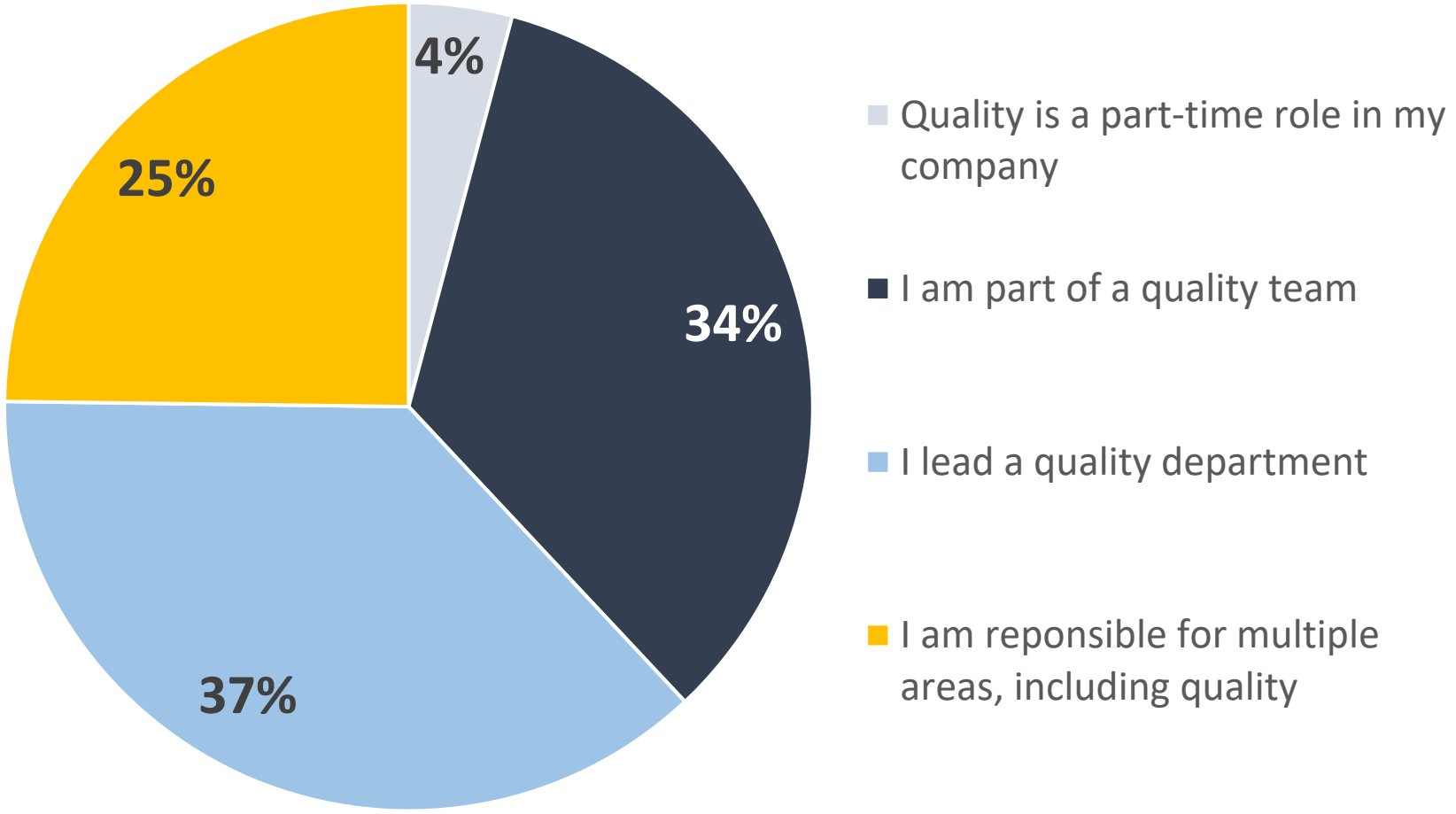
…where technology fits into their world.

Who did we talk to?

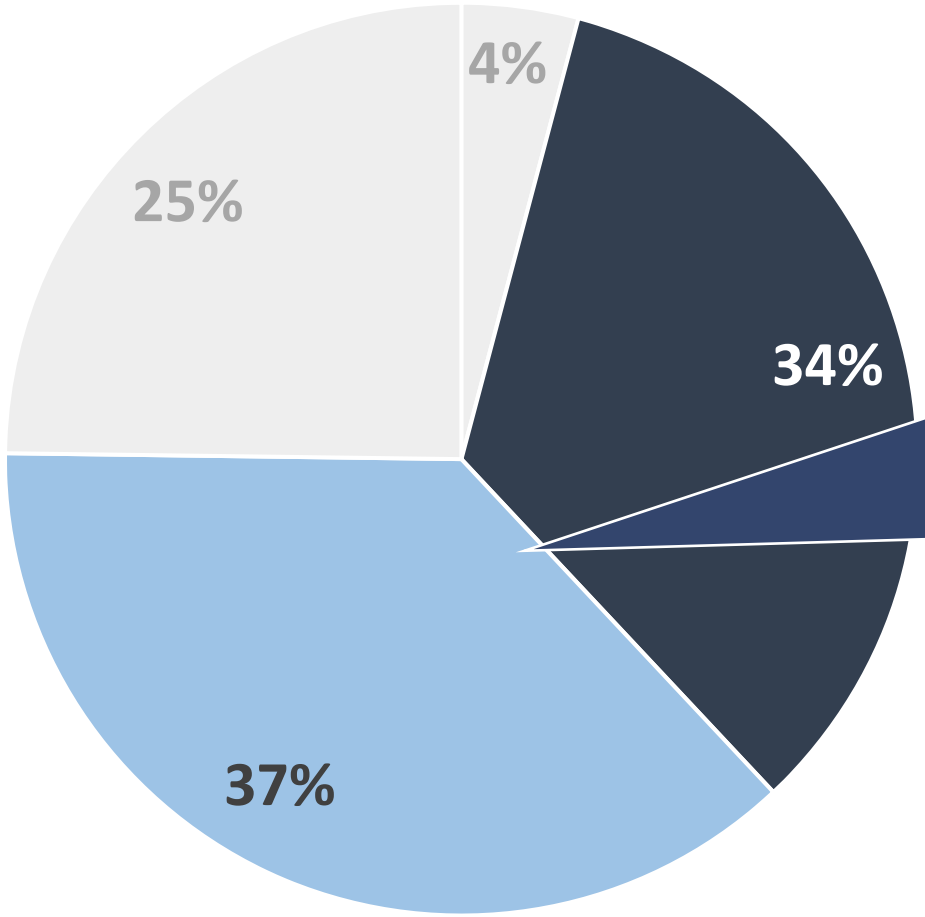
What is the size of your organization (in revenue)?



What does the quality role look like?



