

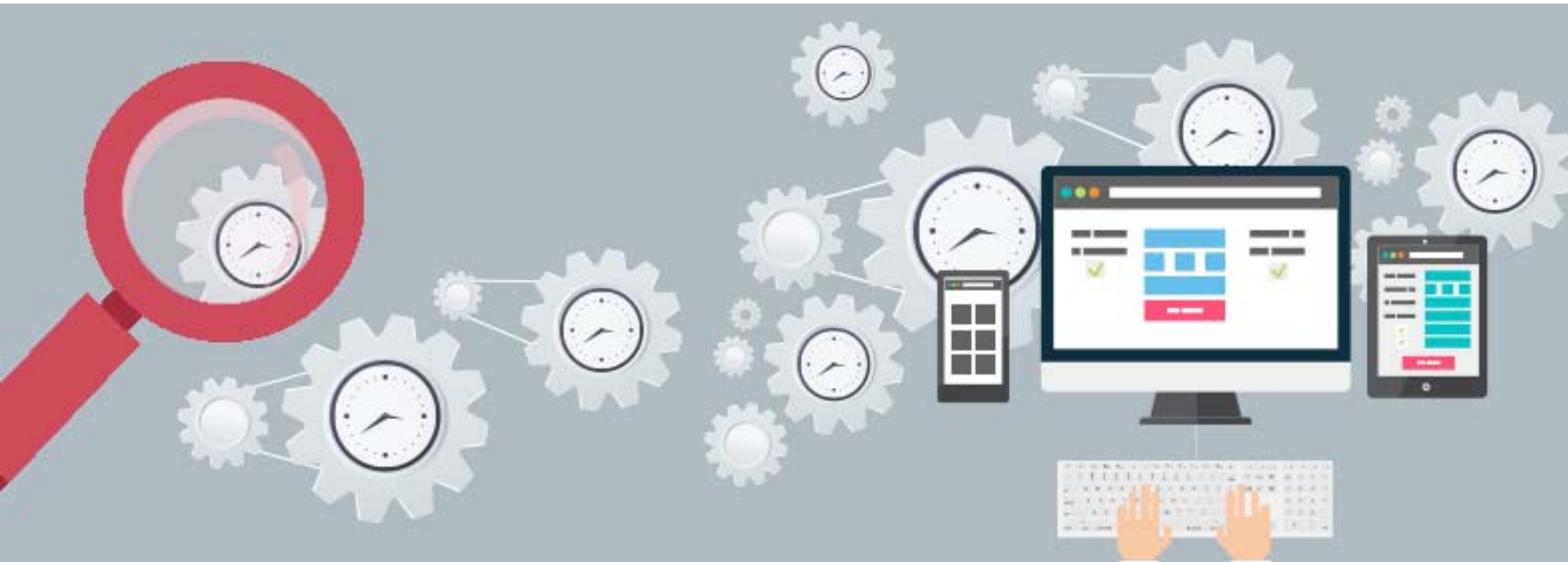


5 Things Your Quality Management System Could Use Right Now (and 5 Ways to Get It)

Tim Lozier, EtQ

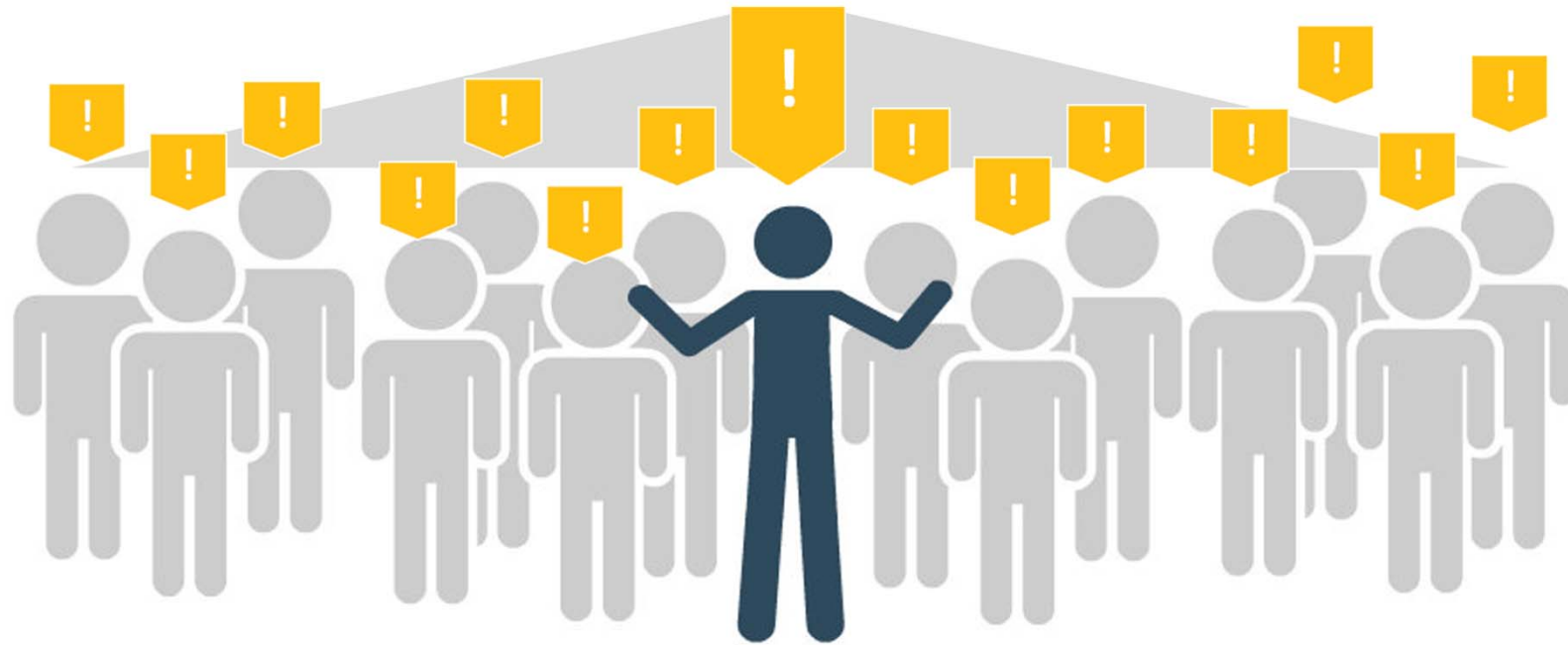
Agenda

- 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?

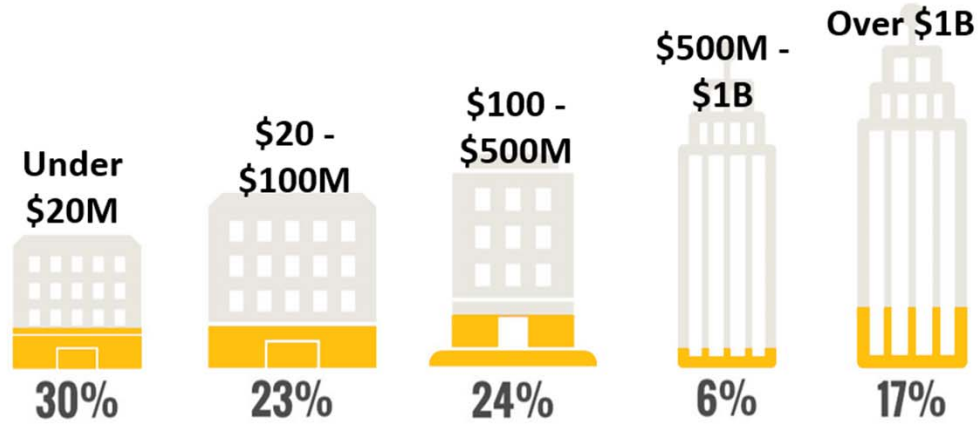
...We asked the market about their mindset on Quality Management...

...specifically around who they are,
what drives them, and...

