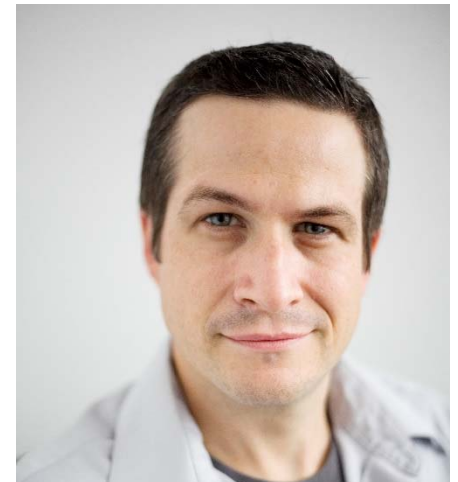


The Market View on Quality Management:

What your peers are doing (or not doing)

Tim Lozier, Director of Product Strategy at Verse Solutions



Tim Lozier
tlozier@versesolutions.com

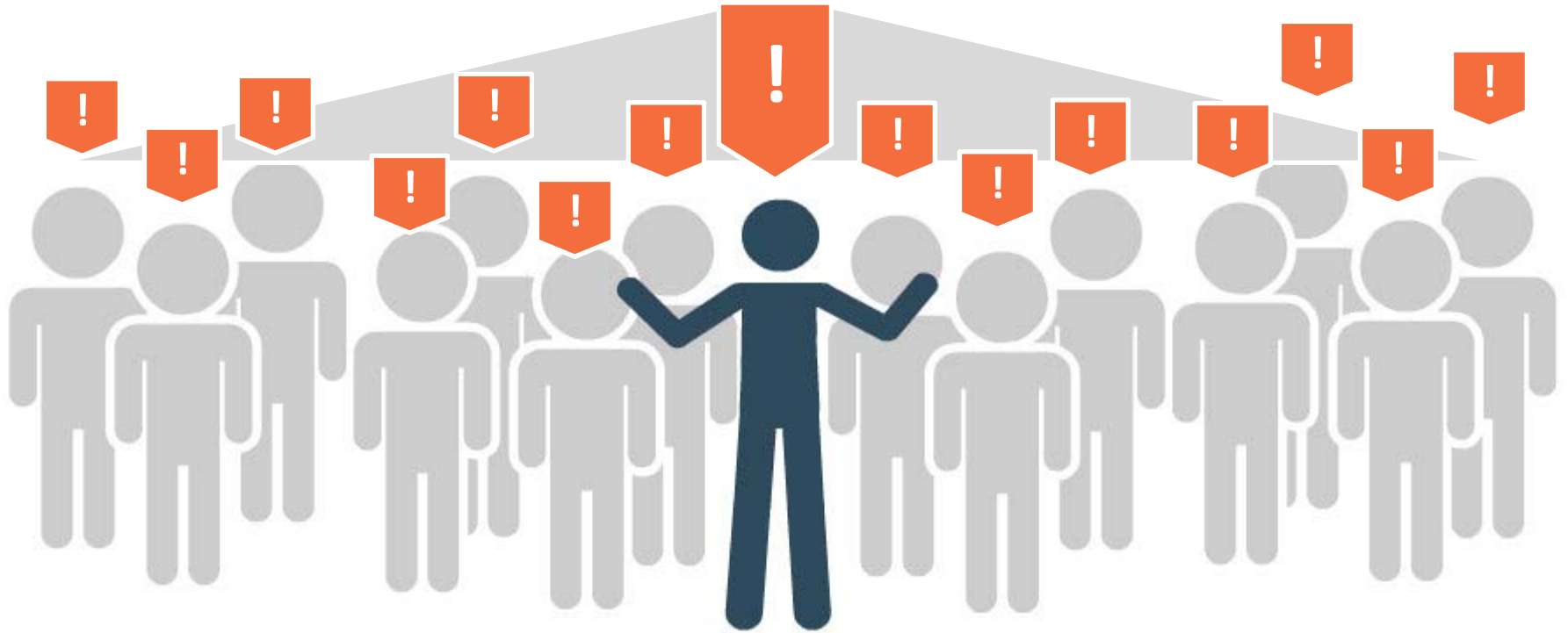
What we're covering today

- The shift in the mindset of Quality Management
- What is the market view on Quality Management?
- Where does technology fit into the dynamic of QMS?
- Recommendations for QMS



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...

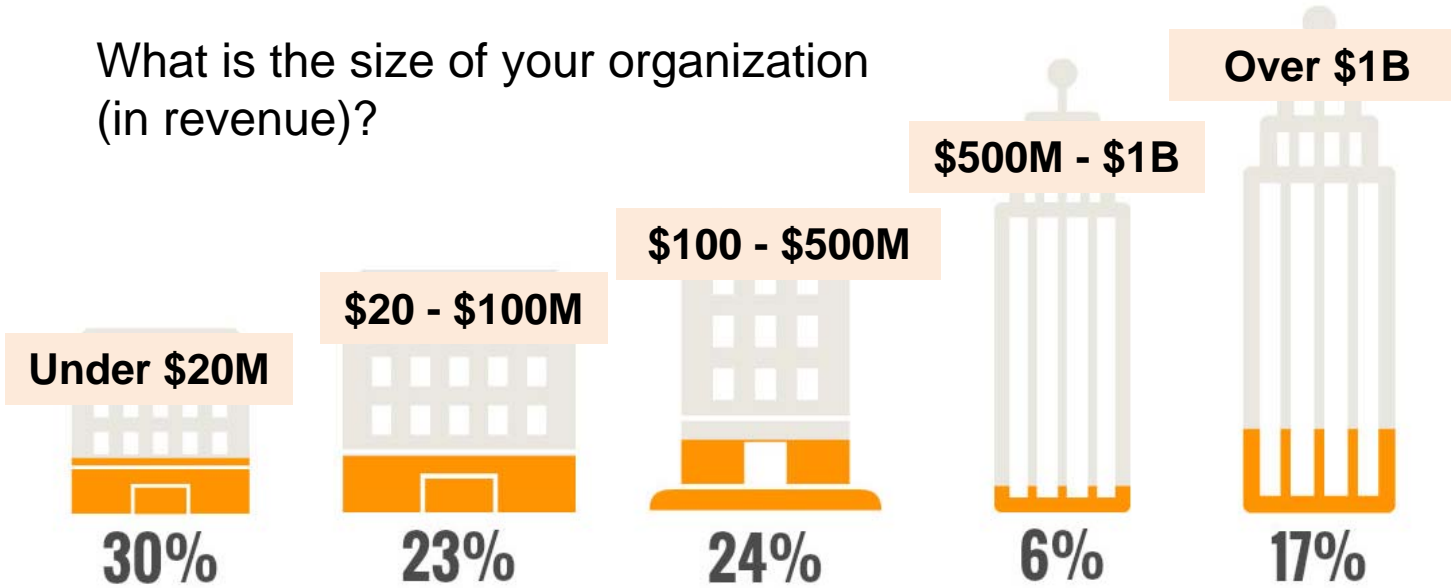
**...specifically around who they are,
what drives them, and...**

...where technology fits into their world.



Who did we talk to?

