ISO 9001:2015 Compliance—How Automation Can Help

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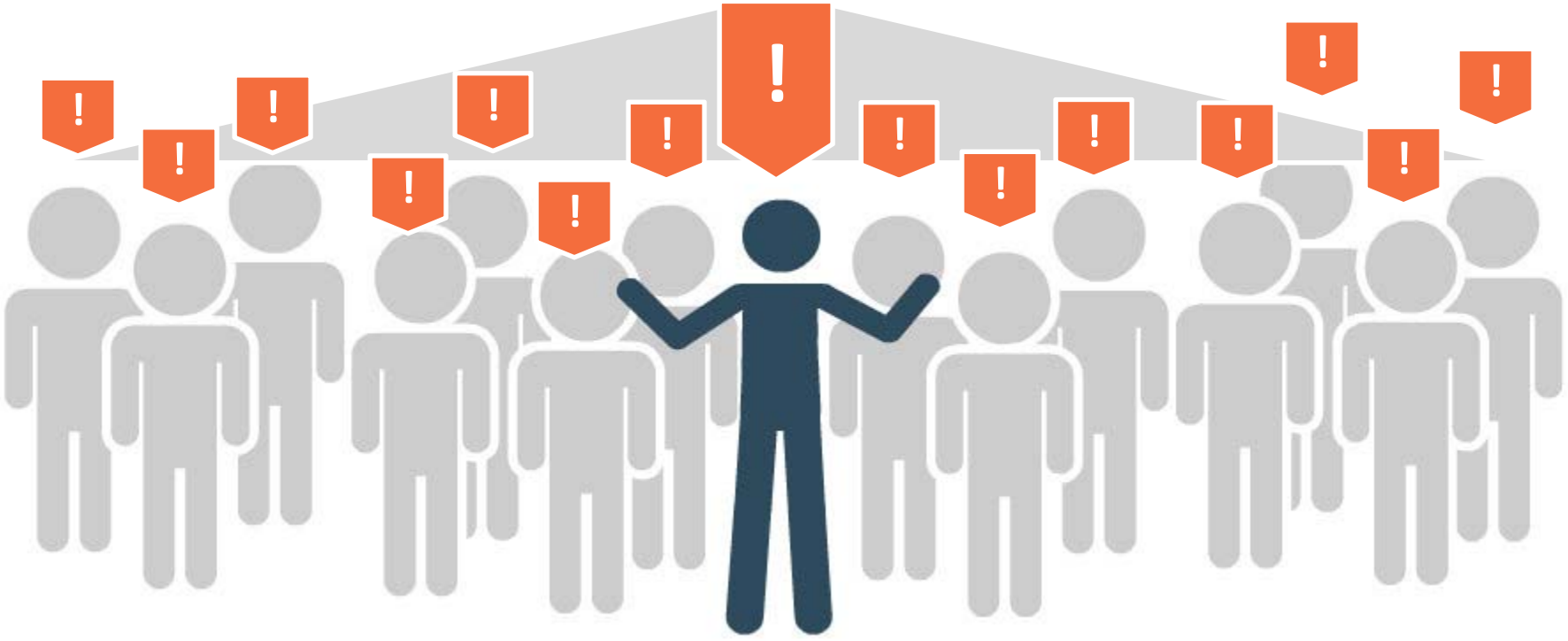
What we're covering today

- What the new ISO 9001:2015 entails
- How technology fits into the dynamic
- Where automation will help with the ISO Standard
- Key Considerations for building a ISO 9001:2015 technology relationship

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.

Common, standardized Processes, across the entire operation

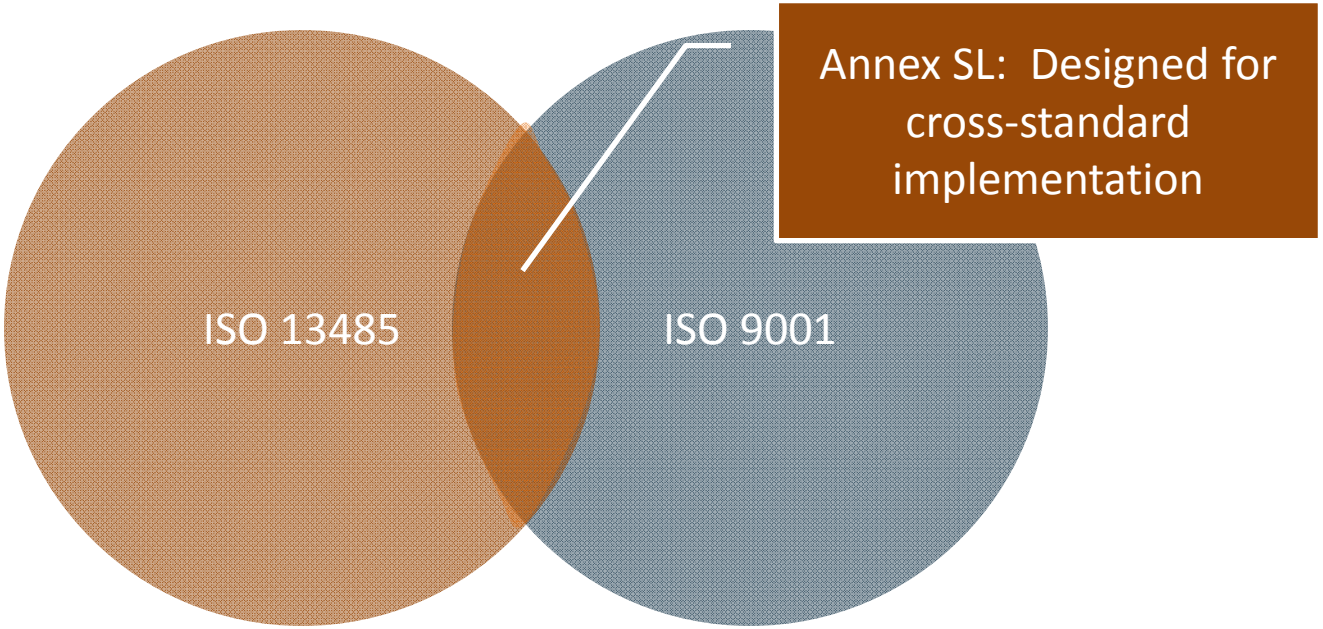
Not just about the requirements….