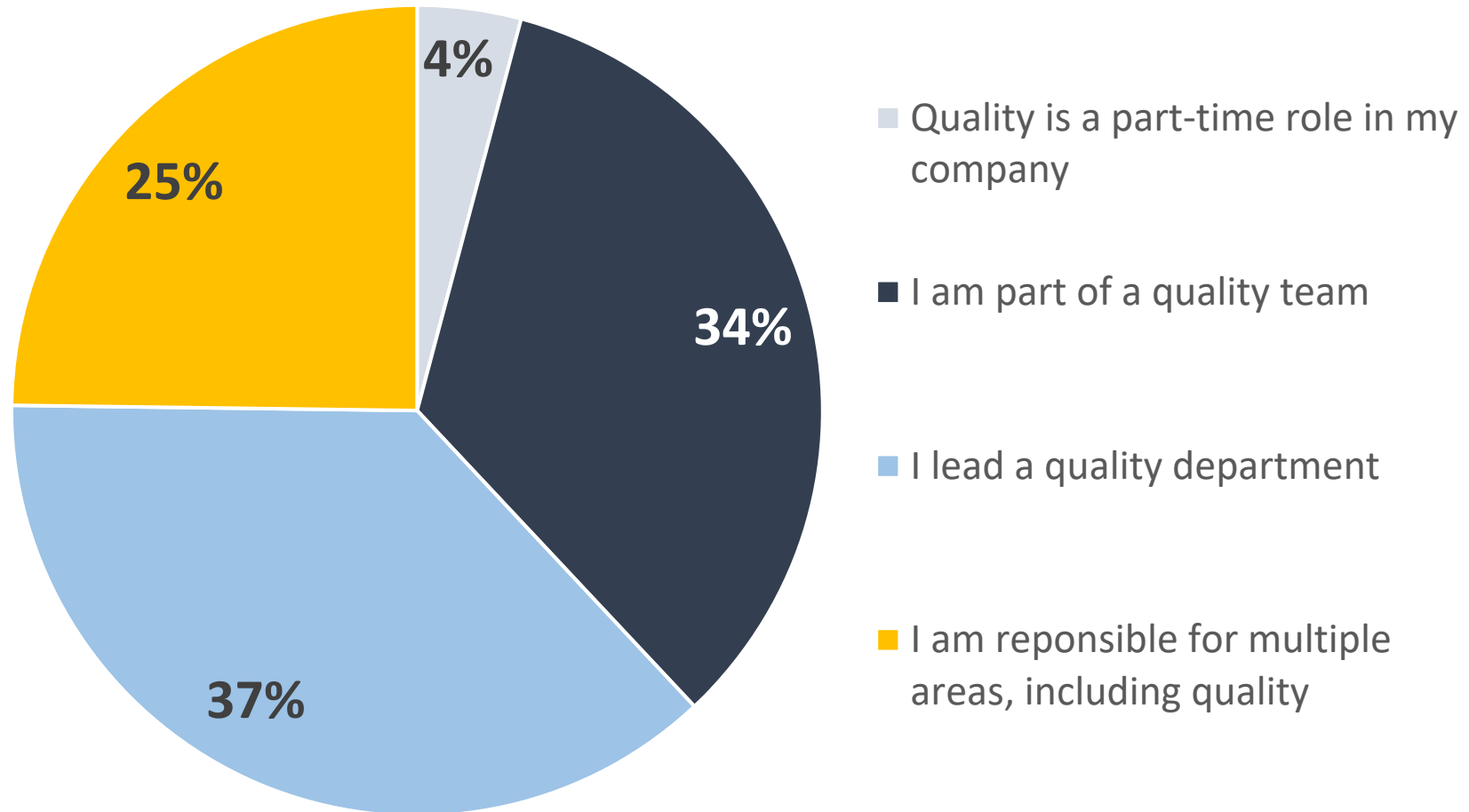
...where technology fits into their world.

Who did we talk to?

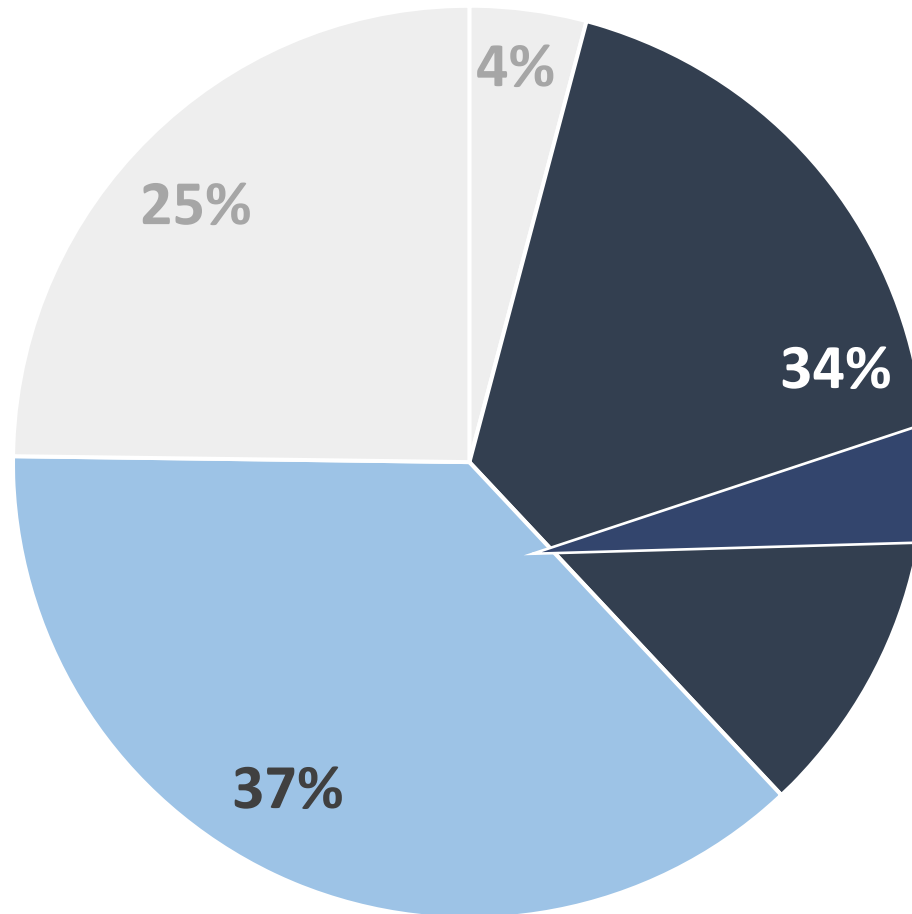
What is the size of your organization (in revenue)?



What does the quality role look like?



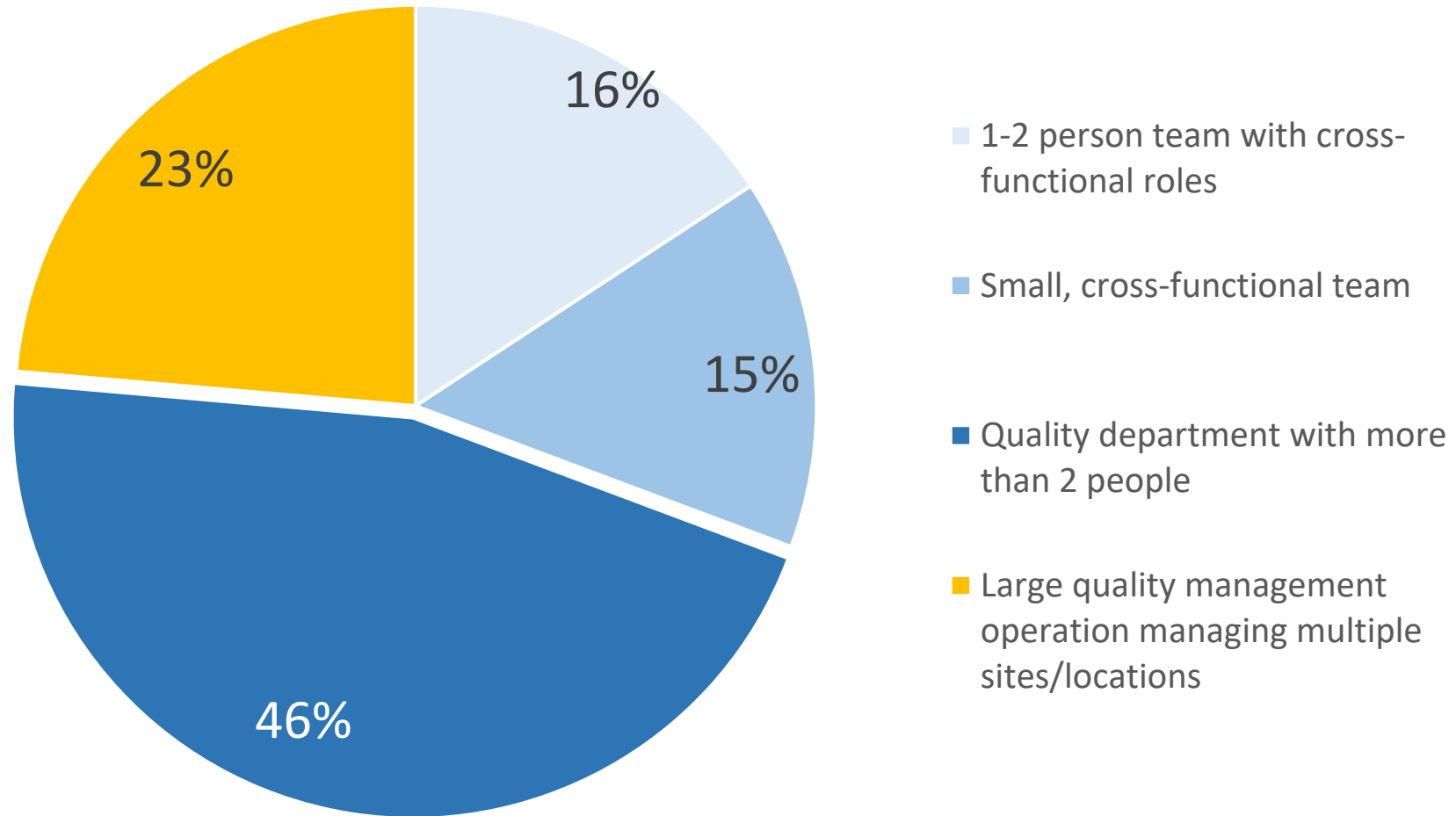
What does the quality role look like?