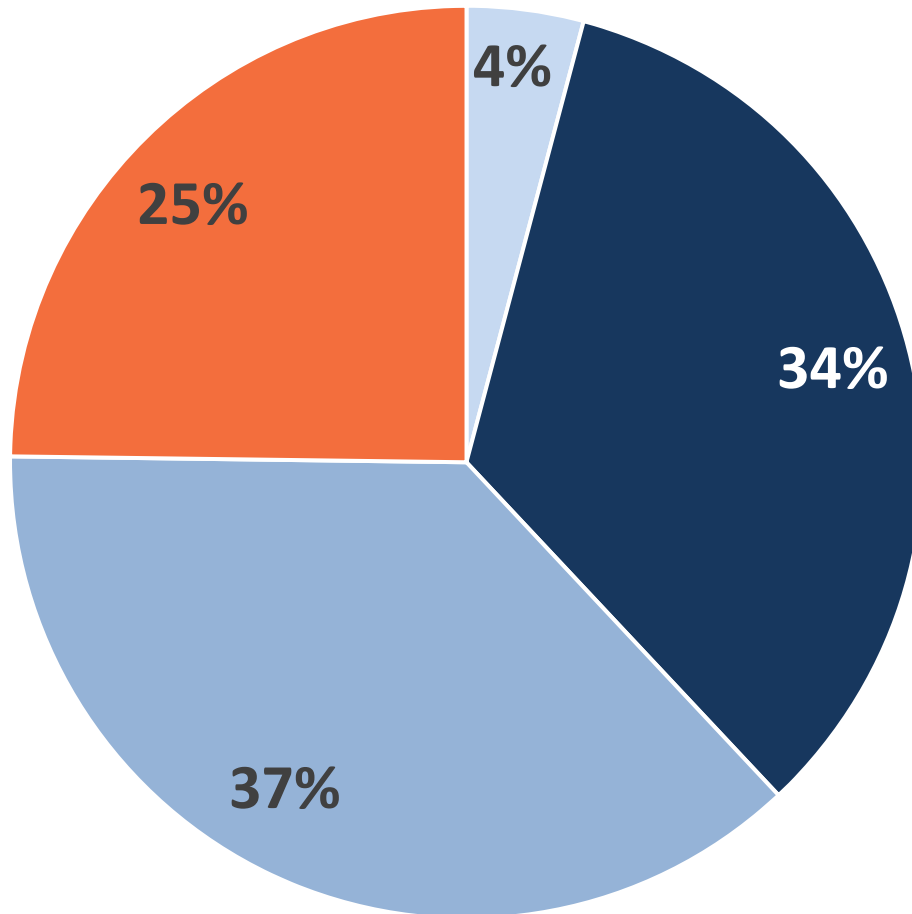
What is the size of your organization (in revenue)?



N=157



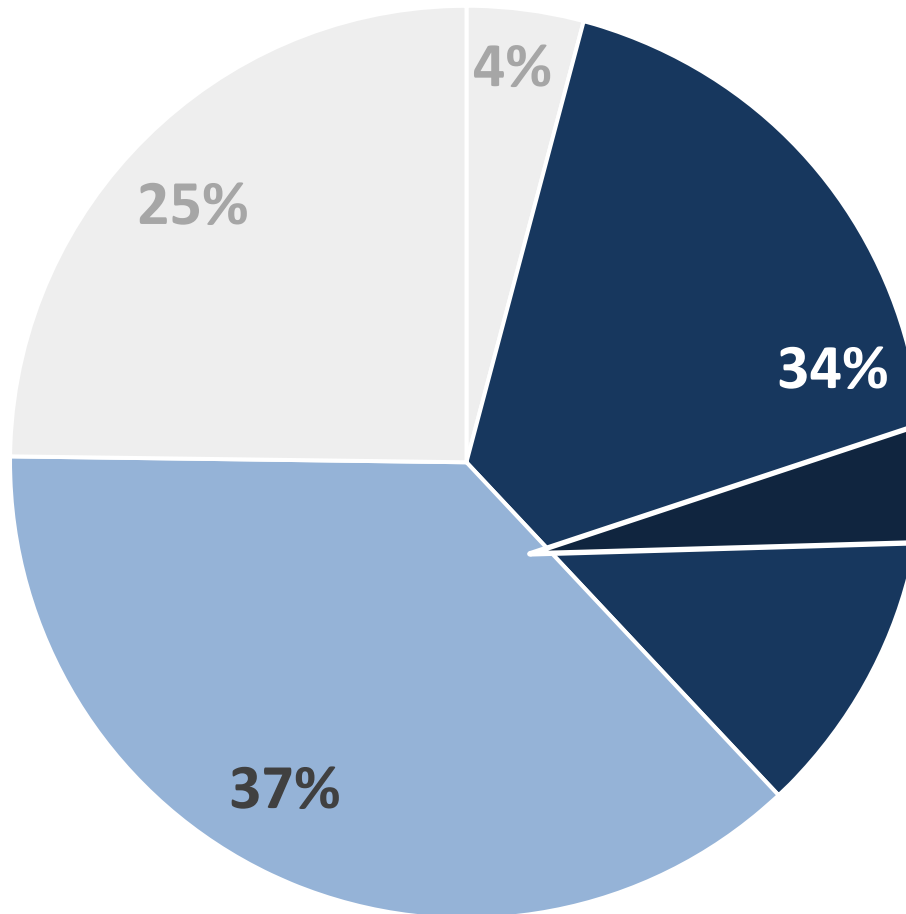
What is the Quality Role look like?



- Quality is a part-time role in my company
- I am part of a quality team
- I lead a quality department
- I am responsible for multiple areas, including quality



What is the Quality Role look like?

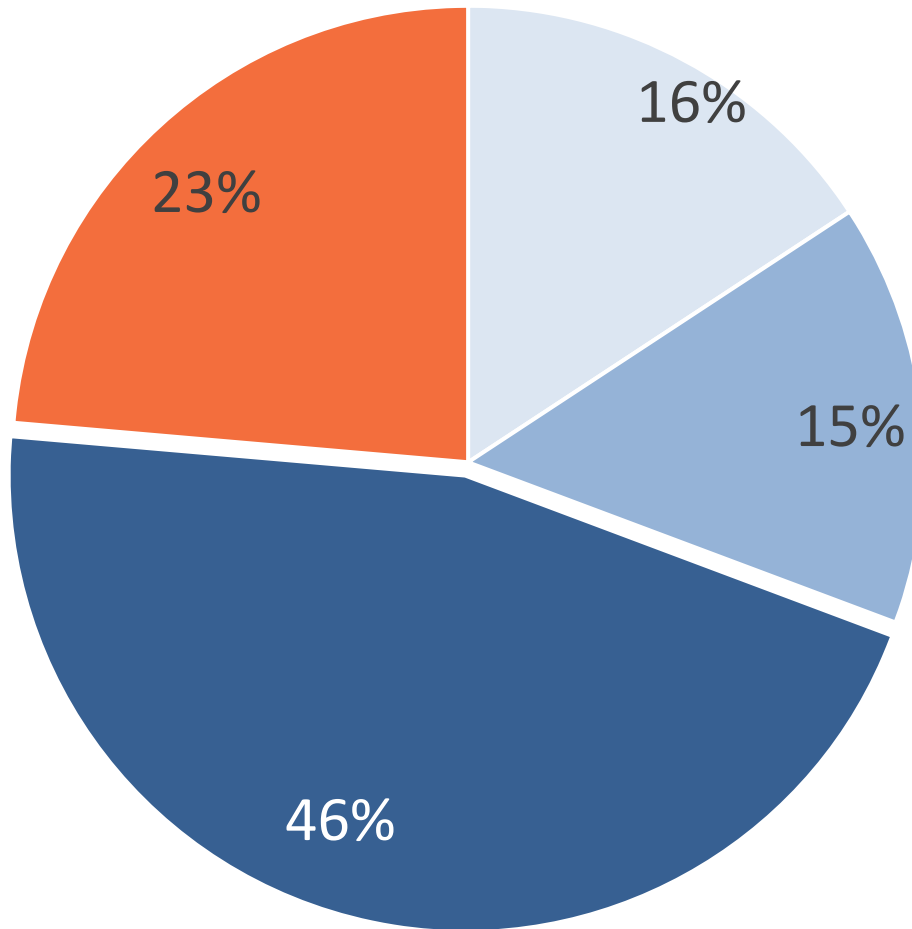


Quality is (thankfully) a dedicated role in most organizations:

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



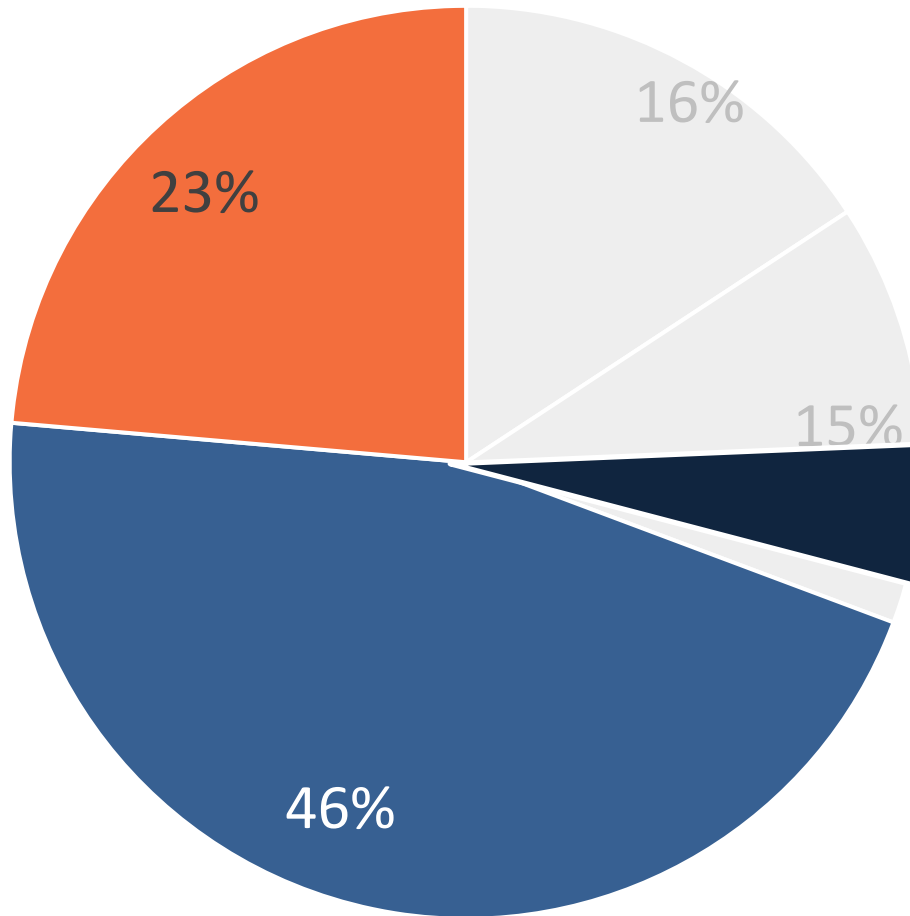
How are Quality Management Teams Structured?



- 1-2 person team with cross-functional roles
- Small, cross-functional team
- Quality department with more than 2 people
- Large quality management operation managing multiple sites/locations



How are Quality Management Teams Structured?

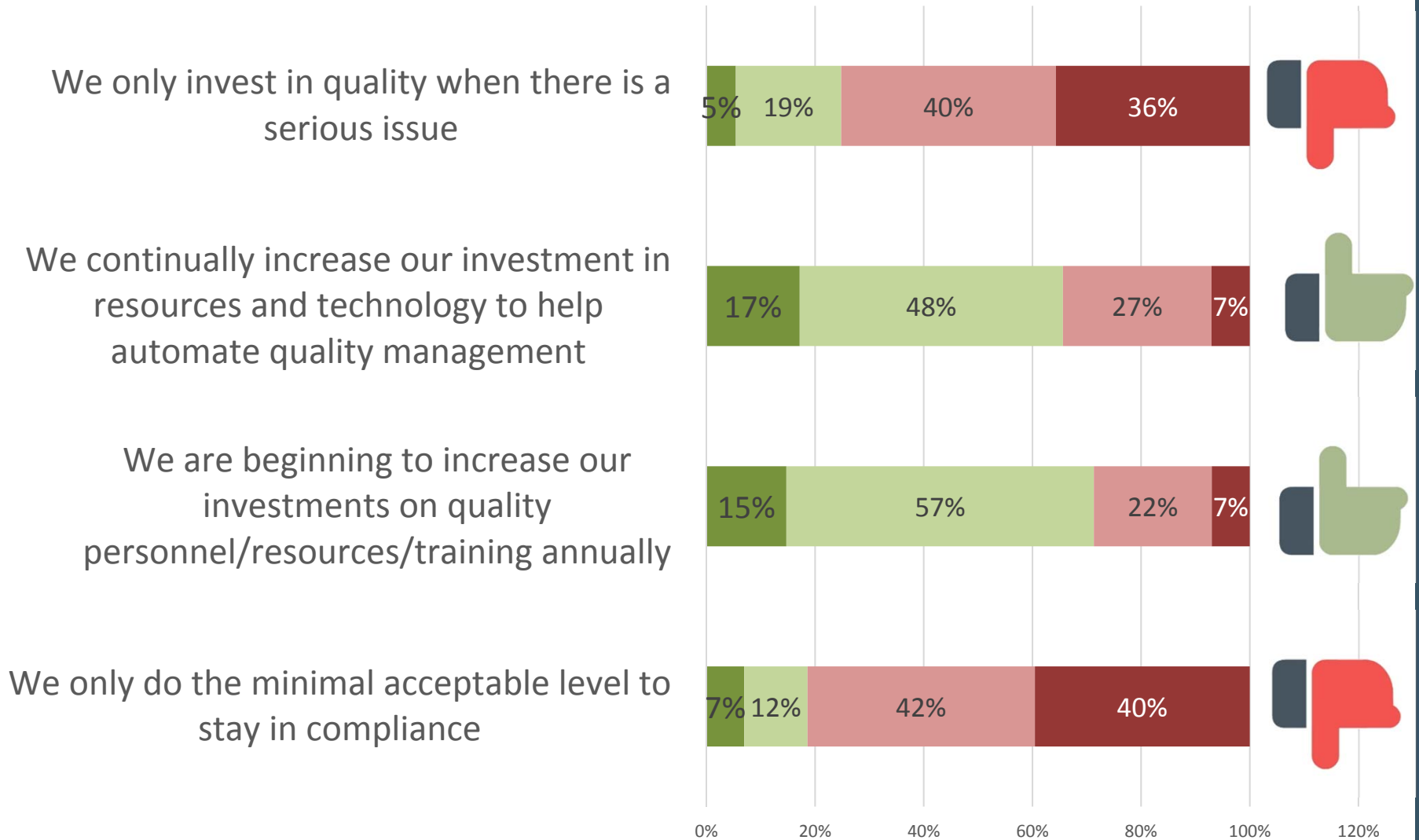


Quality Management Teams are still largely dedicated in nature.

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

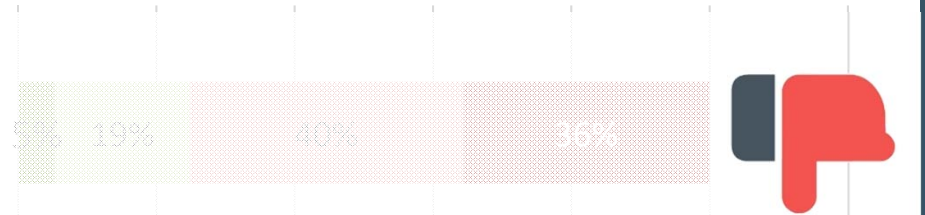


How are they investing in Quality Management?



How are they investing in Quality Management?

We only invest in quality when there is a serious issue



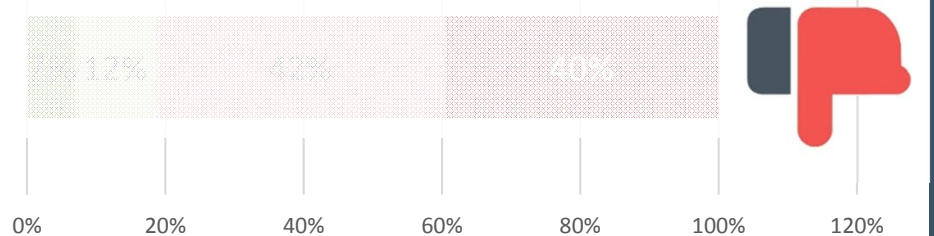
We continually increase our investment in resources and technology to help automate quality management