It's the mindset.

Fostering Traceability throughout the process….

Not just about the requirements….

It's the mindset.



Standards Designed with an Integrated approach.

Why Automation fits into the ISO dynamic

Quality is pervasive to the entire organization

Need centralized, common place to collaborate on Quality

Quality needs a central place to “live”

Need to build a single source for visibility and control

This new interpretation brings ISO to a new level of focus, and also recognizes the changes in technology and best practices for Quality Management.

This is where automation impacts Quality.

Where does Automation Meet ISO?

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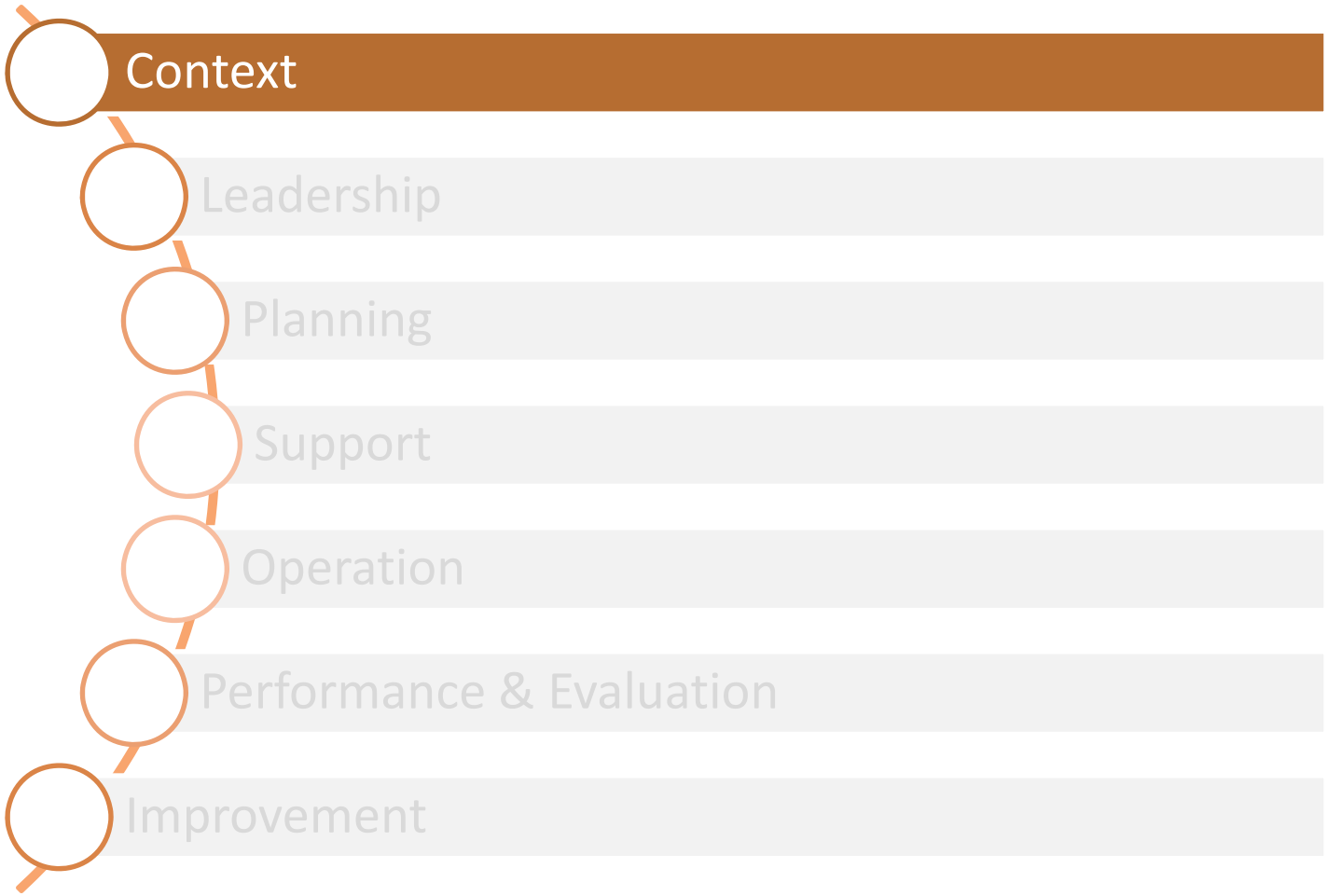


Where does Automation Meet ISO?