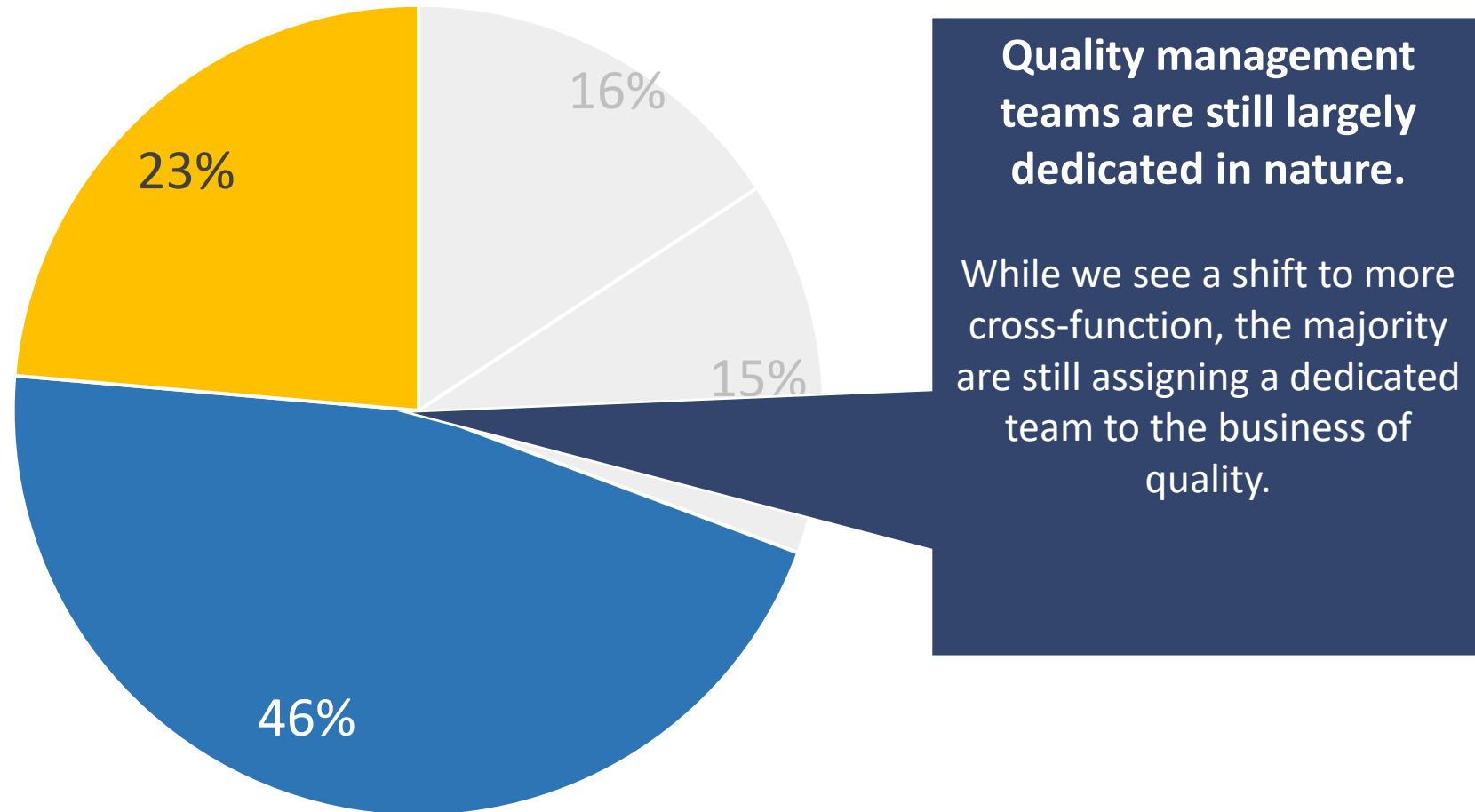
Quality is (thankfully) a dedicated role in most organizations:

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

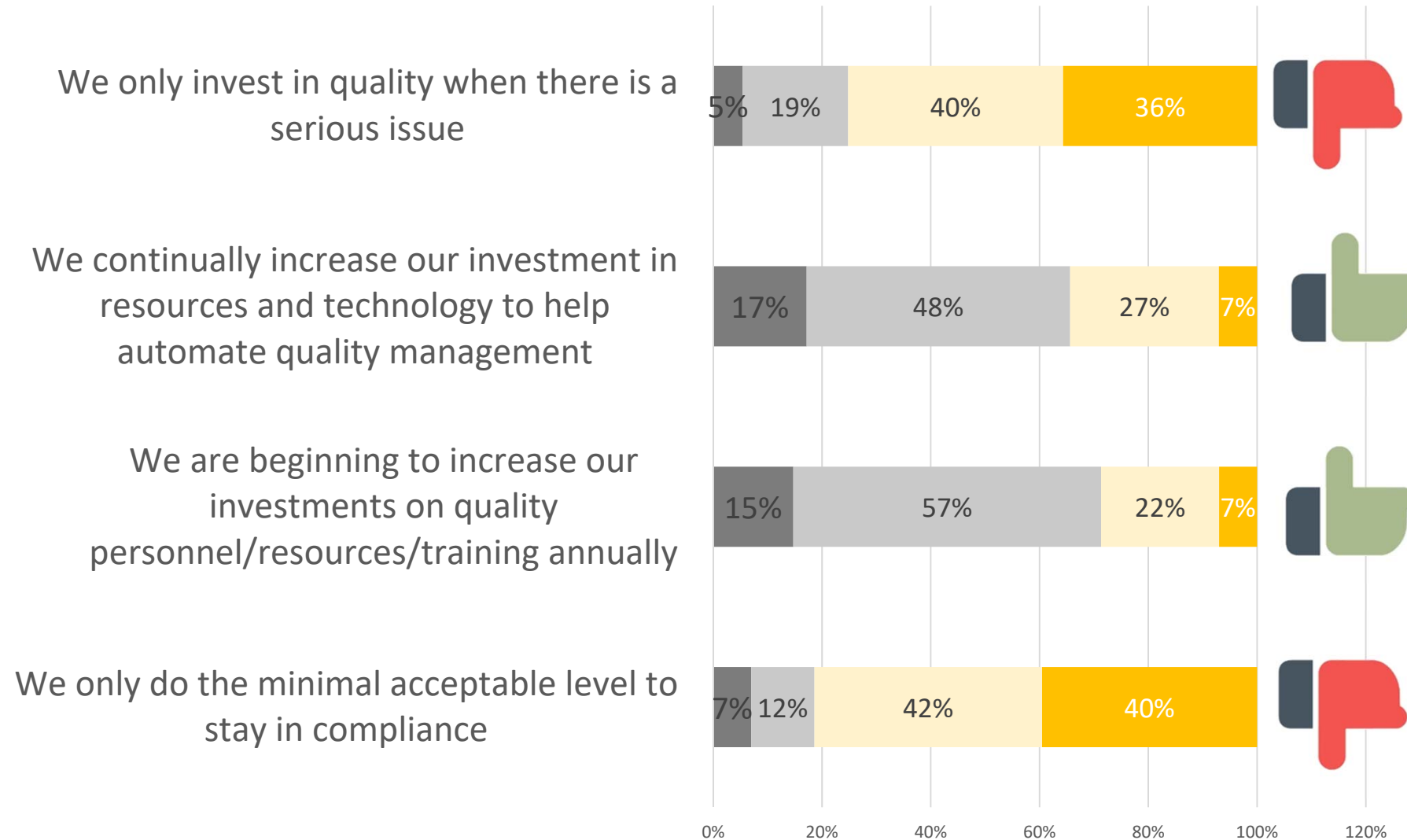
How are quality management teams structured?