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

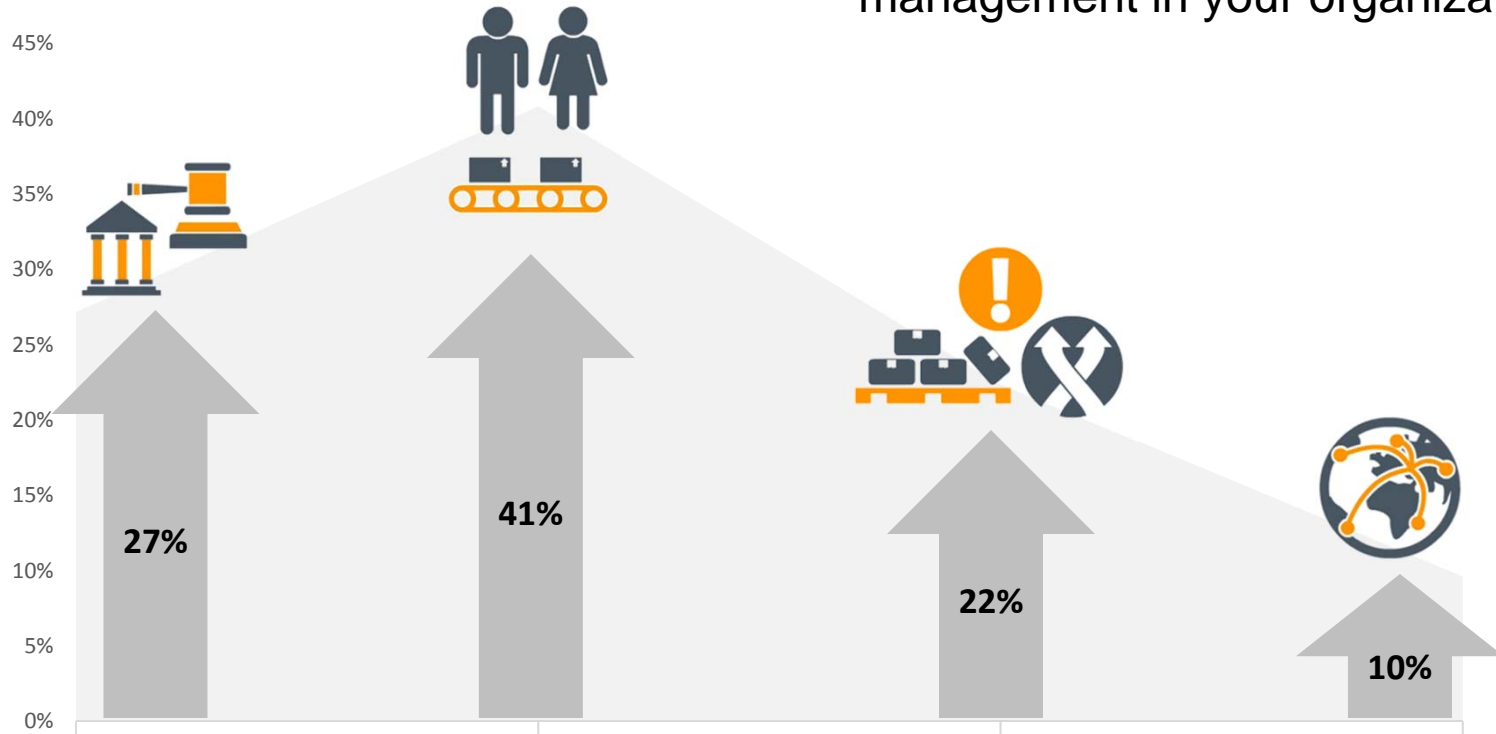


We only do the minimal acceptable level to stay in compliance



What's Driving Quality Management?

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



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)



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 regulatory, 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

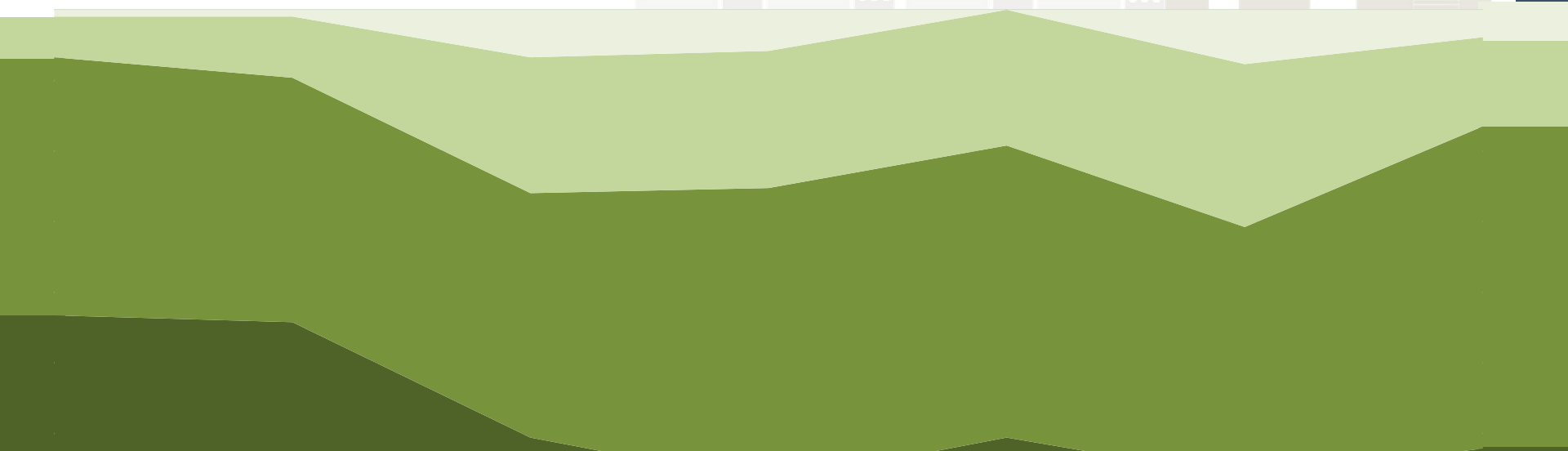
“Our goal is around getting everyone in the organization to own the responsibility of product quality.”

**Supports the
mindset shift!**

“We are continually looking to improve employee knowledge in Quality.”



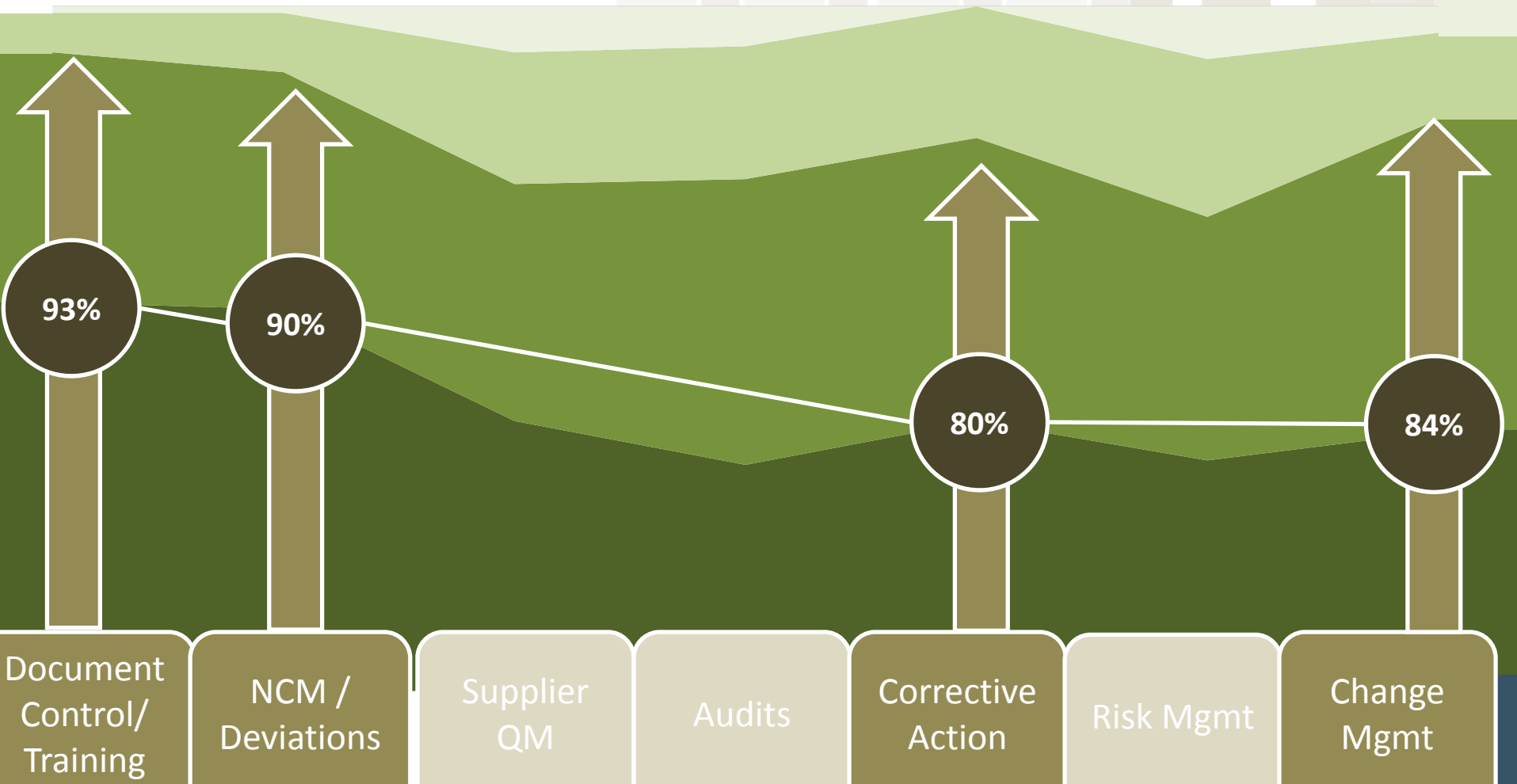
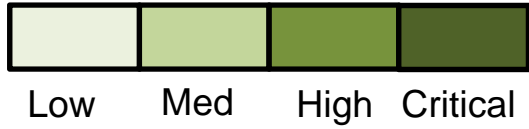
The Quality Management Landscape



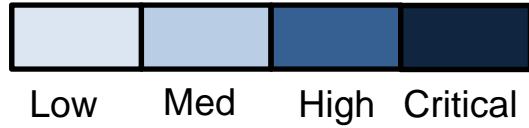
How critical are the below processes towards achieving your quality management objectives?