Context

Mapping out your QMS:
How your organization will manage Quality

Technology fits in Section 4, in which there is language centered on establishing a “Process-Based Quality Management Systems”

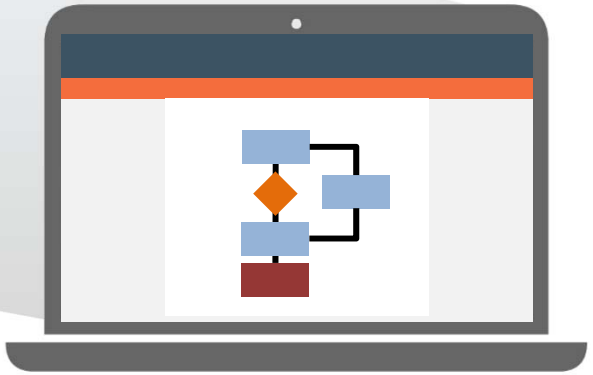
Where does Automation Meet ISO?

Context

Technology Consideration:

Collaborating on Processes

- Build a feedback loop on managing Quality
- Everyone sees the process, agrees upon it
- Visibility, Control….ENROLLMENT!



verse solutions

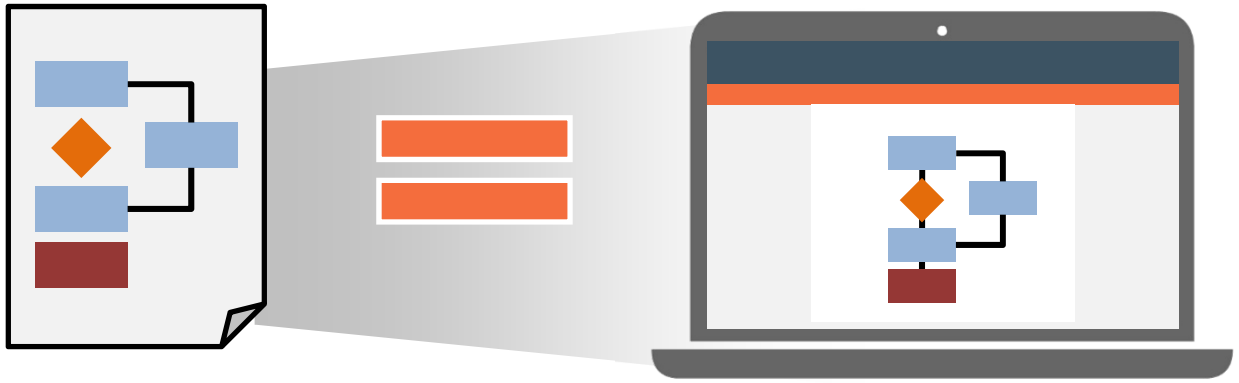
Where does Automation Meet ISO?

Context

Technology Consideration:

Flexibility of a Process-based Solution

- Map the solution to your processes
- Configurable – workflows, forms, fields, etc.
- Solution needs to match your unique processes
- Solution needs to adapt!



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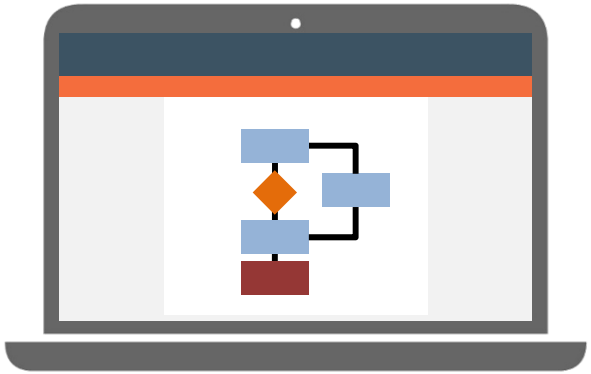
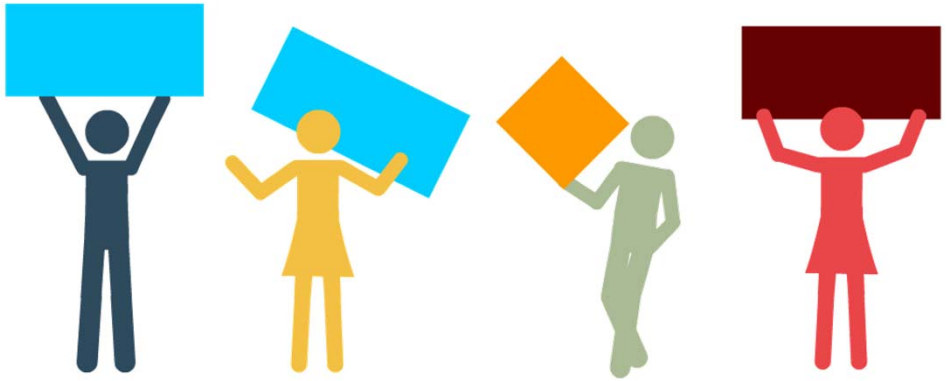
Context

For instance:





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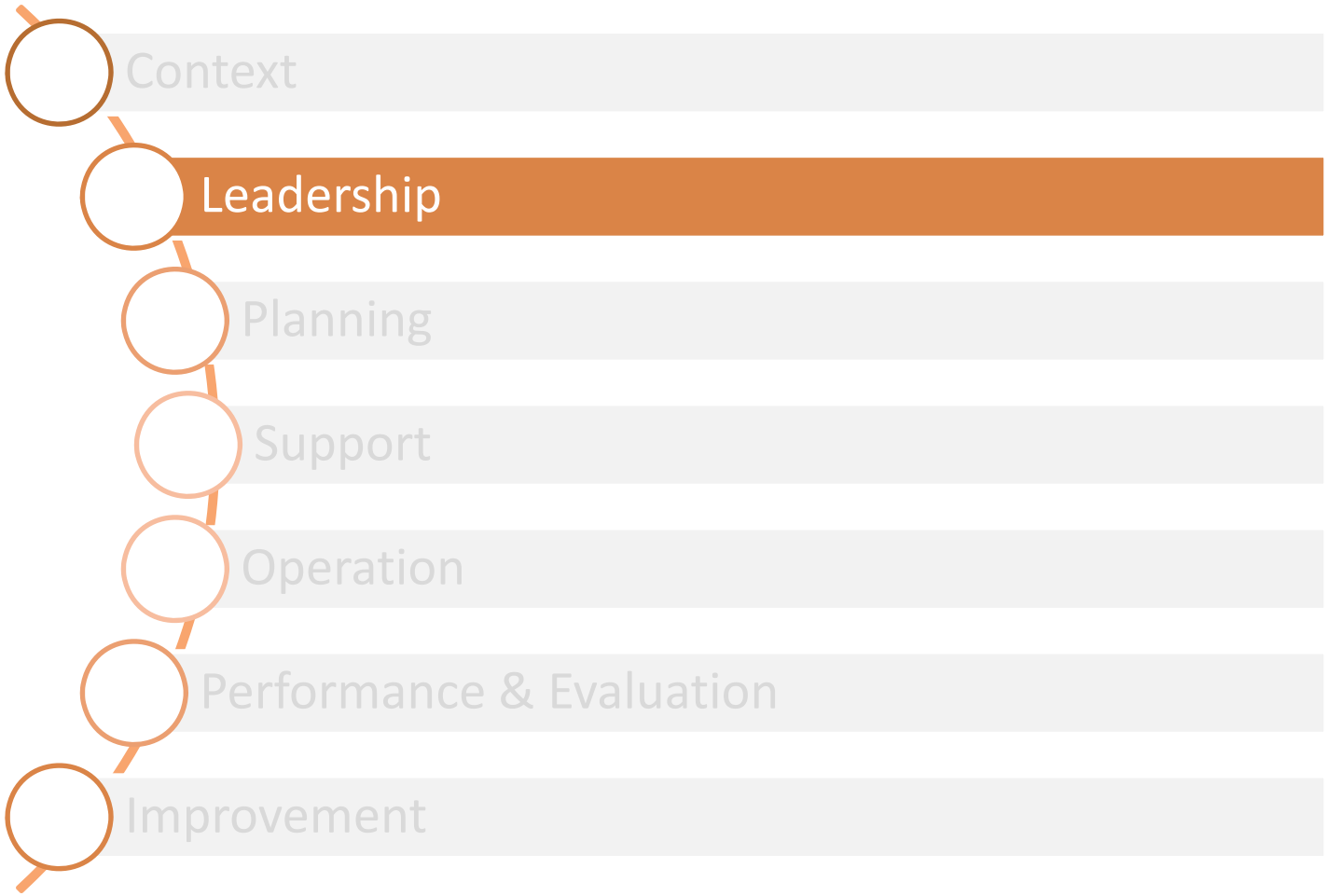

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Leadership

Building Leadership

No one representative; establish a focus on quality, customer and companywide commitment

Establish a quality “policy” – NOT NECESSARILY A MANUAL –broader look at leading Quality

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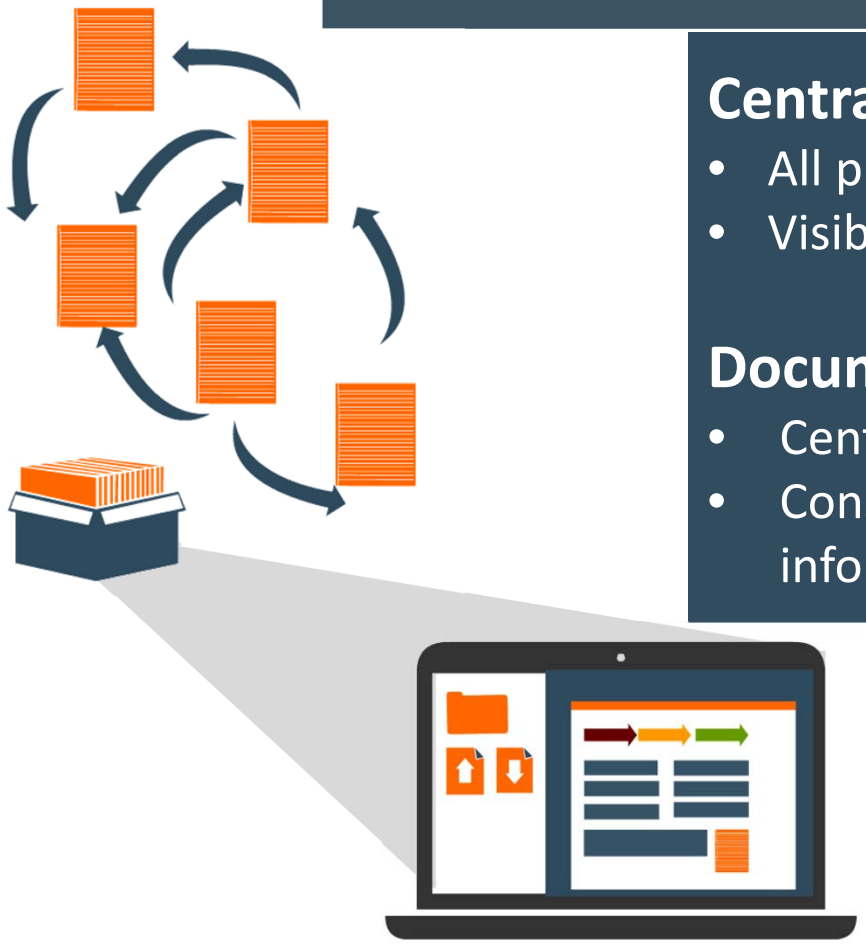
Leadership