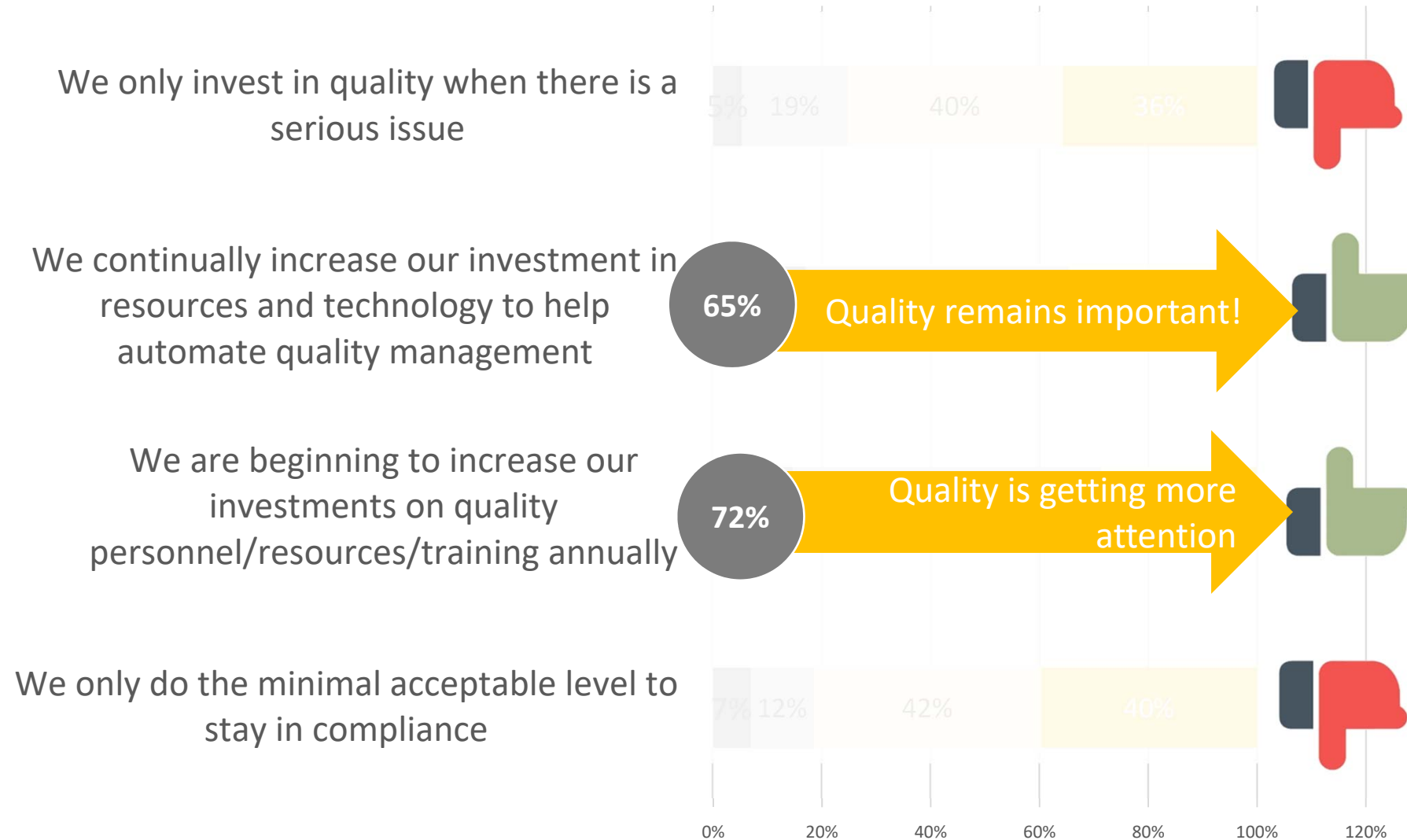
How are quality management teams structured?



How are they investing in quality management?



How are they investing in quality management?



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?



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

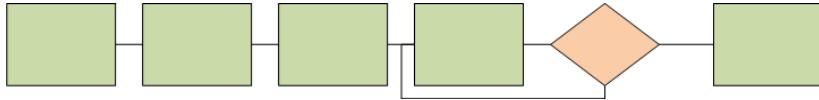
Think Flexibility.



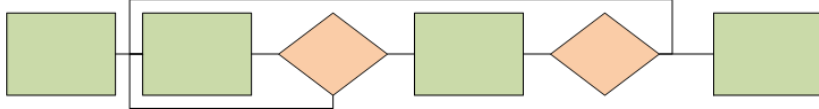
1. Flexibility

- 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

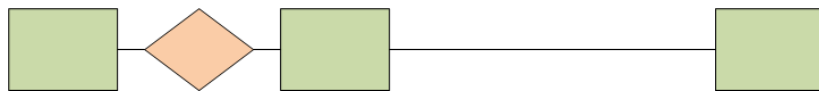
CORRECTIVE ACTION - AUDIT



CORRECTIVE ACTION - CUSTOMER



CORRECTIVE ACTION - SUPPLIER

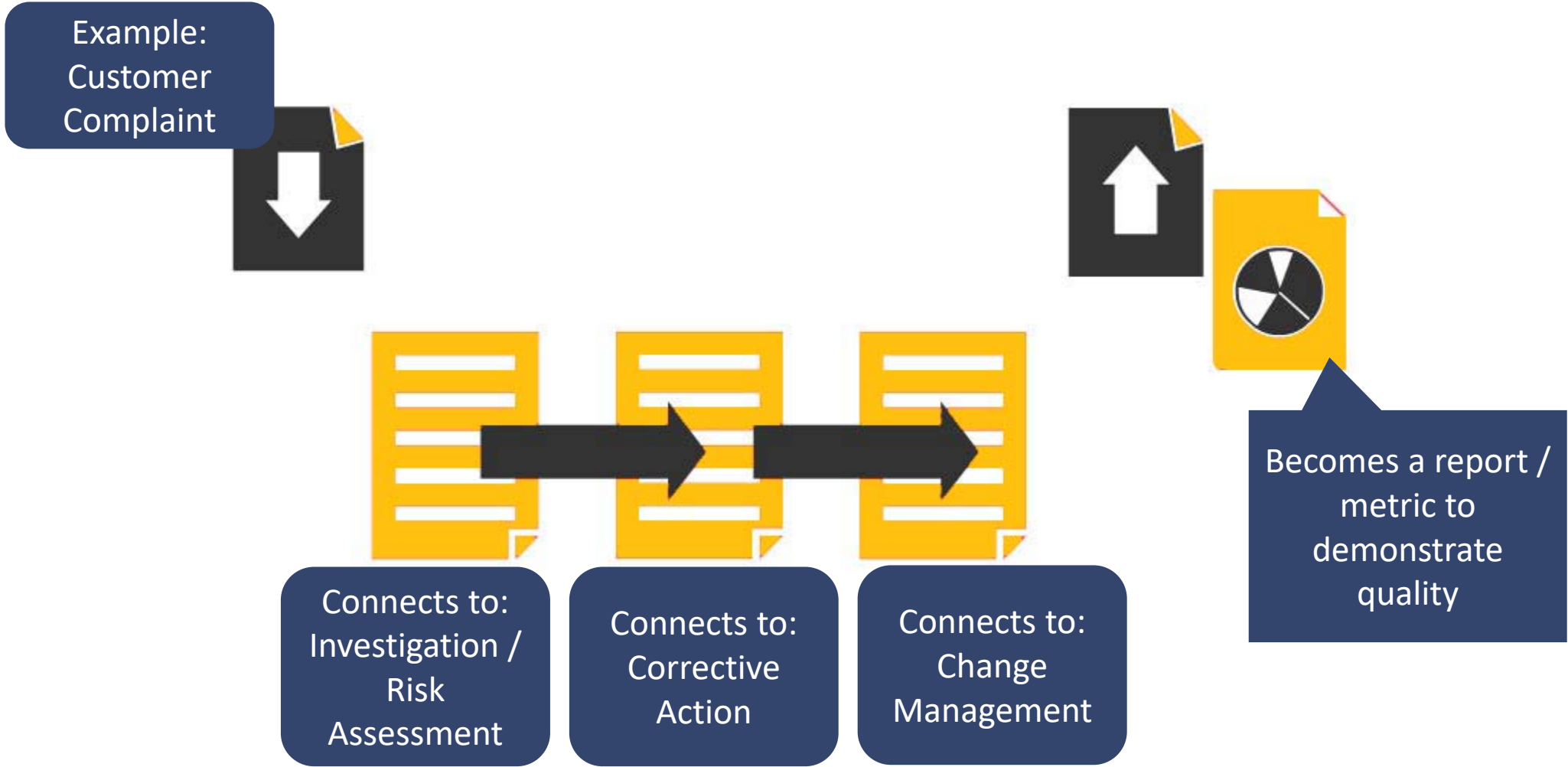


All are corrective action, but may have a different flow, depending on the process....