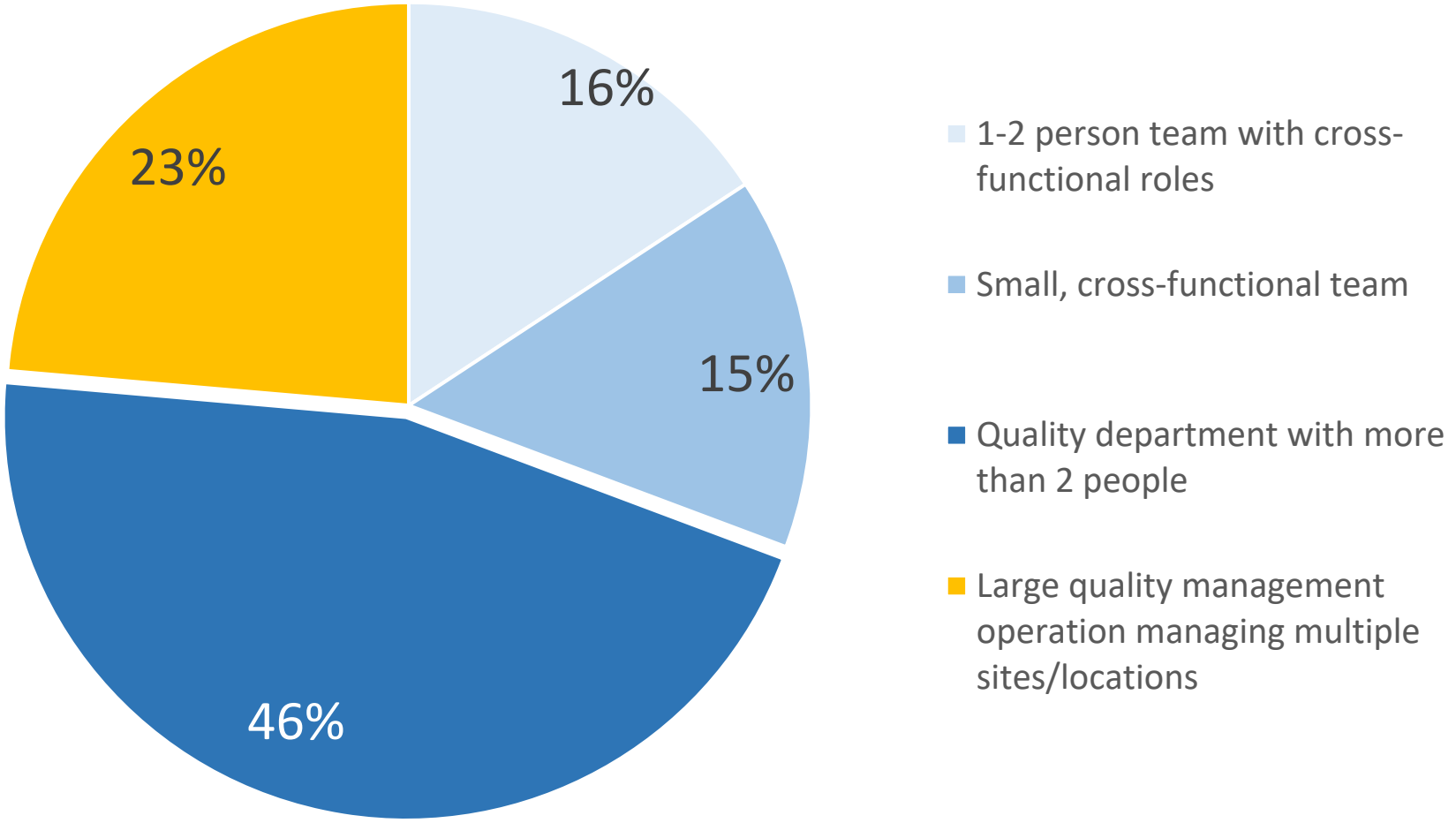
What does the quality role look like?



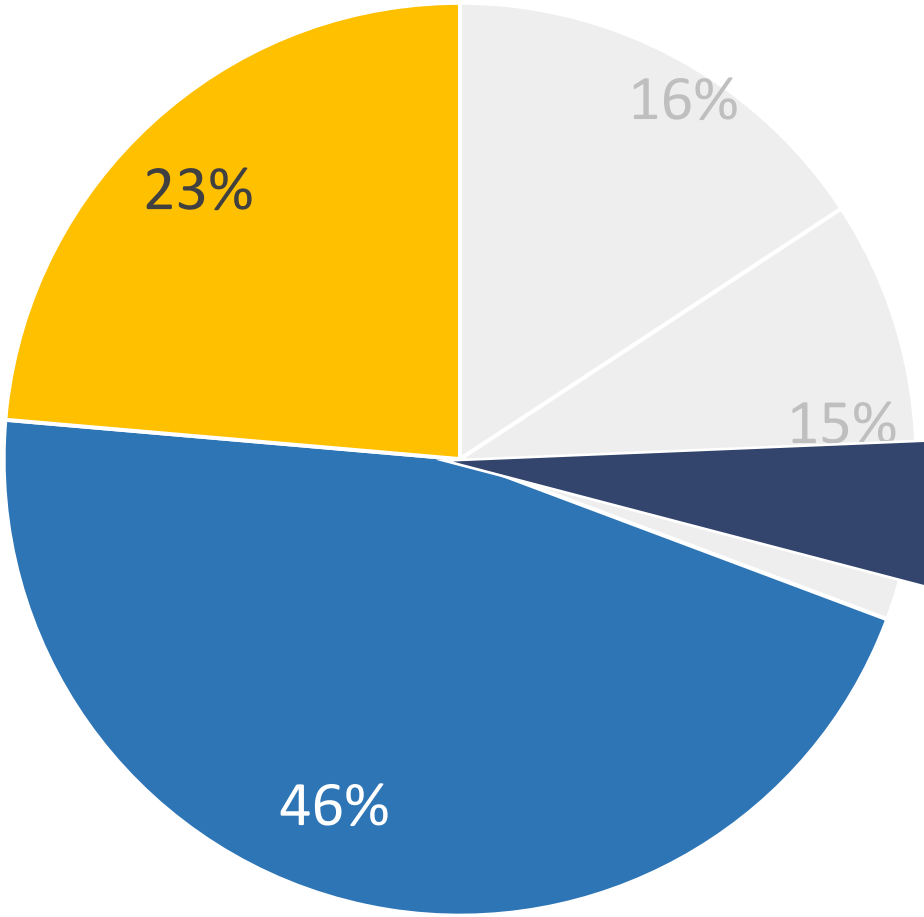
Quality is (thankfully) a dedicated role in most organizations:

There are still some smaller “shops”, but the majority are focused on the Quality management effort.

How are quality management teams structured?



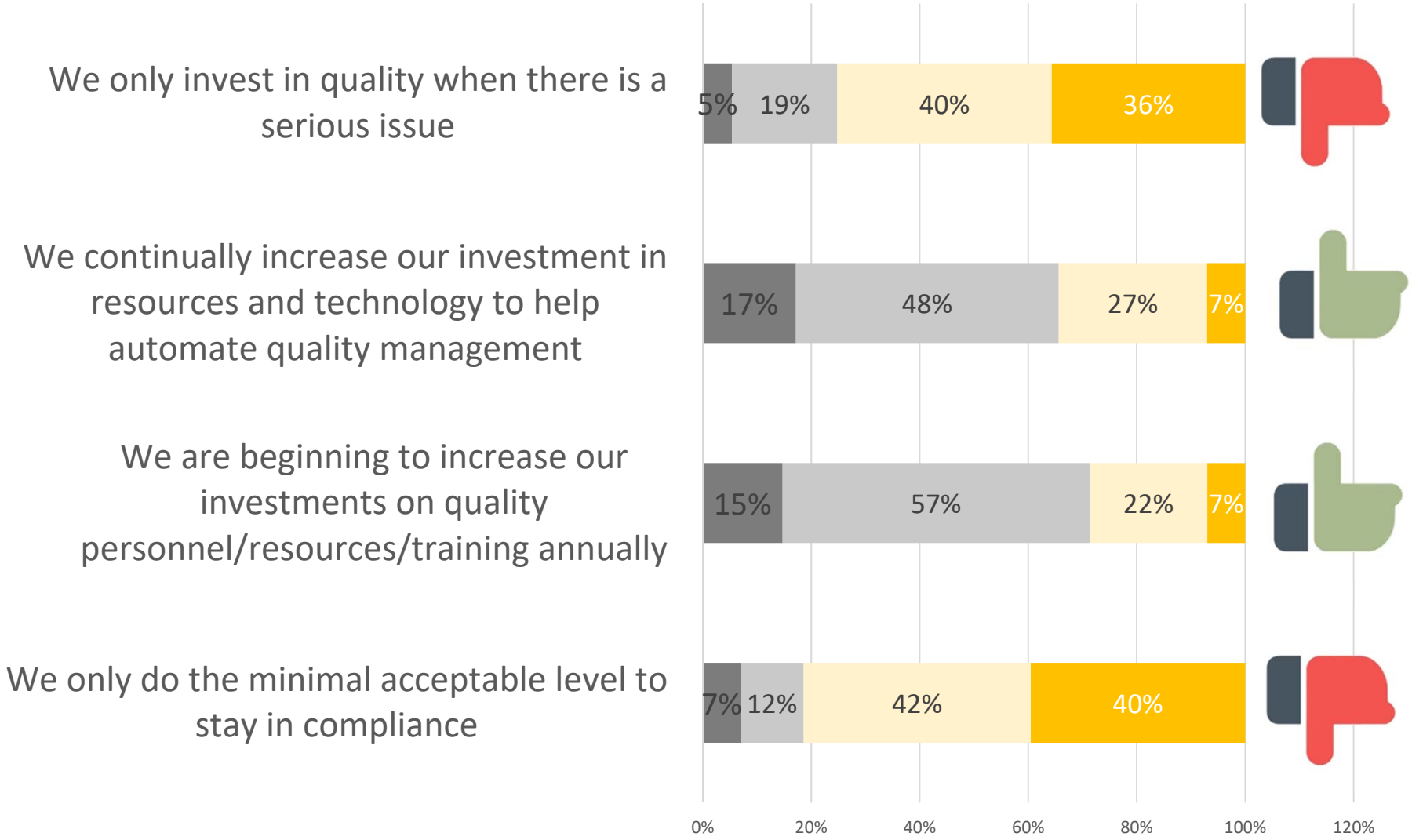
How are quality management teams structured?