- | | | | | | | |
|----------------------------|------------------|-------------|--------|-------------------|-----------|-------------|
| Document Control/ Training | NCM / Deviations | Supplier QM | Audits | Corrective Action | Risk Mgmt | Change Mgmt |
|----------------------------|------------------|-------------|--------|-------------------|-----------|-------------|

The Quality Management Landscape



The Quality Management [automated] Landscape



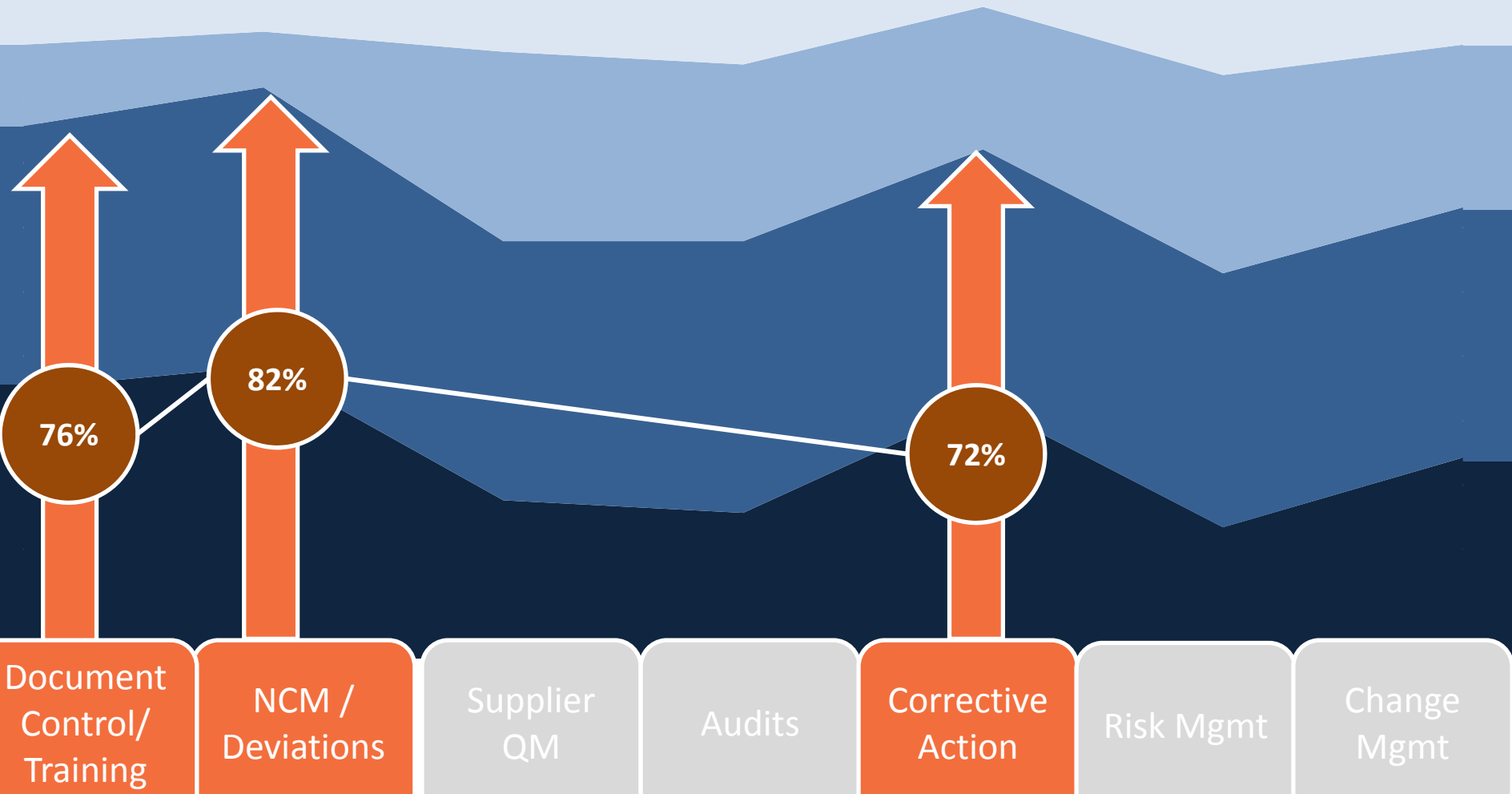
Of the processes below, which are most critical to be automated?

- Document Control/ Training
- NCM / Deviations
- Supplier QM
- Audits
- Corrective Action
- Risk Mgmt
- Change Mgmt

The Quality Management [automated] Landscape



Low Med High Critical



Let's review what we've learned so far....

The ROLE: Quality Management is primarily a dedicated role/team, and growing in investment

The DRIVE: Quality Management is driven by compliance to standards, and serving the needs of the customer

The PROCESSES: Document Control, Training, Nonconformance, Corrective Action and Change Management are most important

The AUTOMATION: Automation of the majority of these process is considered critical or of highest priority



Let's review what we've learned so far....

The **ROLE**: Quality Management is primarily a dedicated role, and growing in investment

The **DRIVE**: Quality Management is driven by compliance to standards, and serving the needs of the customer

So...

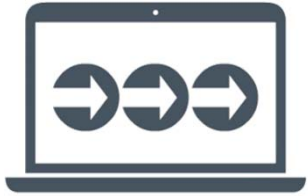
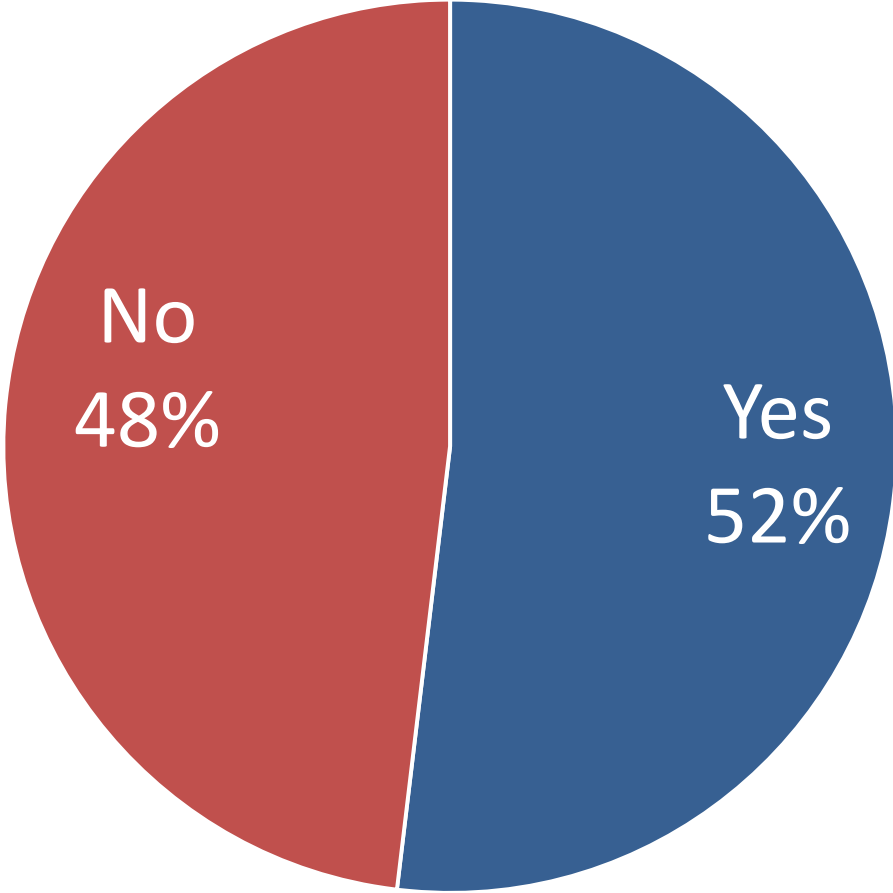
Where does technology sit?