...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 connects to: Corrective Action

The screenshot displays a 'Complaint Handling # COMP-00076' record. It includes sections for 'Investigation', 'Complaint Information', 'Product Information', and 'Risk Assessment'. The 'Complaint Information' section contains fields for Complaint Number (COMP-00076), Site Where Reported (ABC), Complaint Category (Functional), and Complaint Description (Purse distributed with a patient). It also includes checkboxes for 'Point Held?' and 'Response Requested?'. The 'Product Information' section lists Product Number (19822), Product Name (Purse, Pura-Joy), Drawing Revision Number, Product Line Affected, Manufacturing Date (Jun 11, 2017), and Date Received. The 'Risk Assessment' section shows a risk level of 5 with a red indicator. At the bottom, there are buttons for 'Create Deviation' and 'Create ECO'.

Provides a report /
Metric to
Demonstrate
Quality

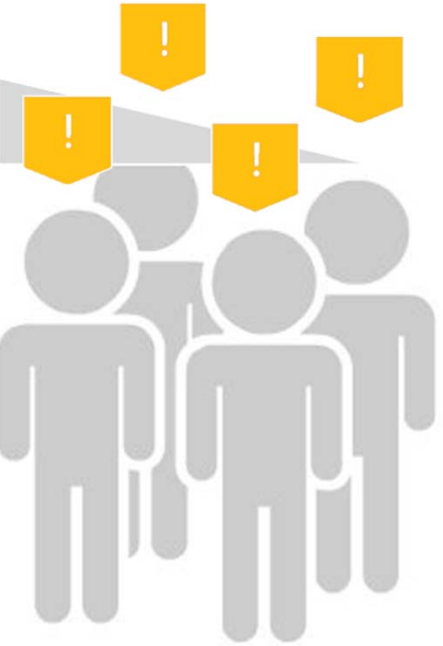
2. Traceability

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.

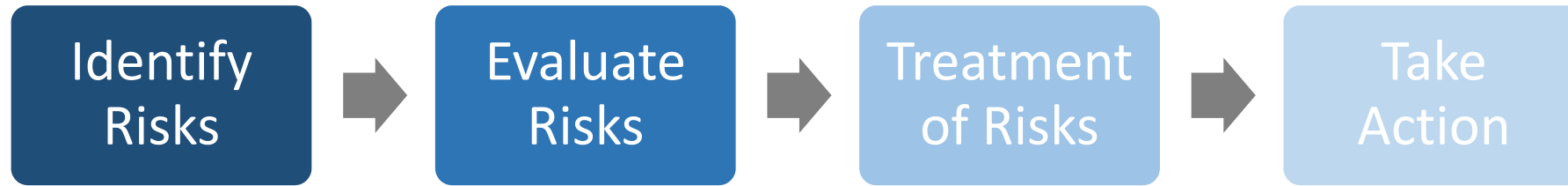
Section 6: Planning

Consider risks and opportunities when you plan your QMS

Plan how you're going to manage risks and opportunities

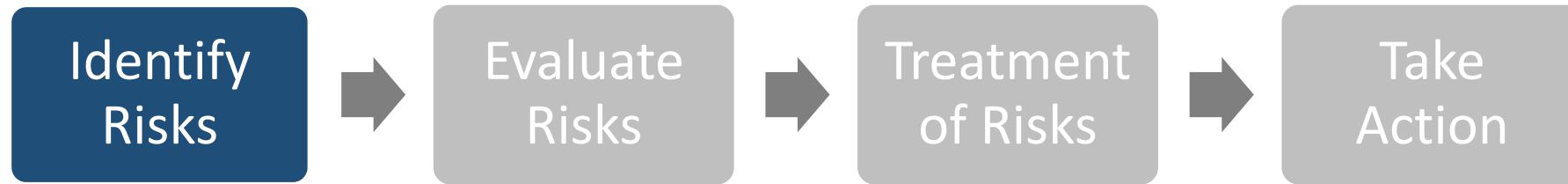
DISCLAIMER: The ISO view on risk is SIMPLY STATED. "Use Risk-based thinking" to manage and plan...but what does that really mean? Broad and simple—lots of interpretation!

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

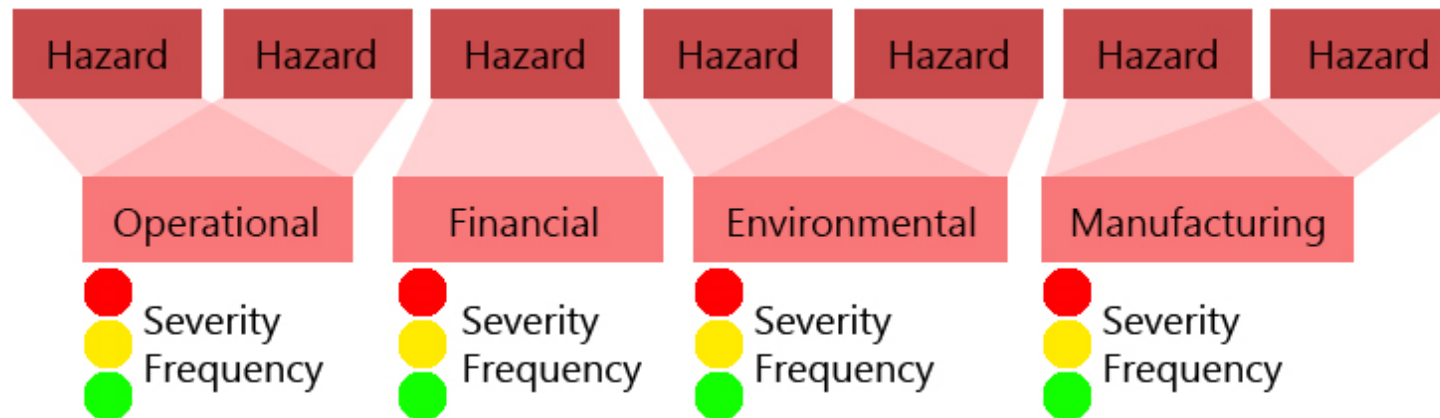


- Identify risks and opportunities to influence QMS performance
- Determine how you're going to measure those risks
- Build risk treatment options
- Define actions to address these risks

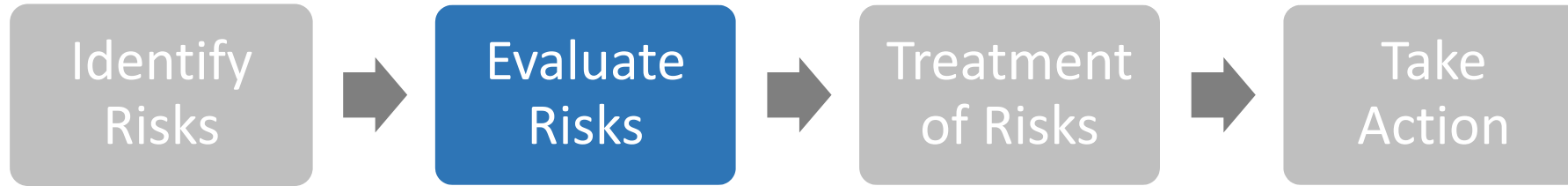
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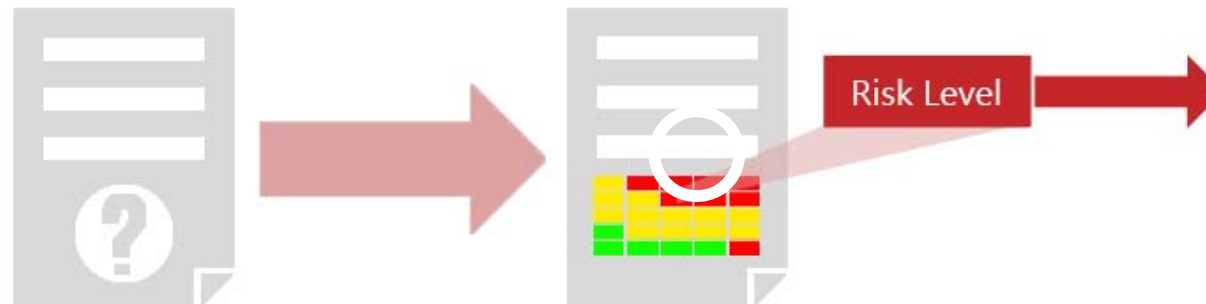
- How to start identifying risks?
 - Survey your operations
 - Audit, survey, collect, analyze