Technology Consideration:



Centralized, Common Solution

- All processes are central to the organization
- Visibility and access of the solution

Document Control:

- Central repository, all policies, roles and access
- Consistency in communication, dissemination of information

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Leadership

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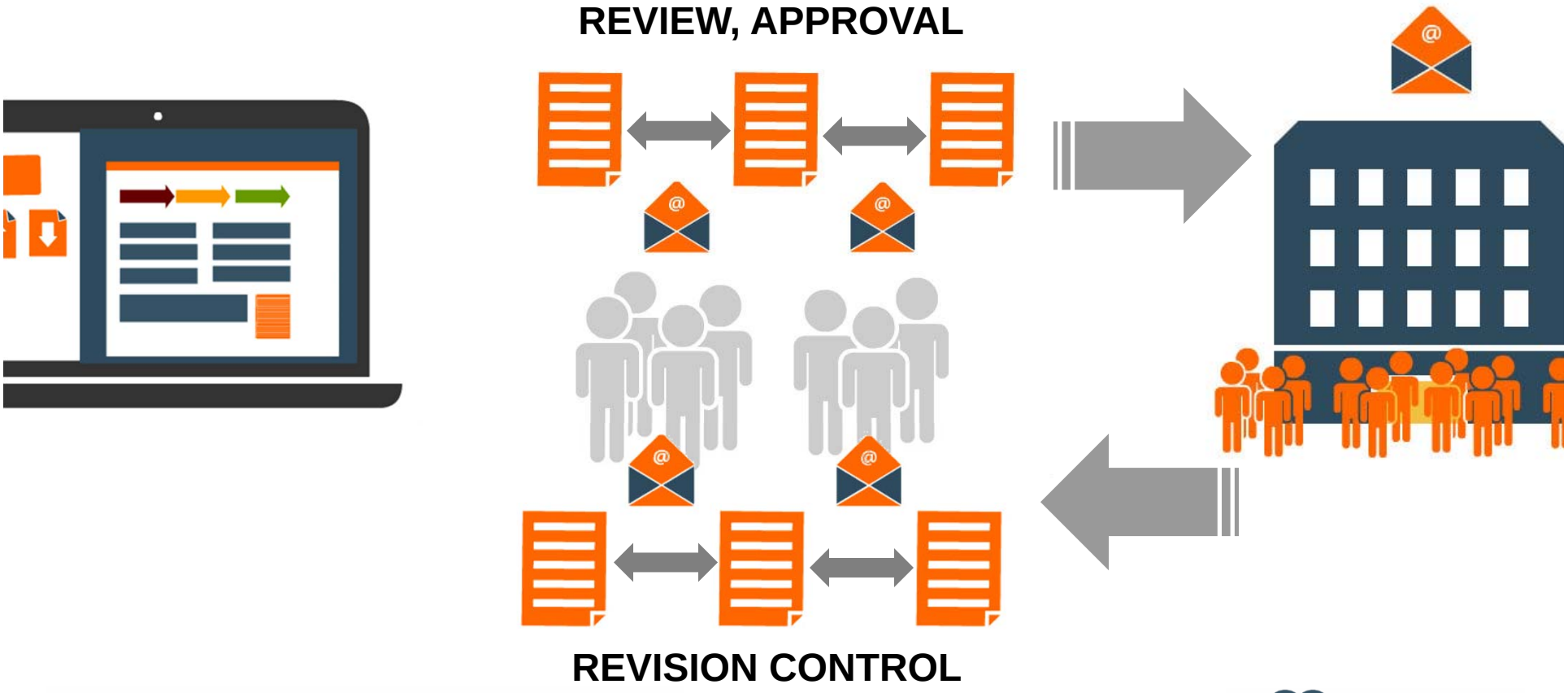