Nonconformance, Corrective Action and Change Management are most important

The **AUTOMATION**: Automation of the majority of these process is considered Critical or of Highest priority



Are you currently using automated solutions for QMS?



(whoa.)



If you're not automated, what are you using?



Email / spreadsheets

50.8%

Paper-based, manual systems

49.2%



Are we introducing unnecessary RISK into the equation?

- Email is not a tracking tool
- Spreadsheets can be risky
- What if a process changes? How do we impact change?
- What about the processes we DON'T know about?



If you ARE automated, what are you using?

Internally
built QMS



40.9%



QMS functions
across different
point solutions



18.2%



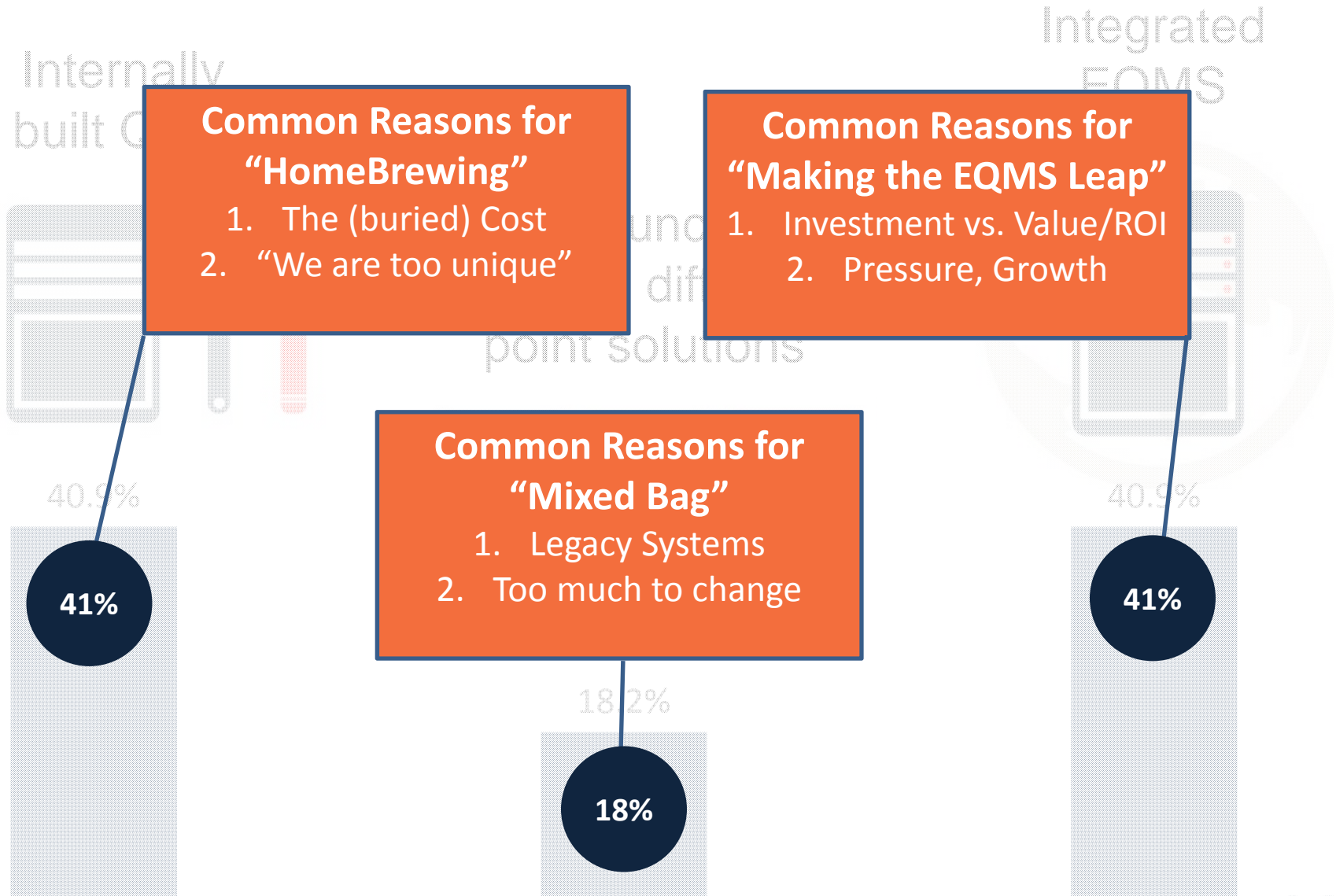
Integrated
EQMS



40.9%

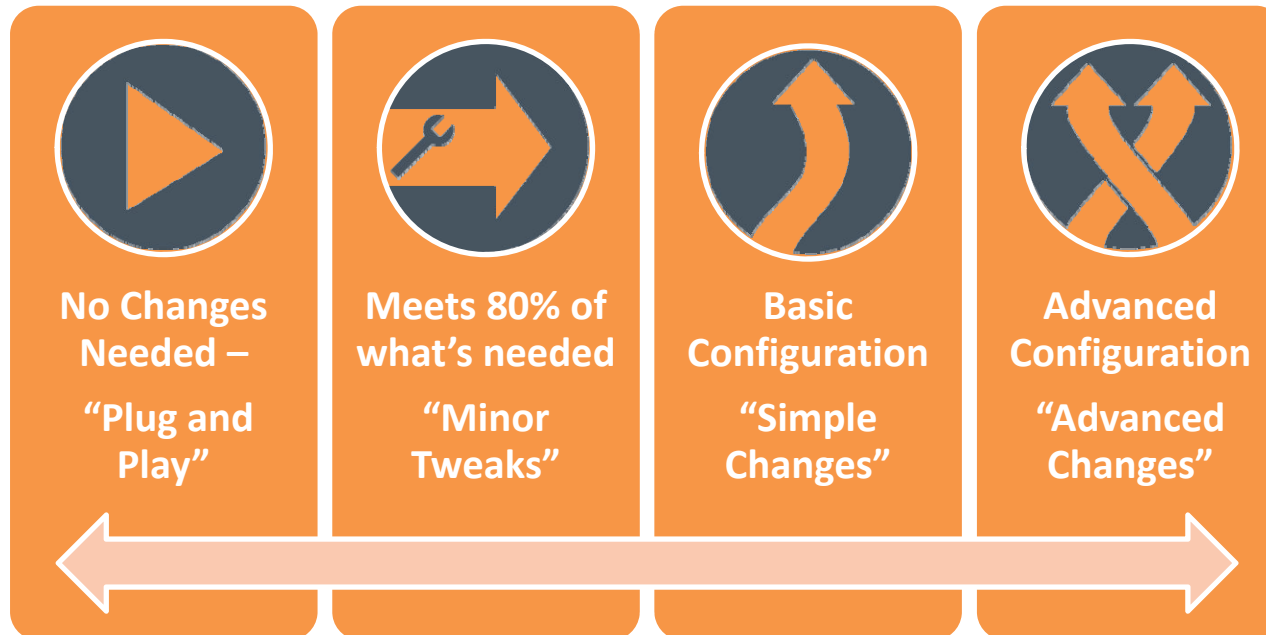


If you ARE automated, what are you using?