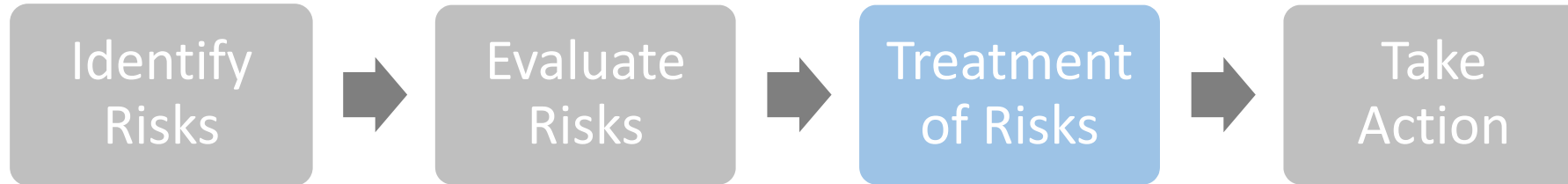
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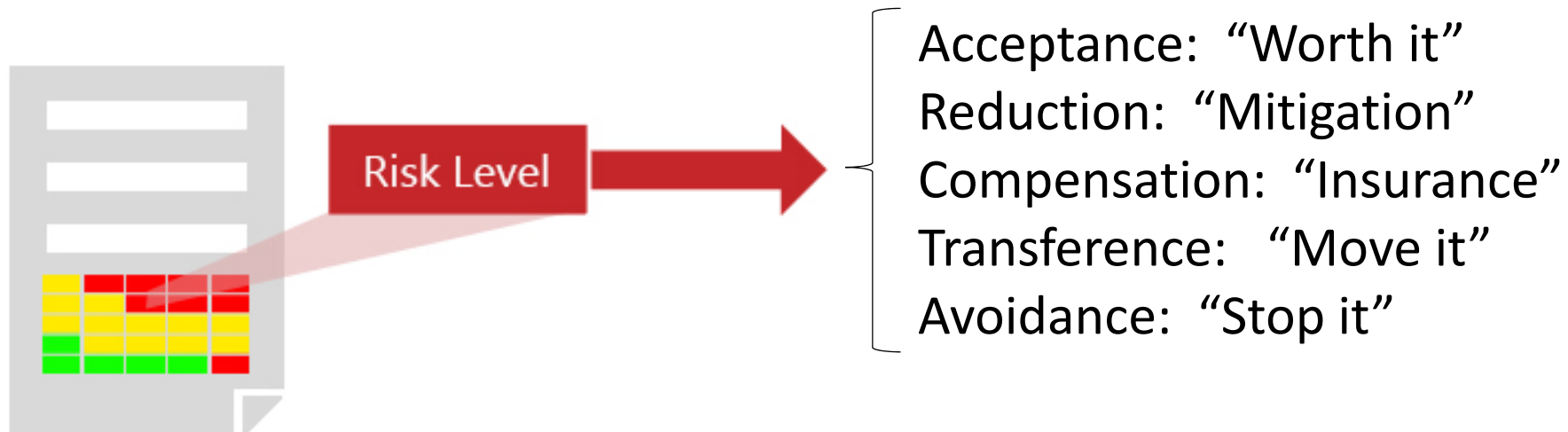
- Evaluate how to handle the risk
- Risk Assessment
 - Should be repeatable, objective
 - Should be backed by REAL-WORLD DATA
- Quantitative means to build a risk assessment



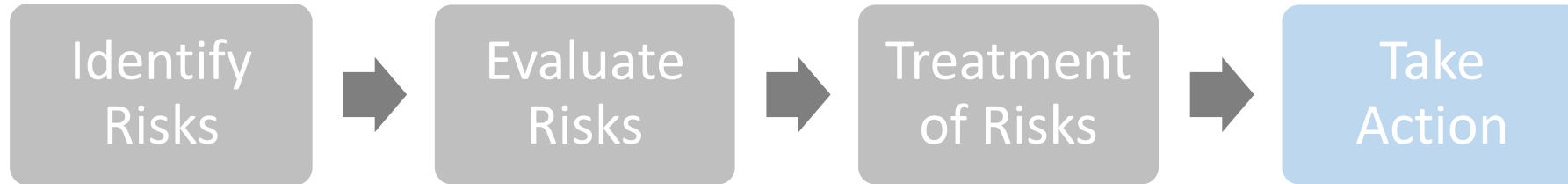
3. Risk-based thinking approach: Planning your QMS with risk in mind



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



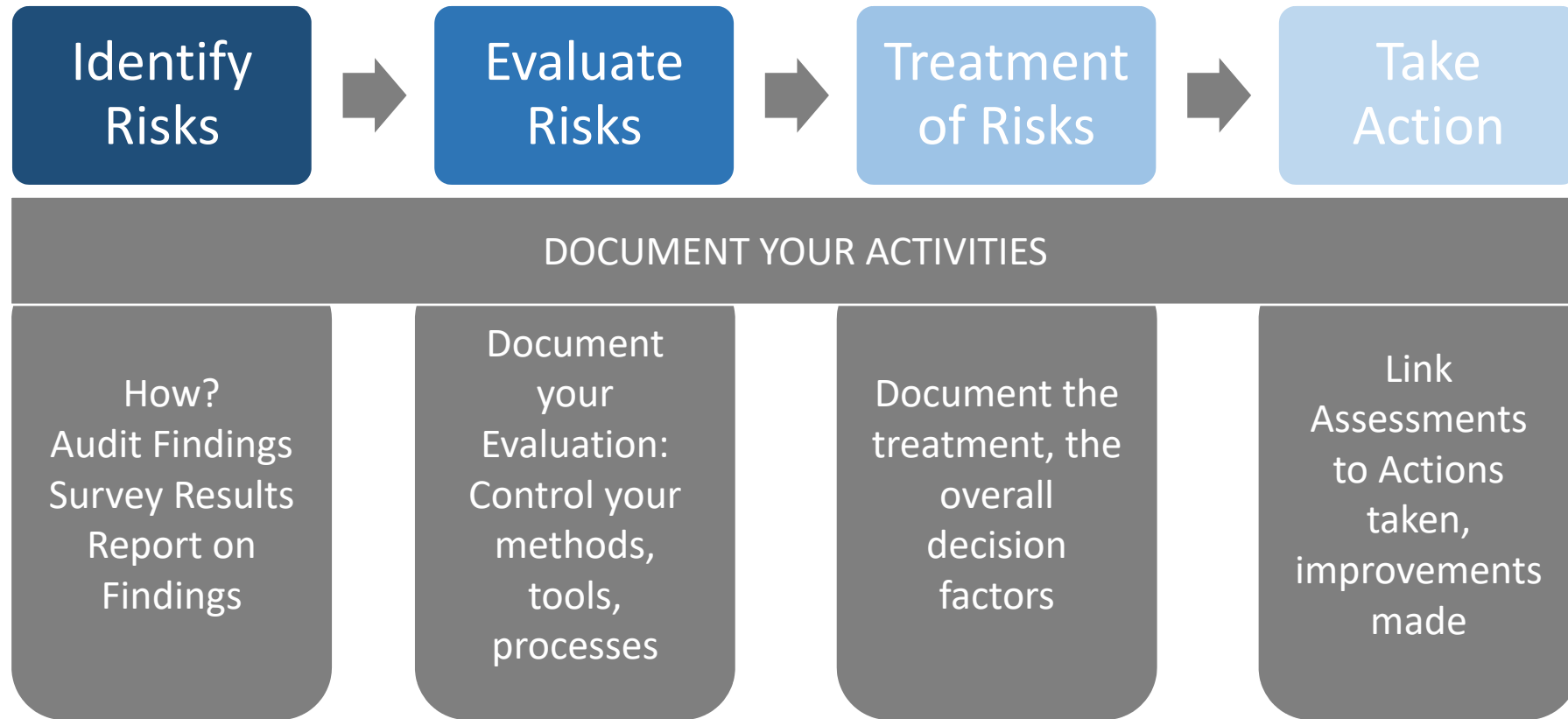
3. Risk-based thinking approach: Planning your QMS with risk in mind