Quality management teams are still largely dedicated in nature.

While we see a shift to more cross-function, the majority are still assigning a dedicated team to the business of quality.

How are they investing in quality management?



How are they investing in quality management?

We only invest in quality when there is a serious issue

We continually increase our investment in resources and technology to help automate quality management

65%

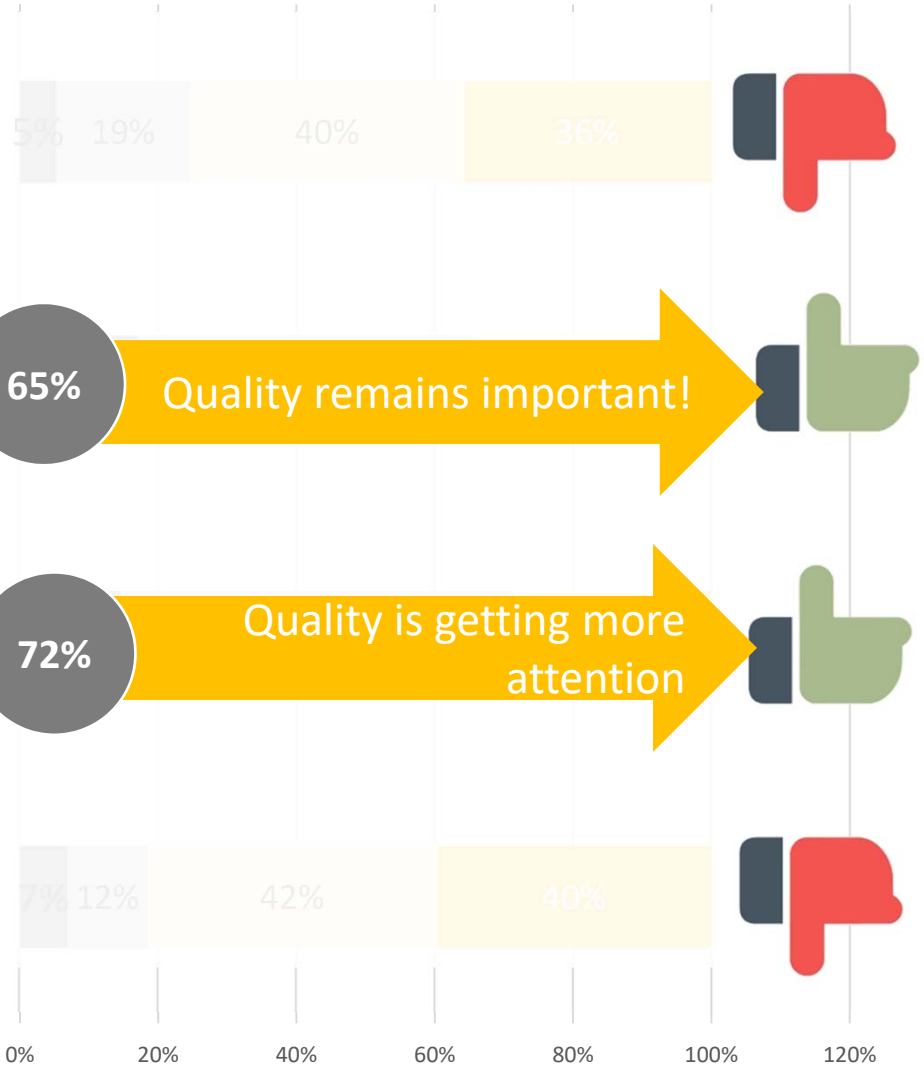
Quality remains important!

We are beginning to increase our investments on quality personnel/resources/training annually

72%

Quality is getting more attention

We only do the minimal acceptable level to stay in compliance



What's driving quality management?

What is the primary driver for quality management in your organization?

What's driving quality management?

What is the primary driver for quality management in your organization?

It's about getting your house in order and the culture of quality:

The majority of organizations are focused primarily on ensuring they are staying compliant with their standards and regulations, while satisfying the customer needs. Improvement and Operational Excellence can only come AFTER you have satisfied these elements.

Voice of the market on goals and drivers

"Our goal is around getting everyone in the organization to own the responsibility of product quality."

Supports the mindset shift!

"We are continually looking to improve employee knowledge in quality."

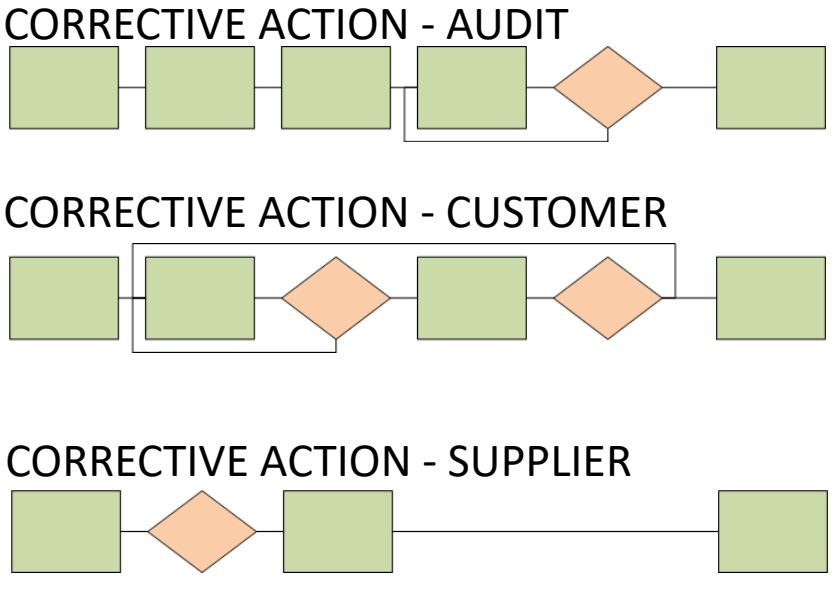
1. Flexibility to adapt to your processes

- Needs to adapt to your business processes, not the other way around
- Don’t settle for rigid or custom forms that make you change the way you work
- Look for configurability – ability to make changes as you see fit:
  - Forms
  - Workflows
  - Reports
  - Business Rules
  - Look and Feel
- A QMS needs to be configurable by the business user

Think Flexibility.