Automating your Quality Management System

- There is a trend towards to simplicity.
- Software should be effective, not add another layer of complexity beyond it's purpose
- To enroll the entire organization, it must meet a certain threshold of simplicity AND effectiveness
- There are four categories we asked:



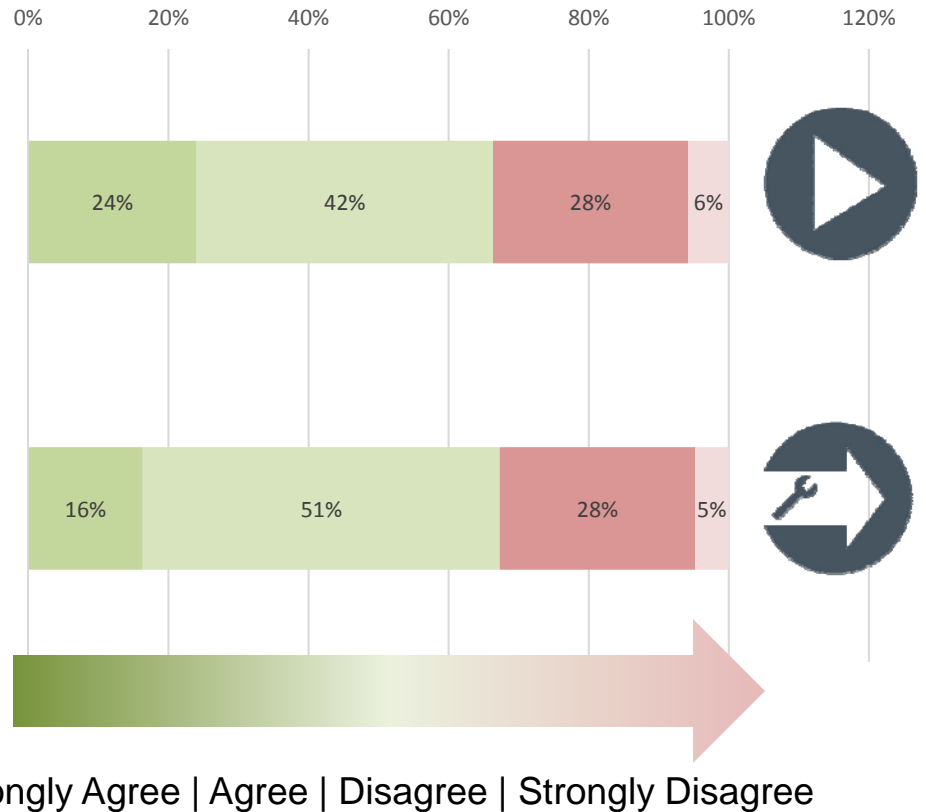
The need for Simplicity

No changes needed:

I need a software solution that provides best practices that I can implement quickly and use without making any changes.

Minor tweaks:

I need a software solution that meets 80% of my business requirements out-of-box. I'm willing to use it by making minor changes as long as it works well enough.



66% agree on “Plug and Play”

67% agree on “Minor Tweaks”



The need for Simplicity

0% 20% 40% 60% 80% 100% 120%

No changes needed:

I need a
practices

But is this enough?

Processes change; people change.

**Are we able to adapt to change if the solution
won't budge?**

Are we back to square one?



Strongly Agree | Agree | Disagree | Strongly Disagree



66% agree on "Plug and Play"

67% agree on "Minor Tweaks"



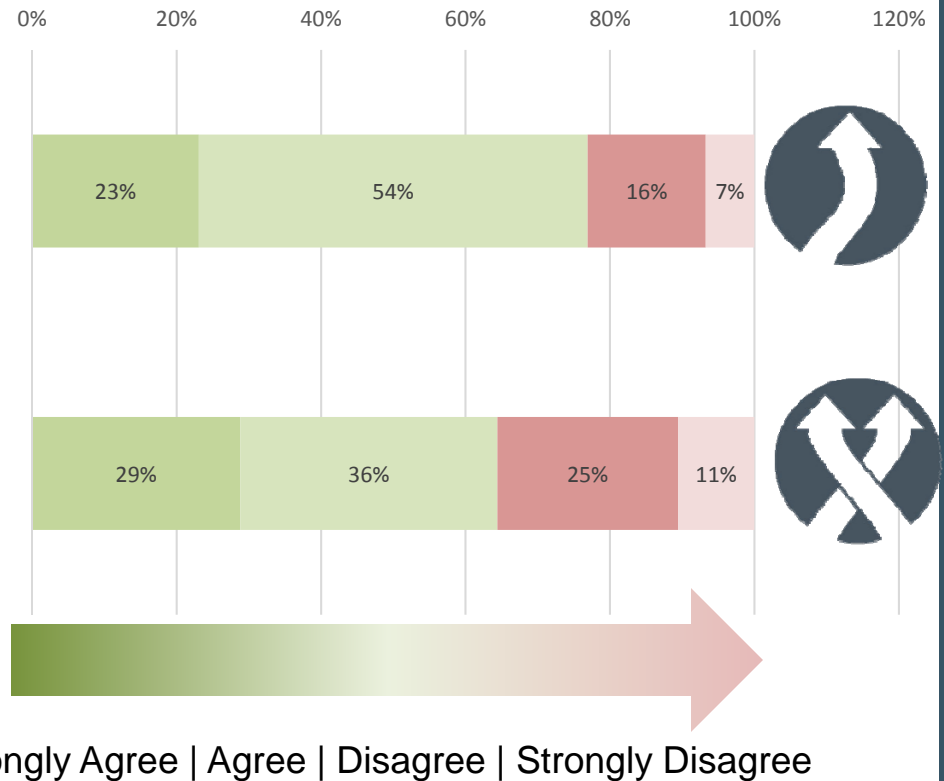
Basic Configuration versus Customization

Basic Configuration:

I need a software solution that lets me build basic forms, make simple configurations and allows me to adapt the software to my changing business requirements.

Advanced Configuration:

I need a software solution that gives me complete customization and configuration abilities to meet my very specific business needs.



 **77% are looking for basic configurations**

65% are looking for more advanced



Basic Configuration versus Customization

Basic Configuration:

It's a matter of effectiveness.

There should be enough flexibility to meet the need, without overwhelming the solution

In some cases, effectiveness may require complexity – but it has to make sense

Strongly Agree | Agree | Disagree | Strongly Disagree

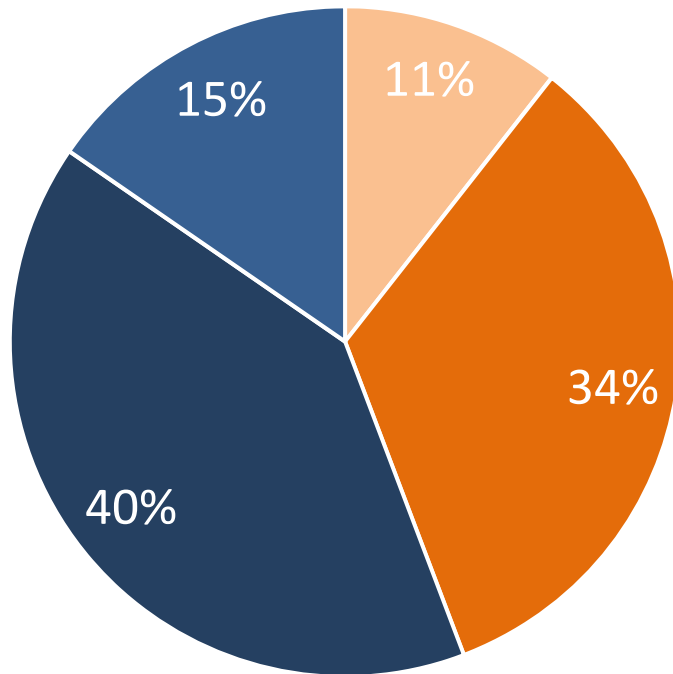
 **77% are looking for basic configurations**

65% are looking for more advanced



Services is a difficult discussion...

I don't mind paying for implementation services, as long as the end result is a solution that meets my needs precisely.



■ Strongly Agree ■ Agree ■ Disagree ■ Strongly Disagree

What do Services provide?

It all depends on the need!