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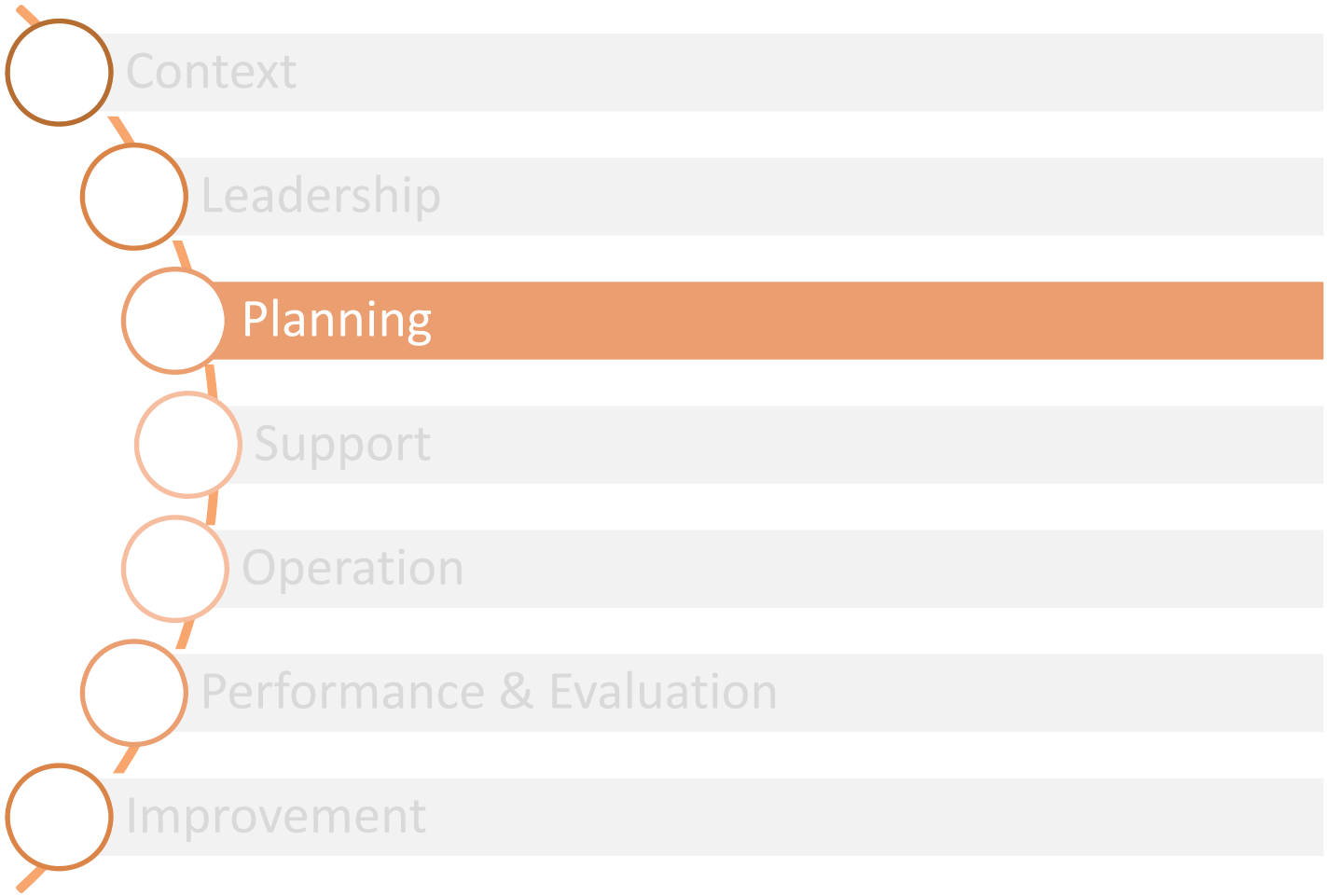

Where does Automation Meet ISO?

Planning

Risk Management takes the stage:
Shifting from a preventive action approach to a risk approach

Not just in identification, but in CONTROL

Benchmarking Risks against overall Quality Objectives

Where does Automation Meet ISO?

Planning

Technology Consideration:

Risk Management Applications & Process

- Identifying and categorization of hazards
- Building Risk levels with decisions

Risk Assessment Tools

- Risk Matrices, Decision Trees, Risk Reporting
- Build them into the process – guide decision making