1. Flexibility

- Not every business process is the same
  - Variations in sites
  - Variations in processes
  - Variations in requirements
- A QMS should be able to adapt to the various types of processes

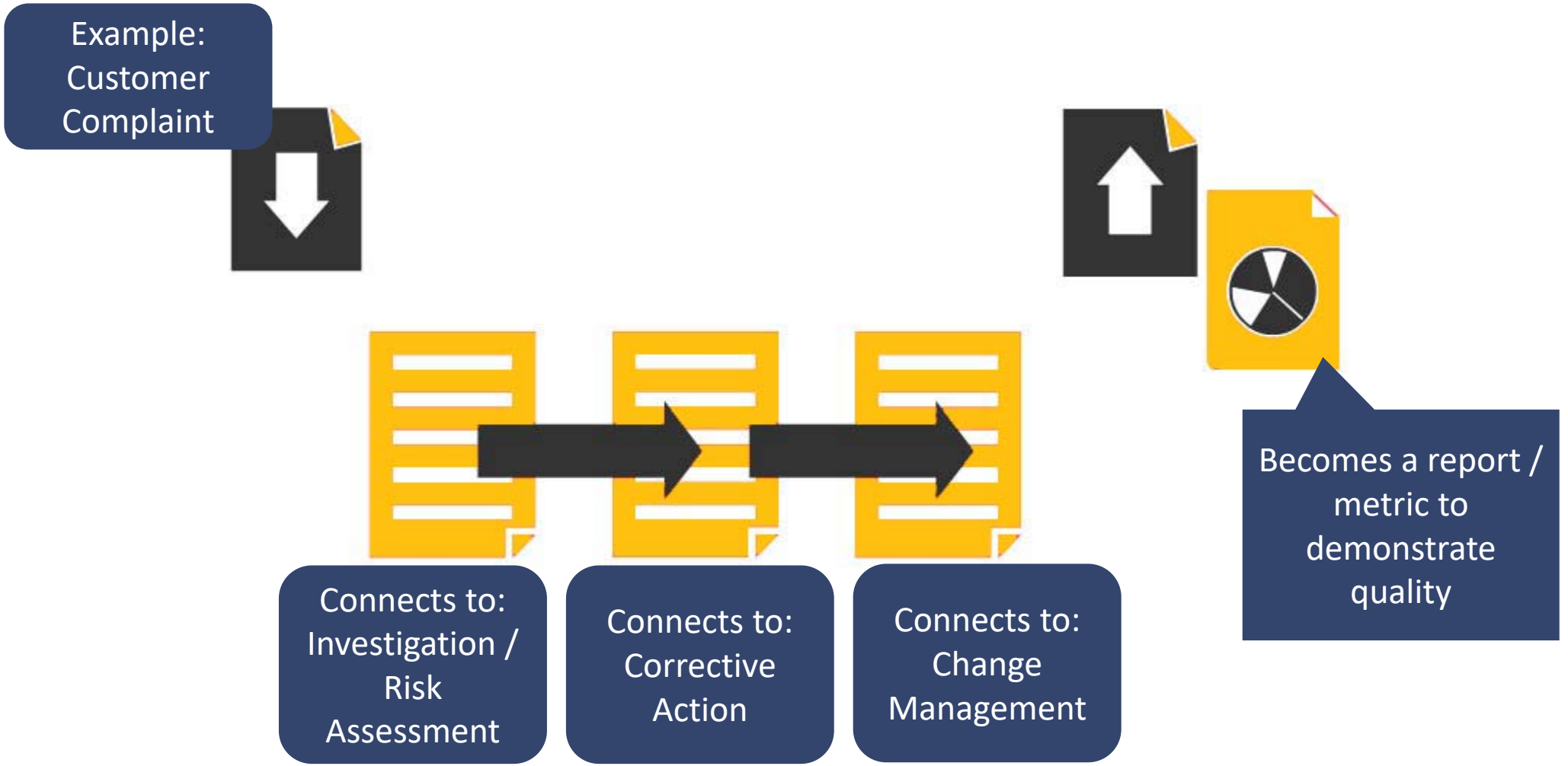


All are corrective action, but may have a different flow, depending on the process….

…cannot be rigid!

2. Traceability

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



2. Traceability

Processes need 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

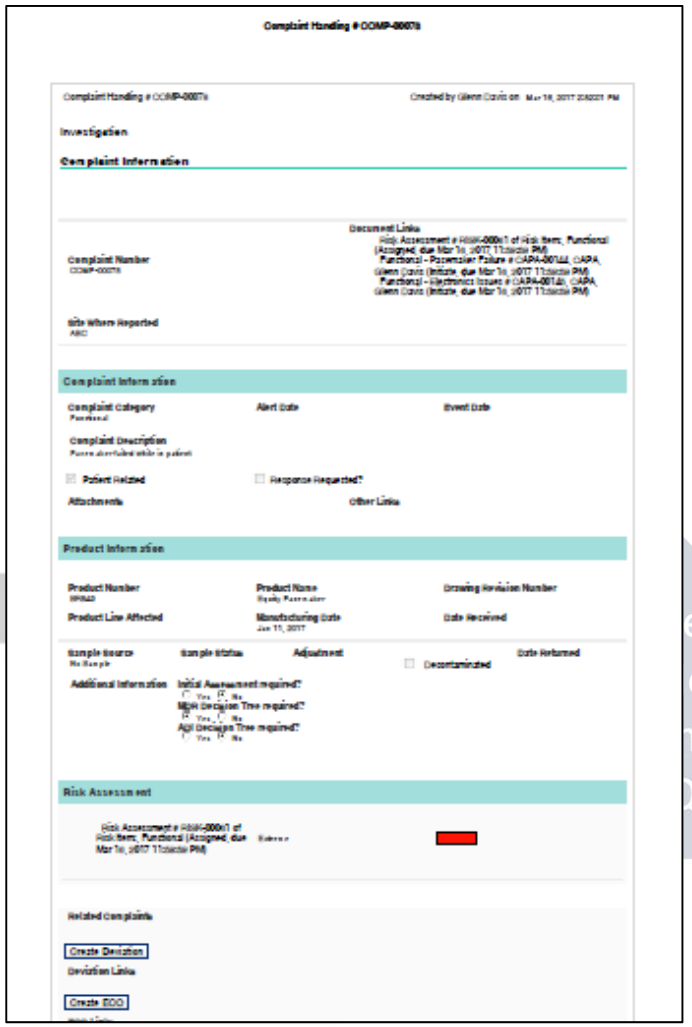
Provides a full report on the history of an occurrence, from event detection to event correction.

Result:

An Audit /Inspection ready state

Risk Assessment

nects to: orrective Action



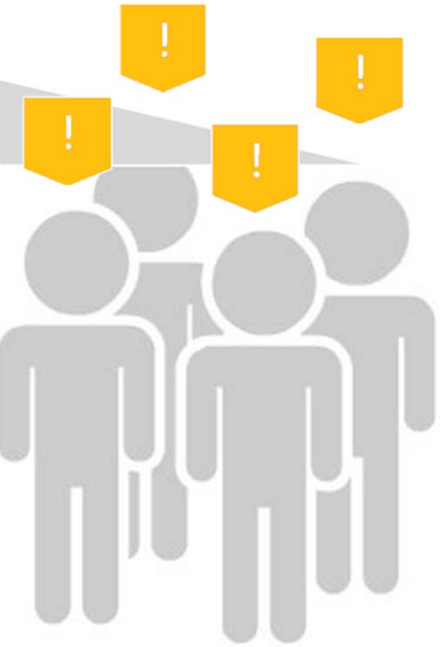
es a report / etric to nonstrate Quality

2. Traceability

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

Fostering traceability throughout the process….

3. Risk-based thinking approach



Section 5: Leadership

Provide leadership by encouraging a focus on quality

Promote the use of risk-based thinking.