Complex needs = more services
Complex solution = more service

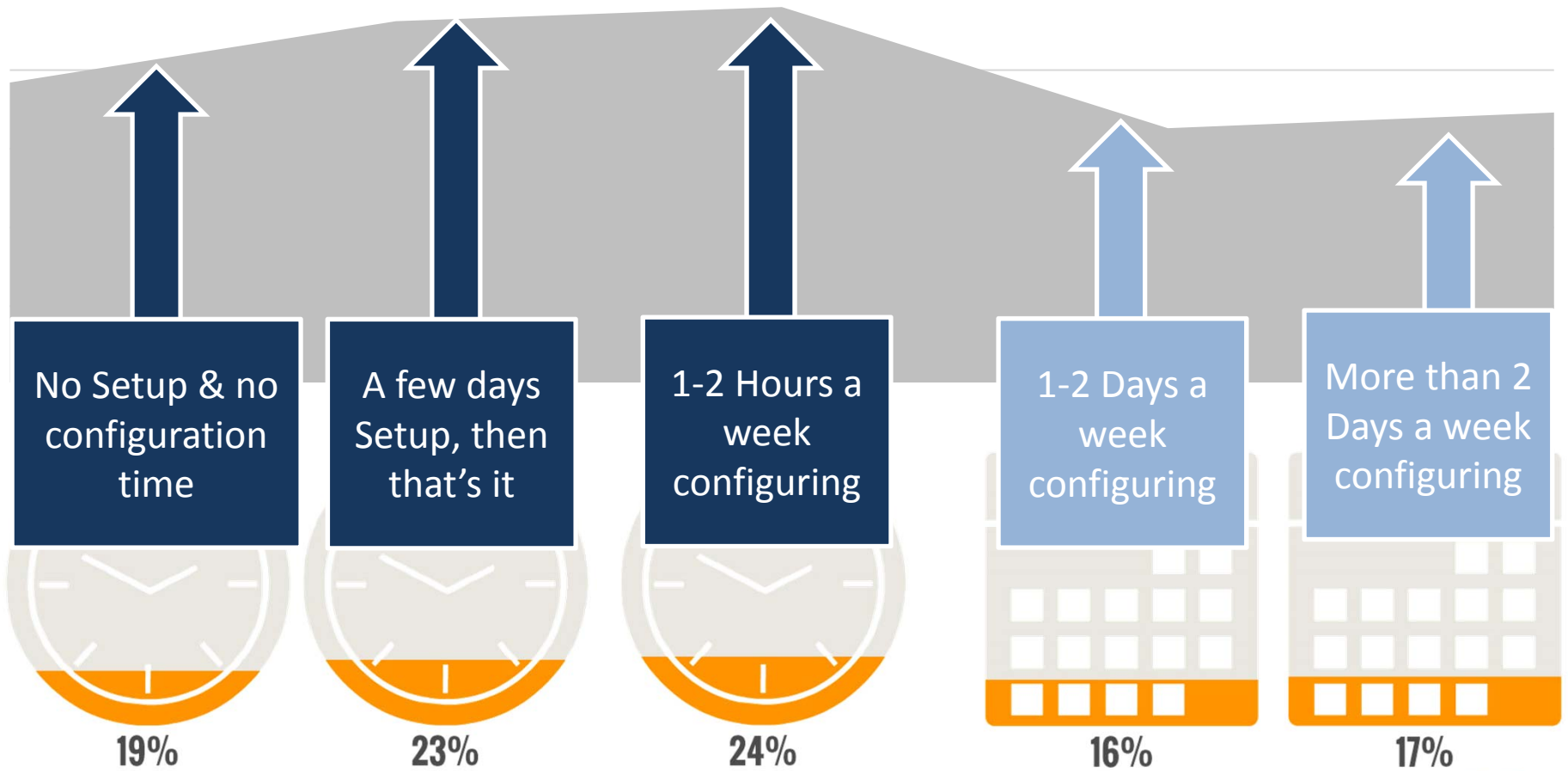
Simple needs = less services
Simple solution = less services

One variable to consider:
What is YOUR time worth?



It's a Time Game with Software...

How much time would you spend setting up and configuring the software solution?



It's a Time Game with Software...

How much time would you spend setting up and configuring the software solution?

66%

Will not want to spend more than 1-2 HOURS per week on Admin

Will spend 1 DAY or more on Admin

33%



19%



23%



24%



16%



17%



Voice of the market on Software, Automation

“Our experience tells us that QMS automation helps us save time from the bureaucracy and leave more time for essential quality issues.”

“An automated QMS would hopefully lead to real time data we can leverage to make informed business decisions and increase our margins.”

“Automated quality management, if implemented correctly and promptly, is a good tool for tracking cost of quality and actual improvement yields. “

“(QMS Software) Must be simple. Must be easily mastered by management.”

Saves time, better “visibility”, implemented promptly, must be simple!

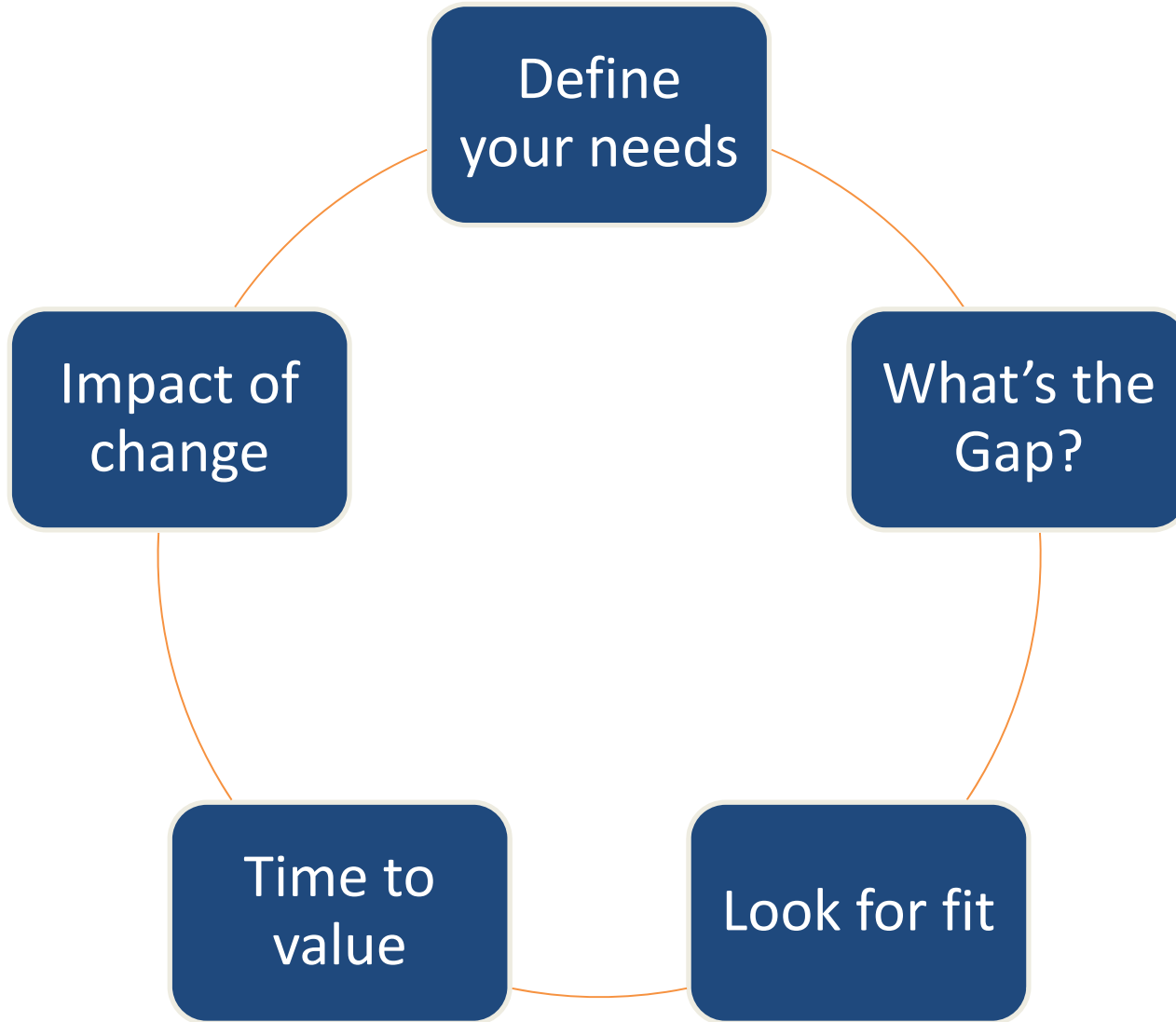


Summary

- **What's the mindset?**
 - Quality is still a dedicated role, with a dedicated team
 - Quality is driven by the need to maintain standards, compliance, while serving the product and customer needs
 - Quality sees processes that are common to the alignment of people, products and actions taken to serve Quality – while seeking ways to improve
- **Technology is a lagging concept for many :**
 - It's a matter of change, effort, time
 - What's the pressure to drive the change?
- **The Ideal technology should:**
 - Meet the need – match the processes
 - Be simple enough to meet the need, but not overwhelm
 - Match the level of complexity your business requires – not all needs are created equal!



Recommendations



Thank you! Questions?



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