- Take Action: Create visibility and control the risk

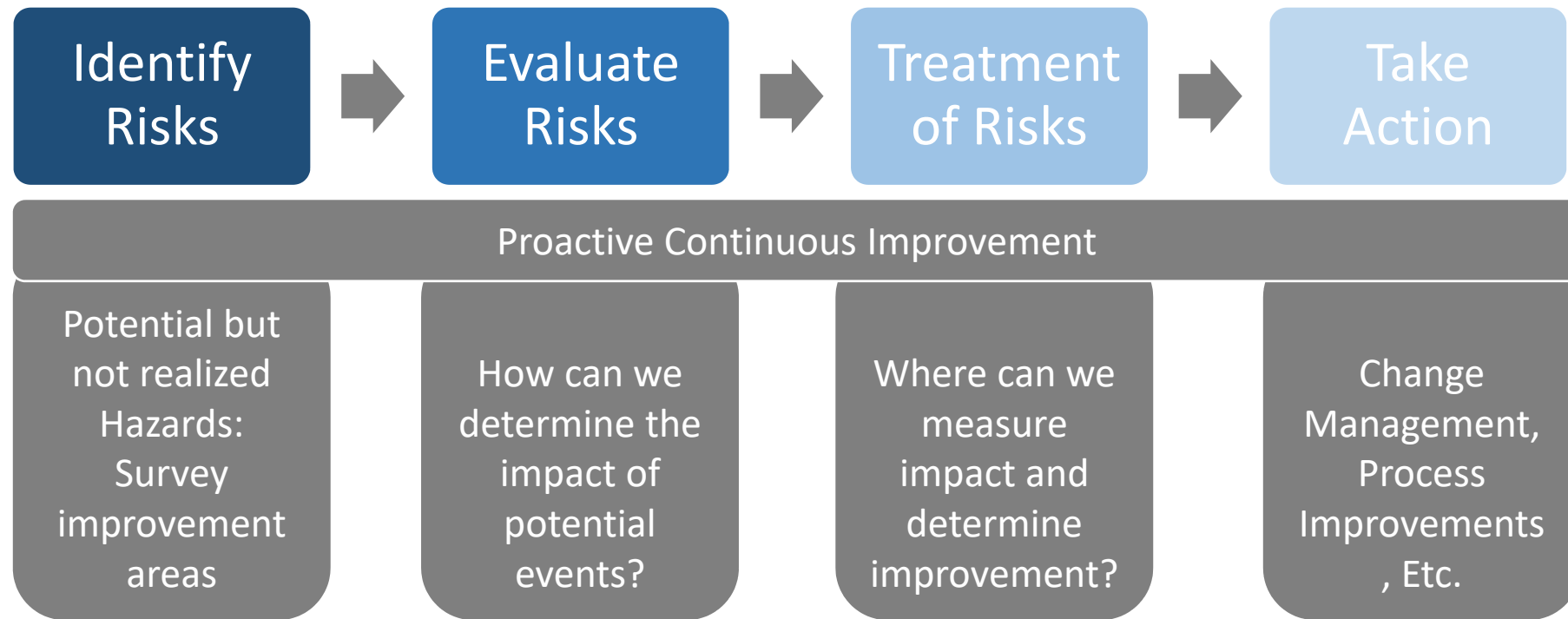


3. Risk-based thinking approach: Planning your QMS with risk in mind



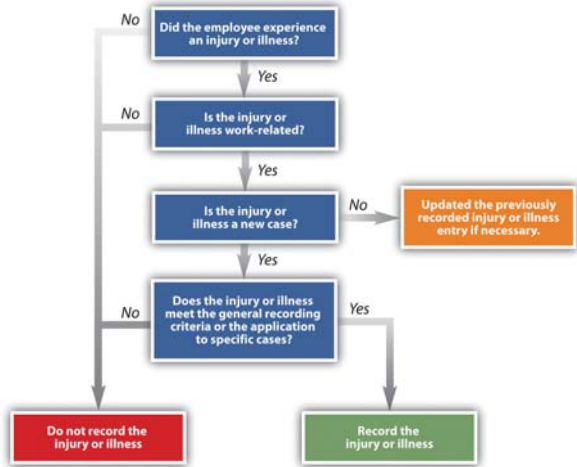
- Document the process in order to have traceability.

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



| | | SEVERITY | | | | |
|-------------|----------------|-----------|----------------|--------------|--------------|------------------|
| | | Minor (1) | Negligible (2) | Marginal (3) | Critical (4) | Catastrophic (5) |
| PROBABILITY | Frequent (5) | Yellow | Red | Red | Red | Red |
| | Probable (4) | Yellow | Yellow | Yellow | Red | Red |
| | Occasional (3) | Yellow | Yellow | Yellow | Yellow | Yellow |
| | Remote (2) | Green | Yellow | Yellow | Yellow | Yellow |
| | Improbable (1) | Green | Green | Green | Green | Green |

(a sample)

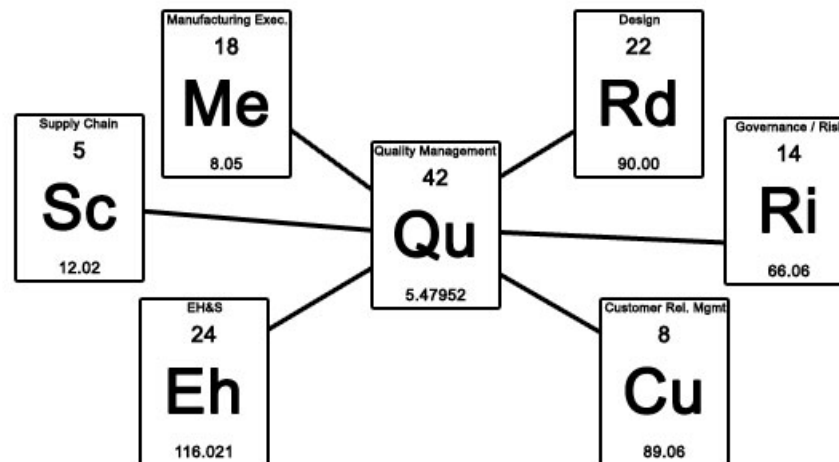
- Decision Tree
- Risk Matrix
- FMEA
- Bowtie
- Risk Register

| FMEA | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---------------------------------------|--|--------------------------------------|---|-------------------------------|---|---------------|---|---------------------|---|---|--|---------|--|---|---|---|---|---|---|---|----|----|----|---|---|
| Revision 6.0 2/11/98 | | Customer: Chrysler Motors Corporation | | Customer Part No: DC-7323-012 | | Org. Date: 2/11/98 | | Page: 1 of 2 | | FMEA No: 12981A-001 | | | | | | | | | | | | | | | | | |
| System: ACJ-021 | | Supplier: Any Company, Inc. | | Code: ACJ-021 | | Supplier Part No: | | Design Rev: 2 | | Key Date: 2/11/98 | | | | | | | | | | | | | | | | | |
| Part Name: | | Design Responsibility: Brad Anderson | | Application/Model Year: Sedan / 1998 | | Prepared By: Brad A. Anderson | | Date: 2/11/98 | | | | | | | | | | | | | | | | | | | |
| Core Team: Brad Anderson, Jerry Berens, Lisa Brown, Alan Carrico, Bill Cox, Fred Jordan, Alan Kirtz | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Item # | Function | Industry Failure Mode | Potential Effects of Failure | C | S | O | D | C | R | R | Recommendation | Responsibility & Target Completion Date | Action Taken | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | | |
| 1 | File for assembly with coverage over 1/4" to 1/2" | Inefficient seal | Overstamped file of door leading to Lineability appearance due to seal through part over time. Impaired function of interior door hardware | 4 | 4 | 4 | 4 | 4 | 4 | 4 | Supplier notification | 1/18/98 | N/A | 2/11/98 | | | | | | | | | | | | | |
| 2 | Controlled interior lower door panels | Improper oxide coating | Untrapped air particles may enter entering compartment | 4 | 4 | 4 | 4 | 4 | 4 | 4 | Free piece setup, in-process, end of run study | 2/4/98 | N/A | 2/11/98 | | | | | | | | | | | | | |
| 3 | Feeder not | Spiky health | Untrapped air particles may enter entering compartment | 4 | 4 | 4 | 4 | 4 | 4 | 4 | Test spray pattern at various and after site periods, and | 5/10/98 | Engineering and Reliability Operations | 2/11/98 | Based on test results (Test #0005) spray head mounted to | 0 | 2 | 5 | 8 | 0 | 2 | 5 | 8 | 0 | 2 | 5 | |
| 4 | Feeder not | Spiky health | Untrapped air particles may enter entering compartment | 4 | 4 | 4 | 4 | 4 | 4 | 4 | Increasing audit per 200.18 installation, SPC Lot/OP | 2/4/98 | ABC Labs | 2/27/98 | Test results show | 0 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| 5 | Feeder not | Spiky health | Untrapped air particles may enter entering compartment | 4 | 4 | 4 | 4 | 4 | 4 | 4 | Laboratory test using "hard case" wax and application hole size | 3/7/98 | ABC Labs | 2/11/98 | Test results show | 0 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| 6 | Feeder not | Spiky health | Untrapped air particles may enter entering compartment | 4 | 4 | 4 | 4 | 4 | 4 | 4 | Add laboratory procedure | 2/11/98 | Engineering Associates | 2/11/98 | DOC shows 20% variation in specified thickness is acceptable | 0 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |