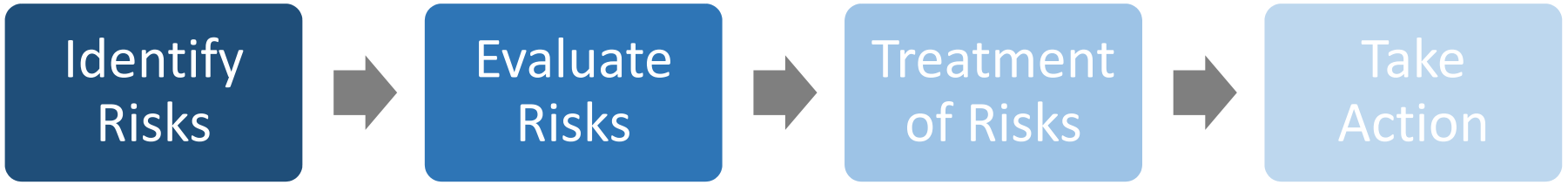
Section 6: Planning

Consider risks and opportunities when you plan your QMS

Plan how you're going to manage risks and opportunities

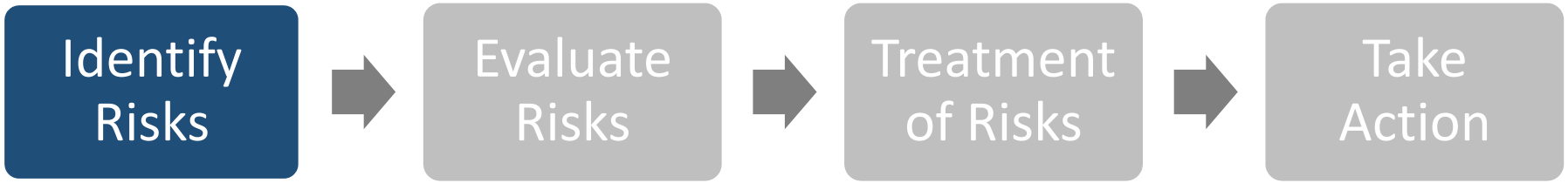
DISCLAIMER: The ISO view on risk is SIMPLY STATED. "Use Risk-based thinking" to manage and plan…but what does that really mean? Broad and simple–lots of interpretation!

3. Risk-based thinking approach:
Planning your QMS with risk in mind

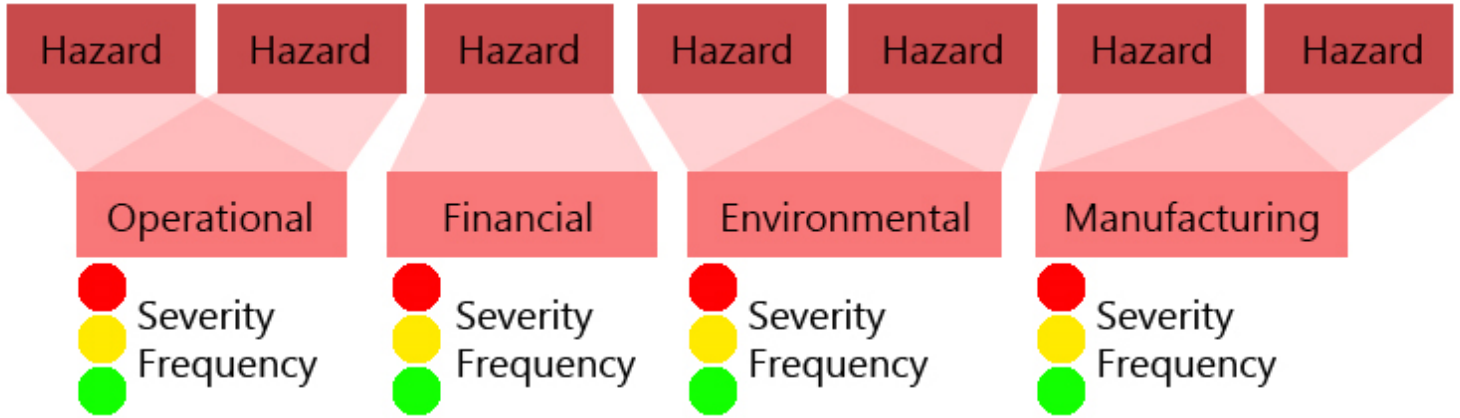


- Identify risks and opportunities to influence QMS performance
- Determine how you're going to measure those risks
- Build risk treatment options
- Define actions to address these risks

3. Risk-based thinking approach:
Planning your QMS with risk in mind



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



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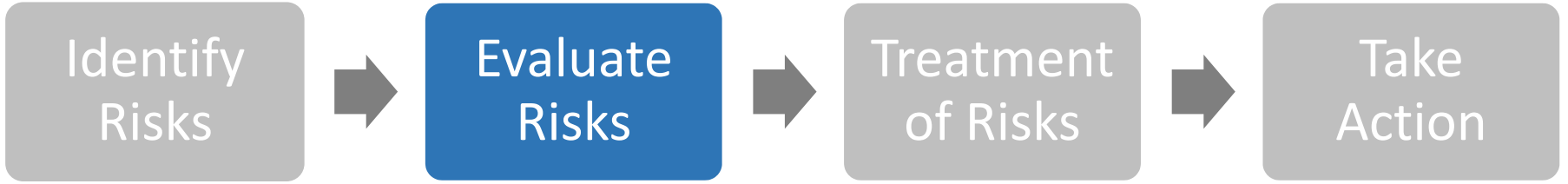
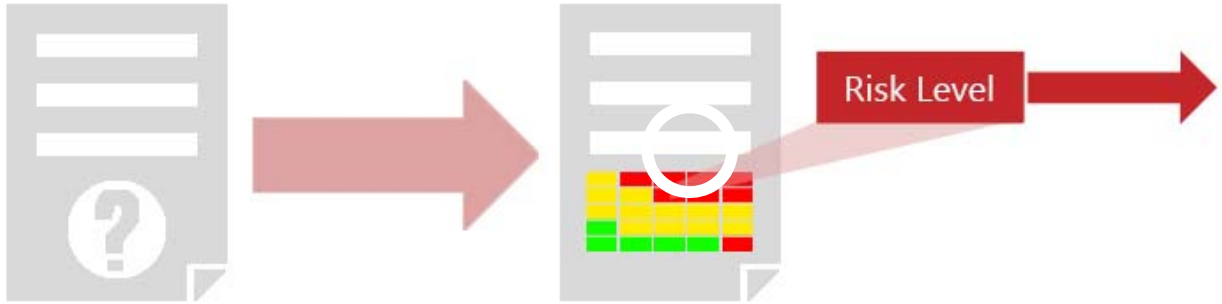


- Evaluate how to handle the risk
- Risk Assessment
  - Should be repeatable, objective
  - Should be backed by REAL-WORLD DATA
- Quantitative means to build a risk assessment



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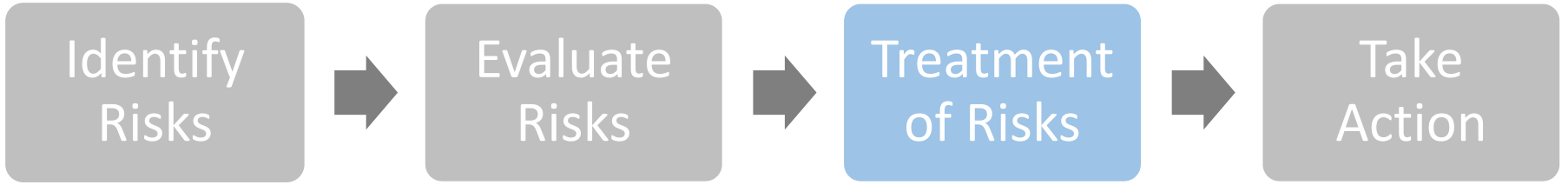
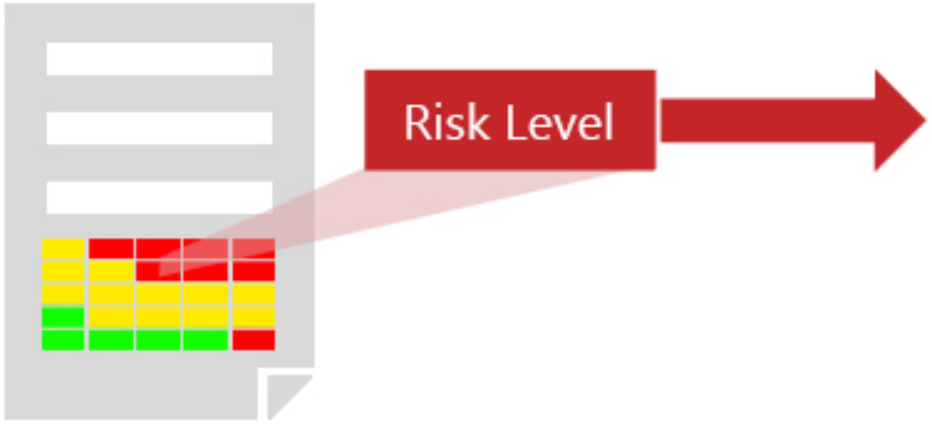
Planning your QMS with risk in mind