Free Risk Assessment Tool:
http://risktracker.versetools.com

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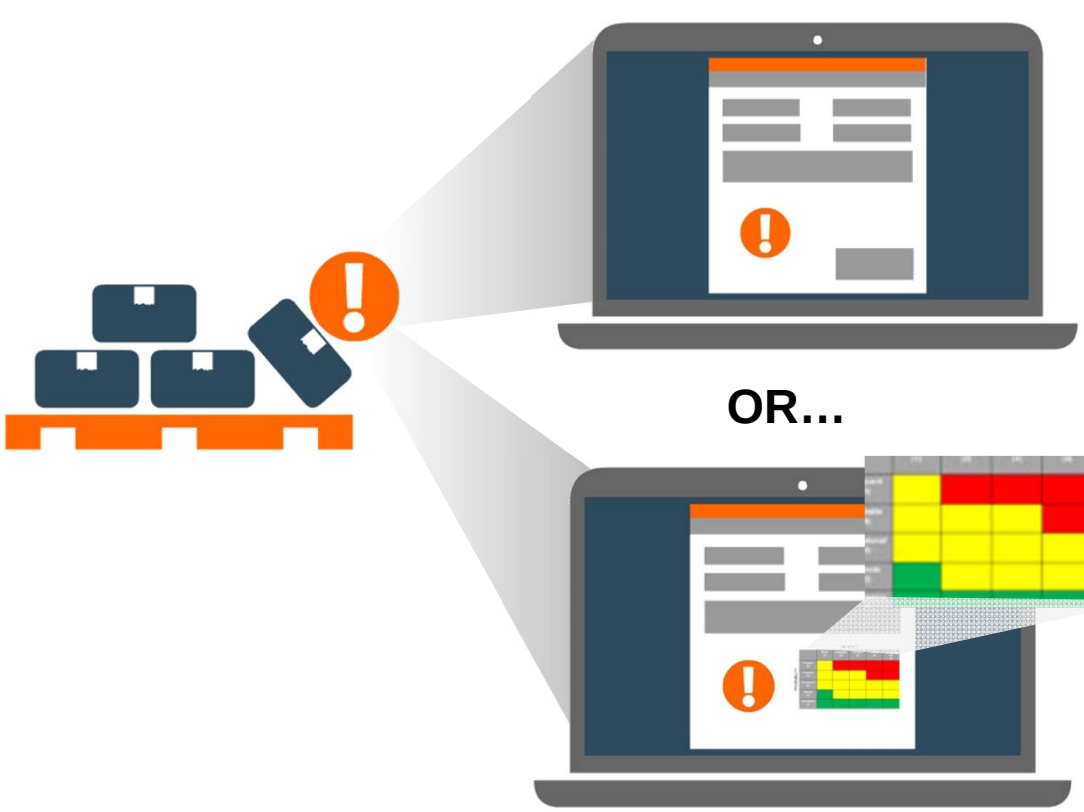

Potentially Subjective
Variable Decisions / event
Repeatable?
Qualitative by nature

OR…

Objective, Systematic
Consistent Decisions / event
Repeatable!
Quantitative by nature

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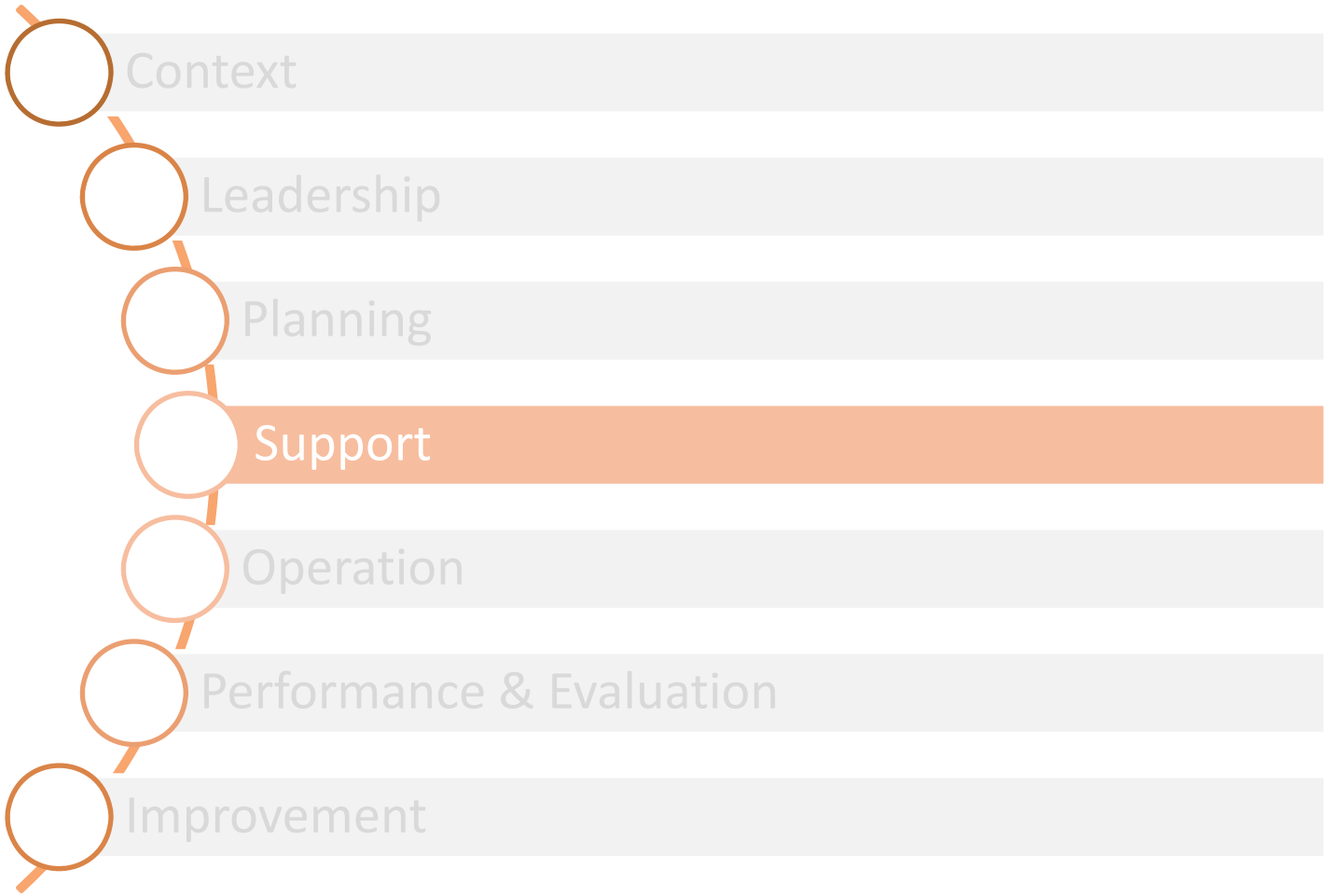

Where does Automation Meet ISO?