4. Integration: internal and external

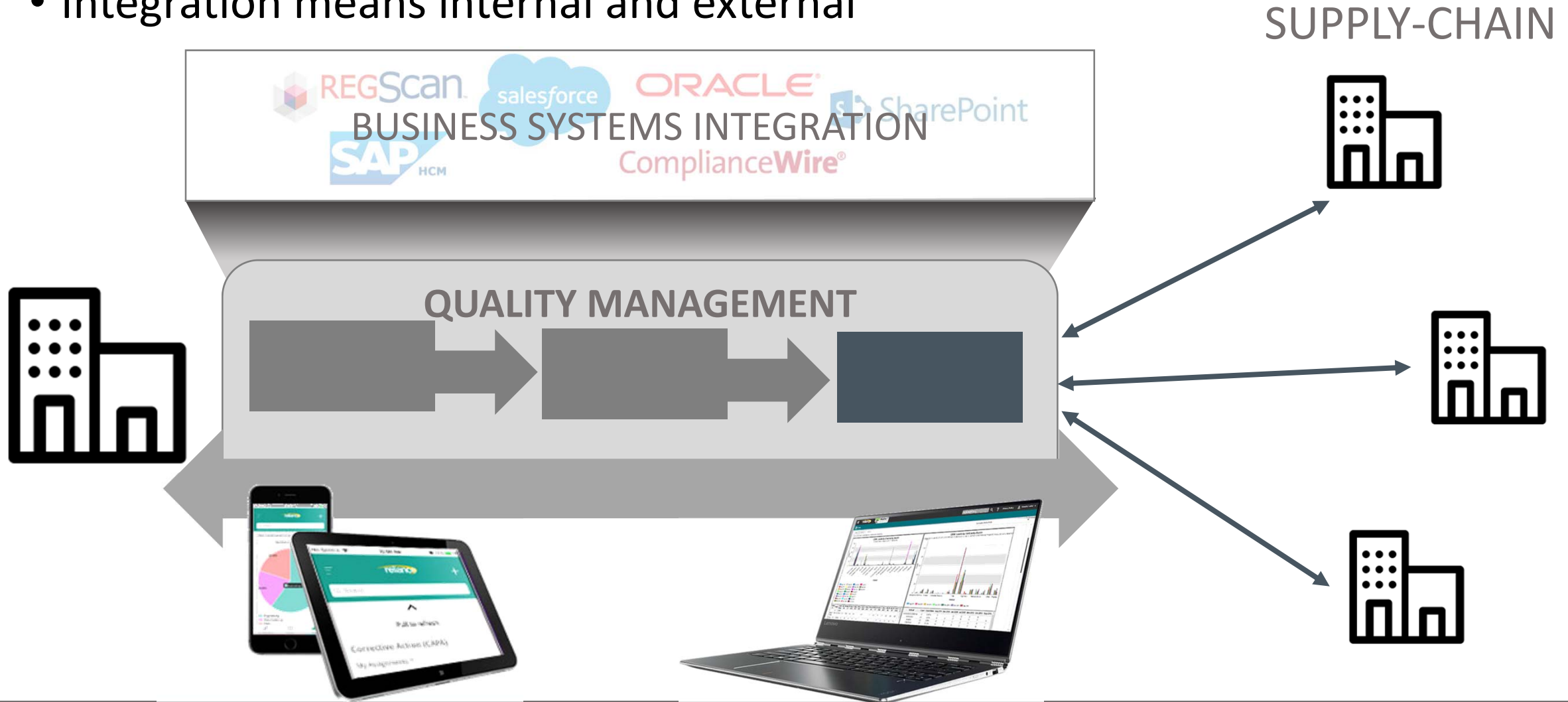
- We no longer live in information silos – business systems need to talk to each other
- Can the system integrate with ERP, MRP, SCM, CRM, PLM....ASAP?
- Look for more than just “basic” integration
 - Lookup data
 - Push data from QMS to other systems
 - Interact with other business systems on an operational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

Avoid the Data Paralysis Effect!

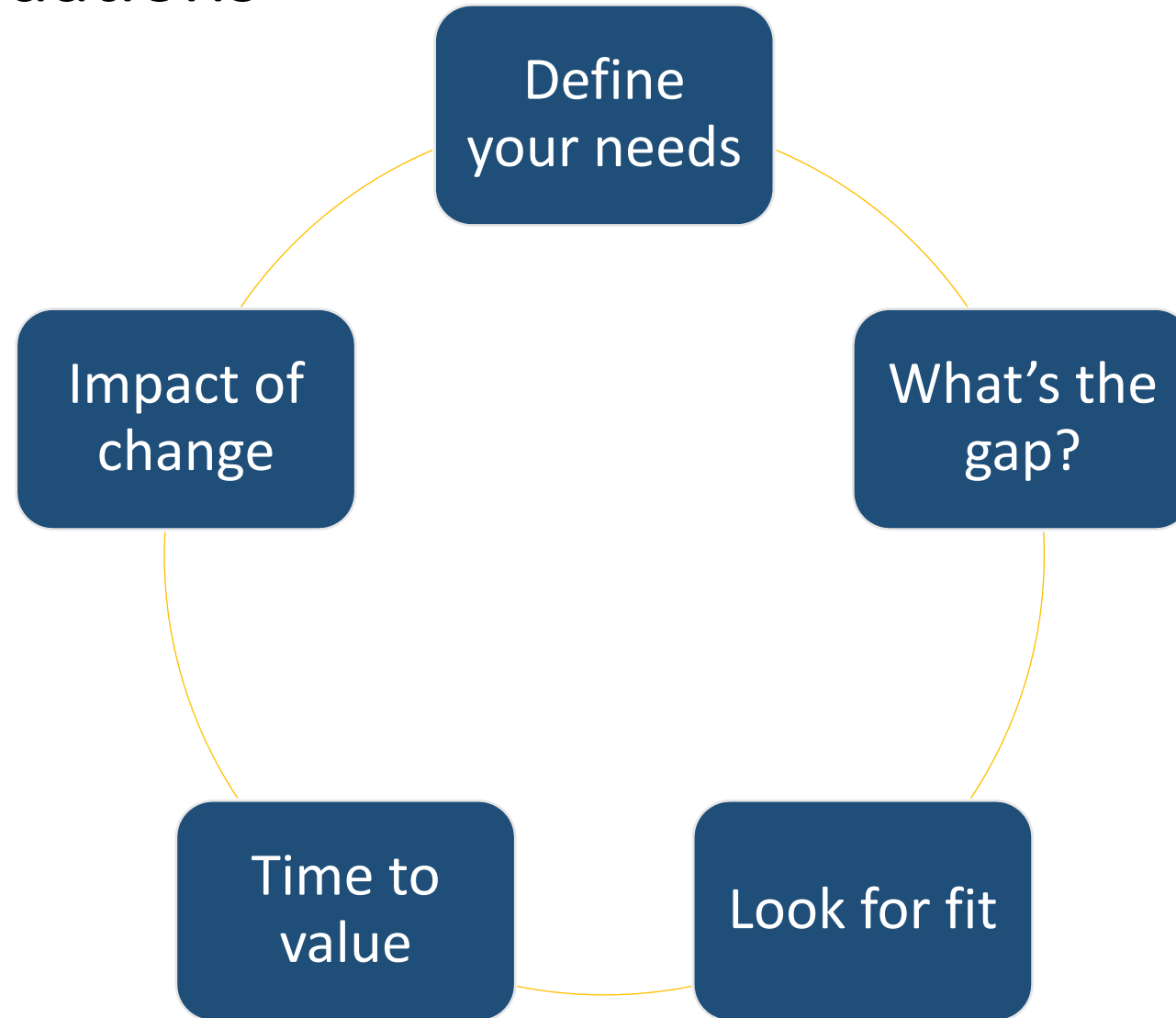


5. Reporting

- 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

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