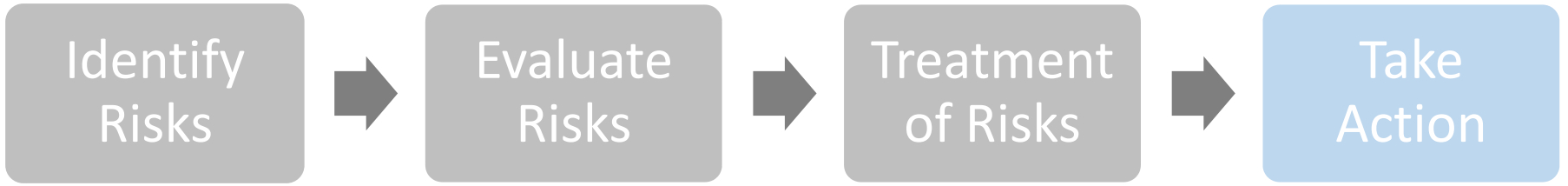


- We know the risk….how do we handle it?



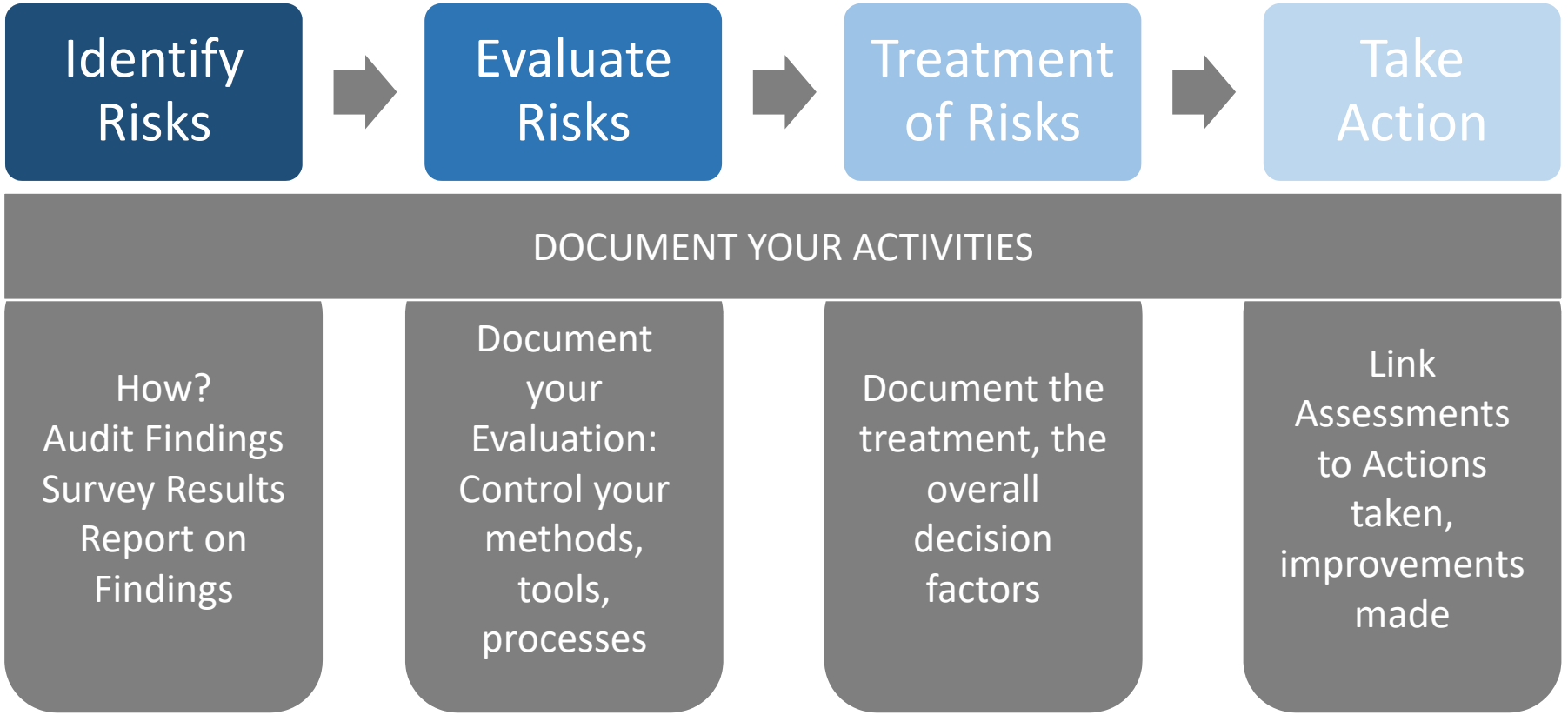
Acceptance: “Worth it”
Reduction: “Mitigation”
Compensation: “Insurance”
Transference: “Move it”
Avoidance: “Stop it”

3. Risk-based thinking approach:
Planning your QMS with risk in mind



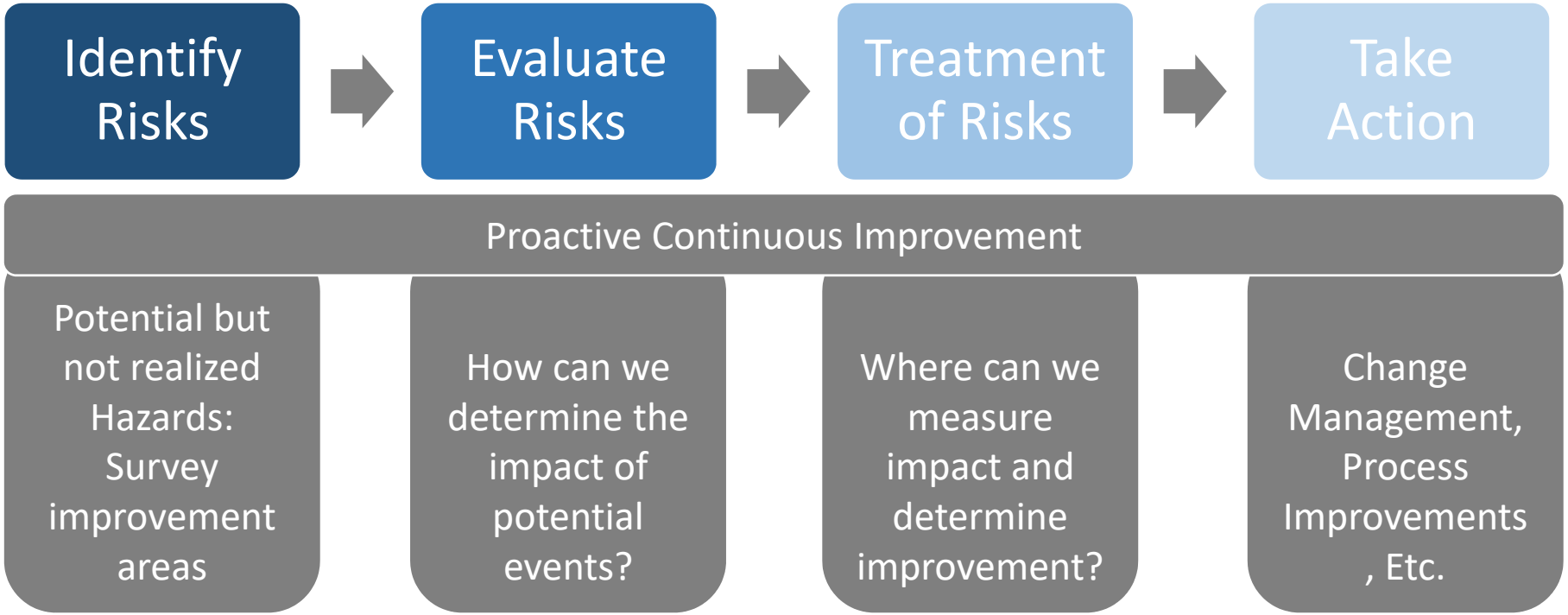
- Take Action: Create visibility and control the risk

3. Risk-based thinking approach:
Planning your QMS with risk in mind



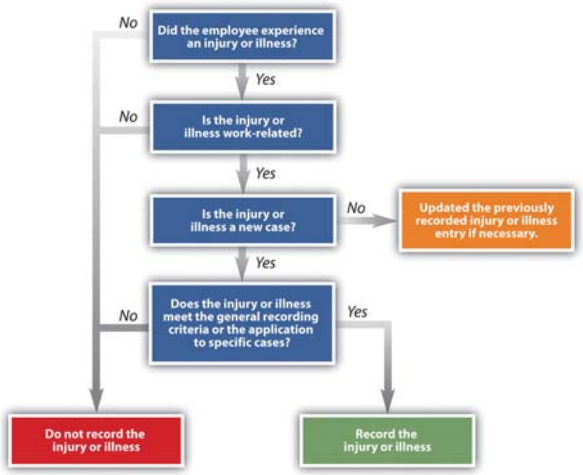
- Document the process in order to have traceability.

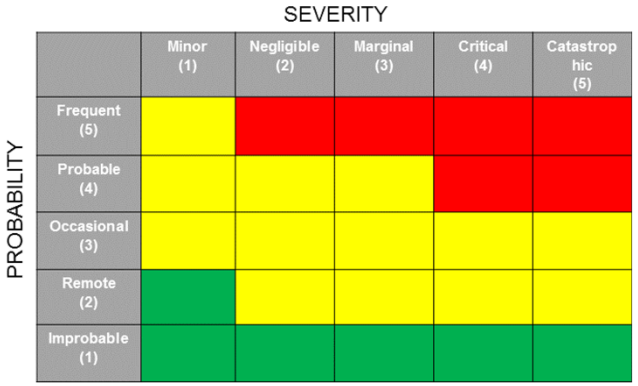
3. Risk-based thinking approach:
Planning your QMS with risk in mind

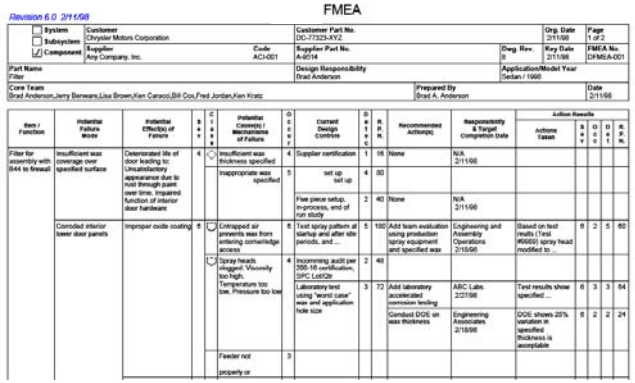


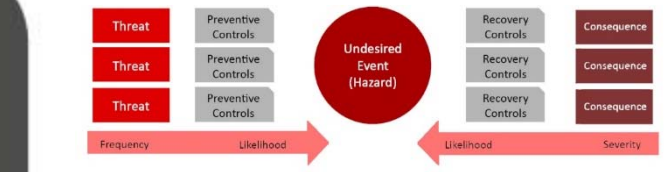
- It's not all for just the risks! Identify opportunities too!

Common tools for risk management treatment





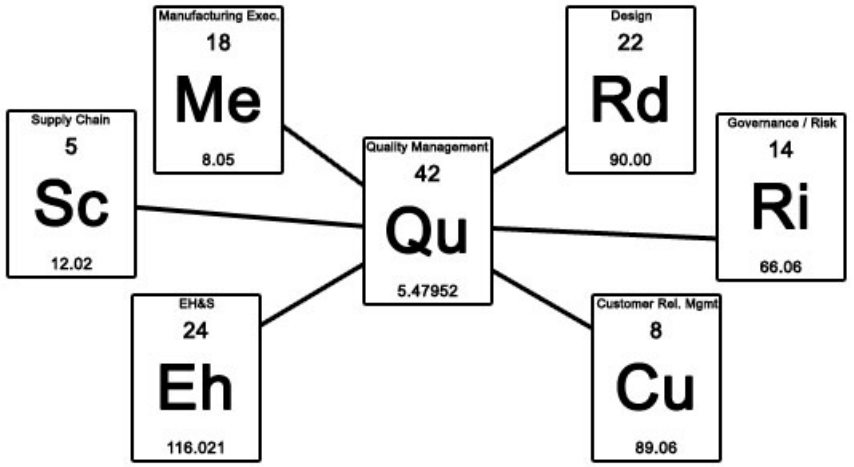




PDCA Cycle

4. Integration: internal and external

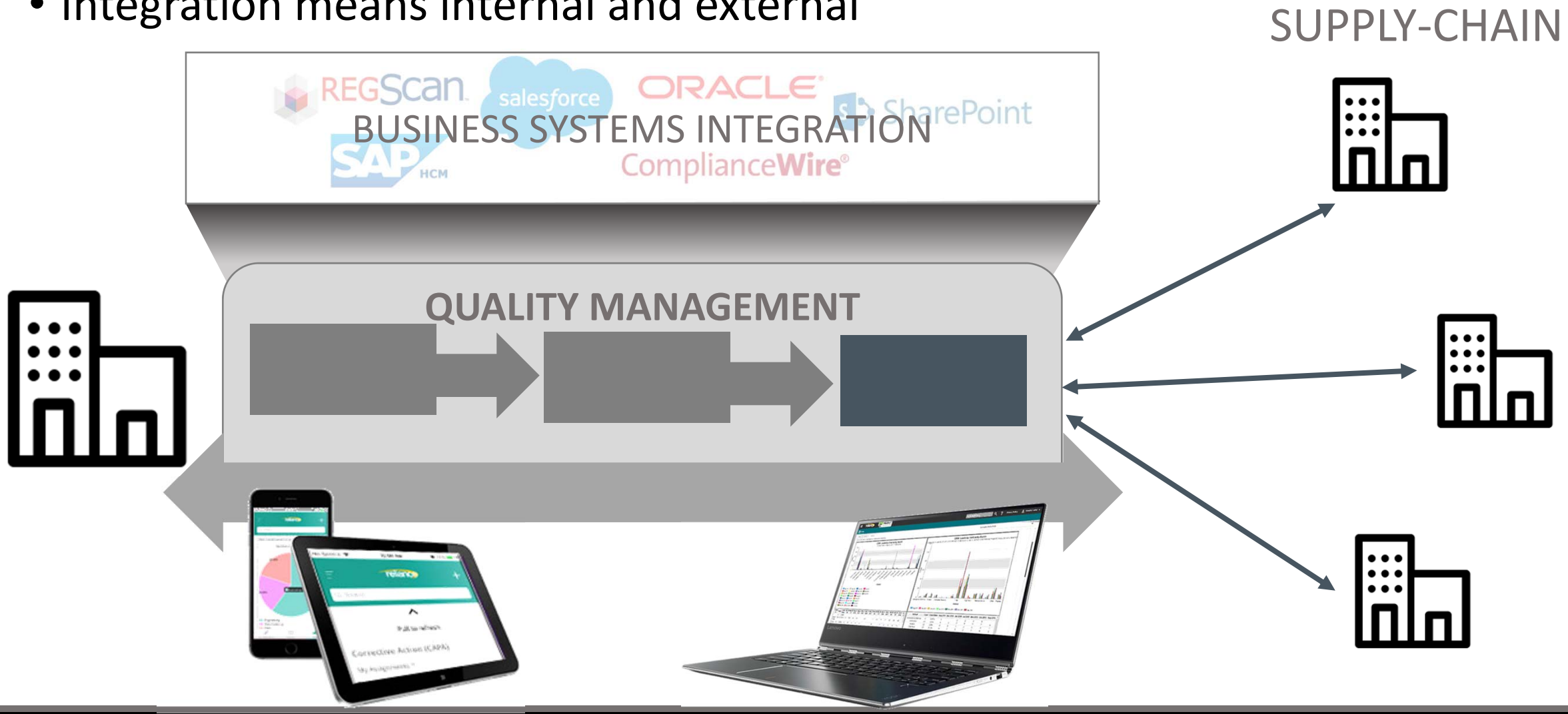
- We no longer live in information silos – business systems need to talk to each other
- Can the system integrate with ERP, MRP, SCM, CRM, PLM….ASAP?
- Look for more than just “basic” integration
  - Lookup data
  - Push data from QMS to other systems
  - Interact with other business systems on an operational level



Can the system integrate with all other business elements?

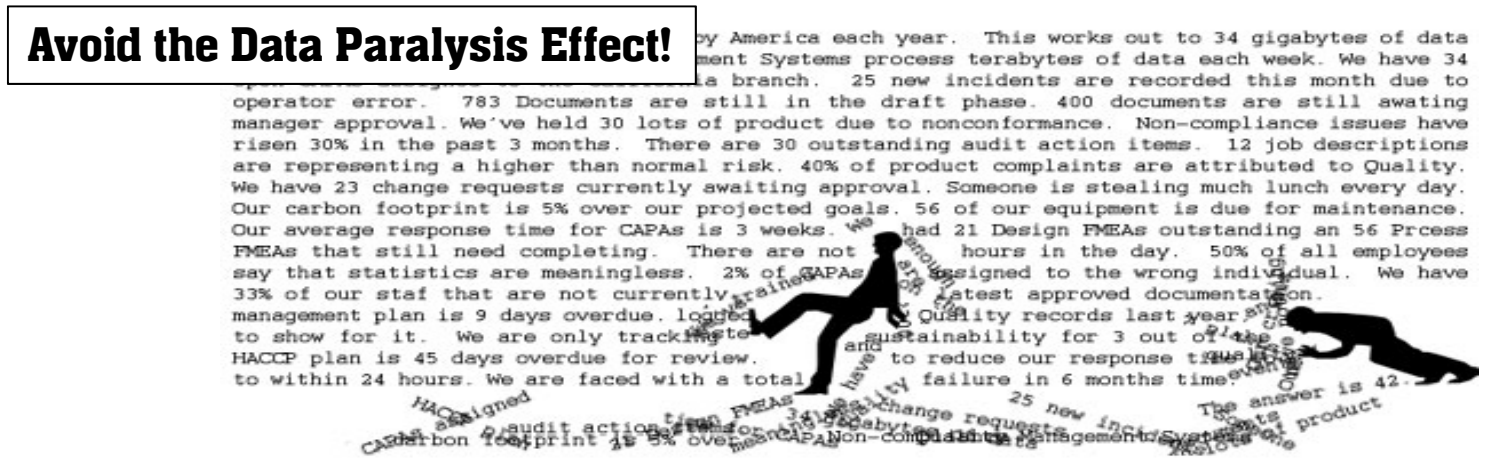
4. Integration: internal and external

- Integration means internal and external



5. Reporting

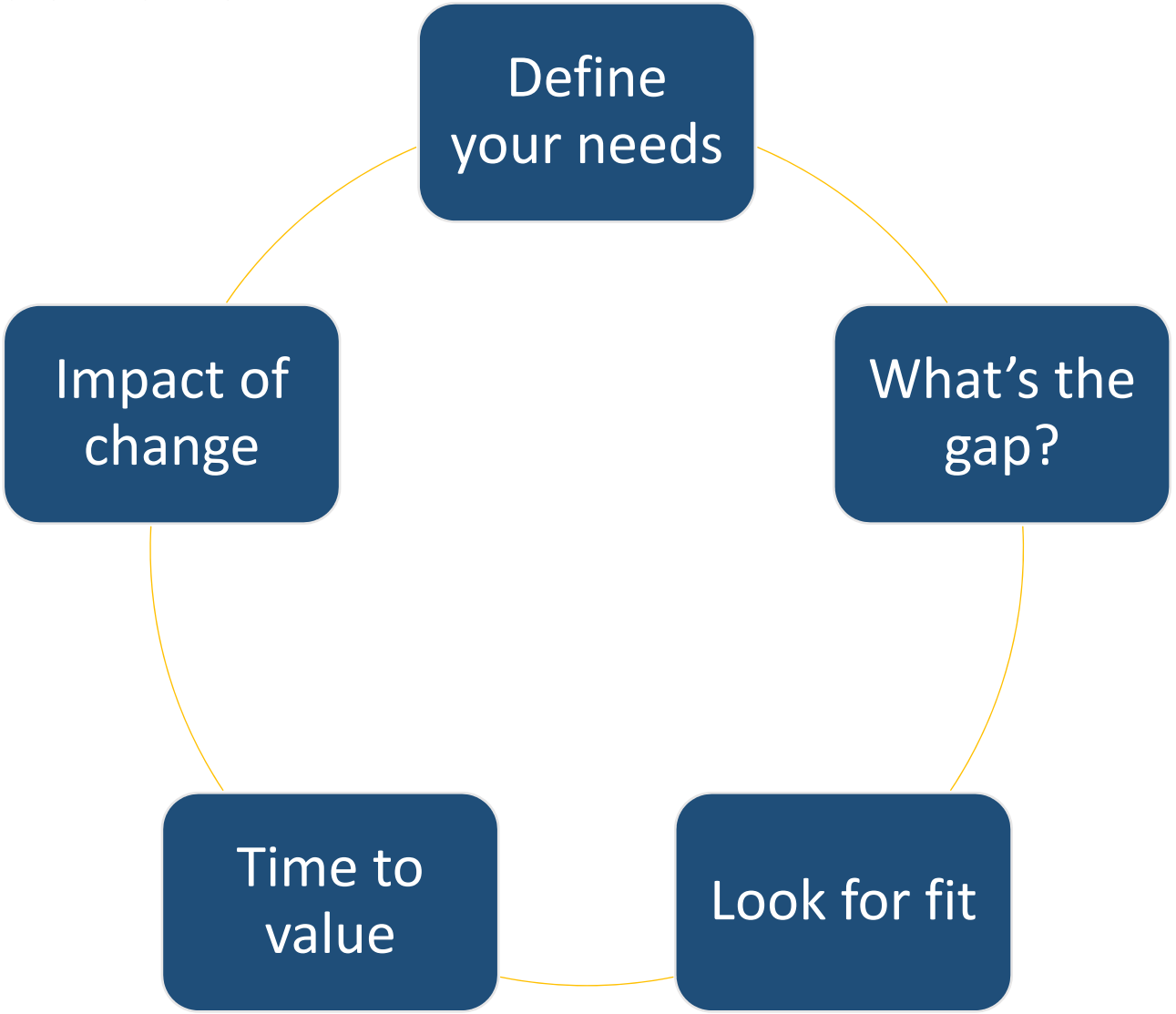
- QMS software generates an enormous amount of data
- Need to avoid “Data Paralysis”
- Searching and reporting tools are a key component
  - Quickly search for records
  - Run scheduled and ad-hoc reports
  - Have built-in reporting
- Biggest draw in QMS is the ability to pull a report within minutes of when management asks for it



5. Reporting

- What to look for:
  - Built-in functionality, as well as integrated functionality
  - Organization of your data
  - Search for exceptions!
  - Scheduled templated reports
  - User-friendly

Recommendations



Summary

- The market is driving quality as a strategic element
- Companies are looking for ways to streamline to a culture of quality
- There are several areas that make a QMS valuable:
  - Flexibility
  - Traceability
  - Risk Management
  - Integration
  - Reporting
- Do your homework and follow a process for QMS selection