Support

How do we Deliver Quality?

Focusing not only on the people but also the infrastructure

Ensuring Competency and Documentation

Where does Automation Meet ISO?

Support

Technology Consideration:

Document Control & Training

- Centralized your documentation - Single Source! Controlled – no errant copies

PLUS…….

- Integrate documents to your training
- Link approved documents to a training system
- Approved documents are automatically flagged
- Training – take tests, self-certify, update records

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Support

For instance:

verse solutions

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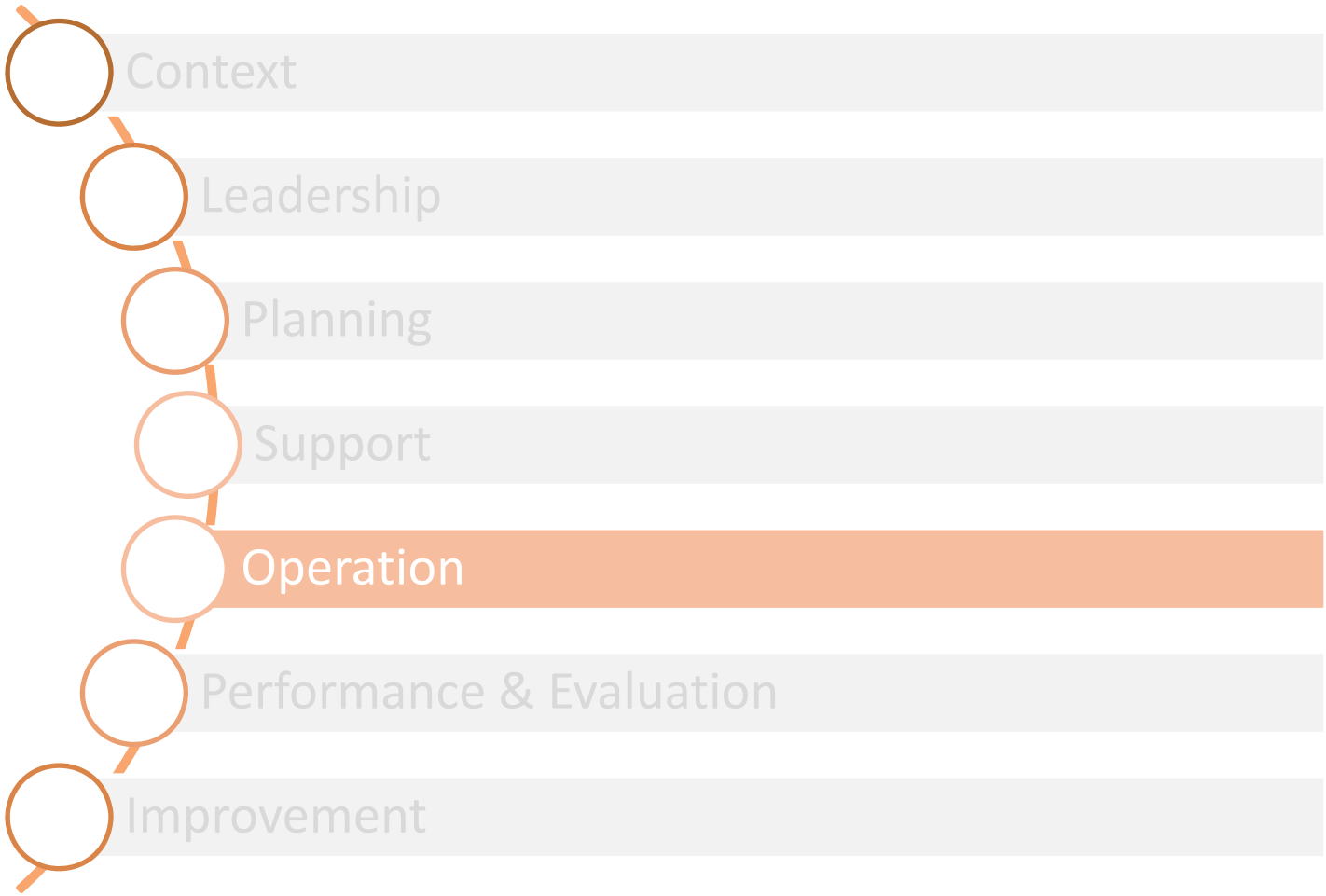

Where does Automation Meet ISO?

Operation

Framework of traceability

The design, source, produce and monitoring of operations

Mapping the processes by which you evaluate and plan your product

Also measurement of controls within your operations.

Where does Automation Meet ISO?

Operation

Technology Consideration:

Linking processes to provide traceability

- Single, integrated path from design, to sourcing, to monitoring, to inspection, etc.
- Link one process to another – full traceability
- Builds an "operational story" with Quality at the forefront of the workflow

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Operation

For instance…

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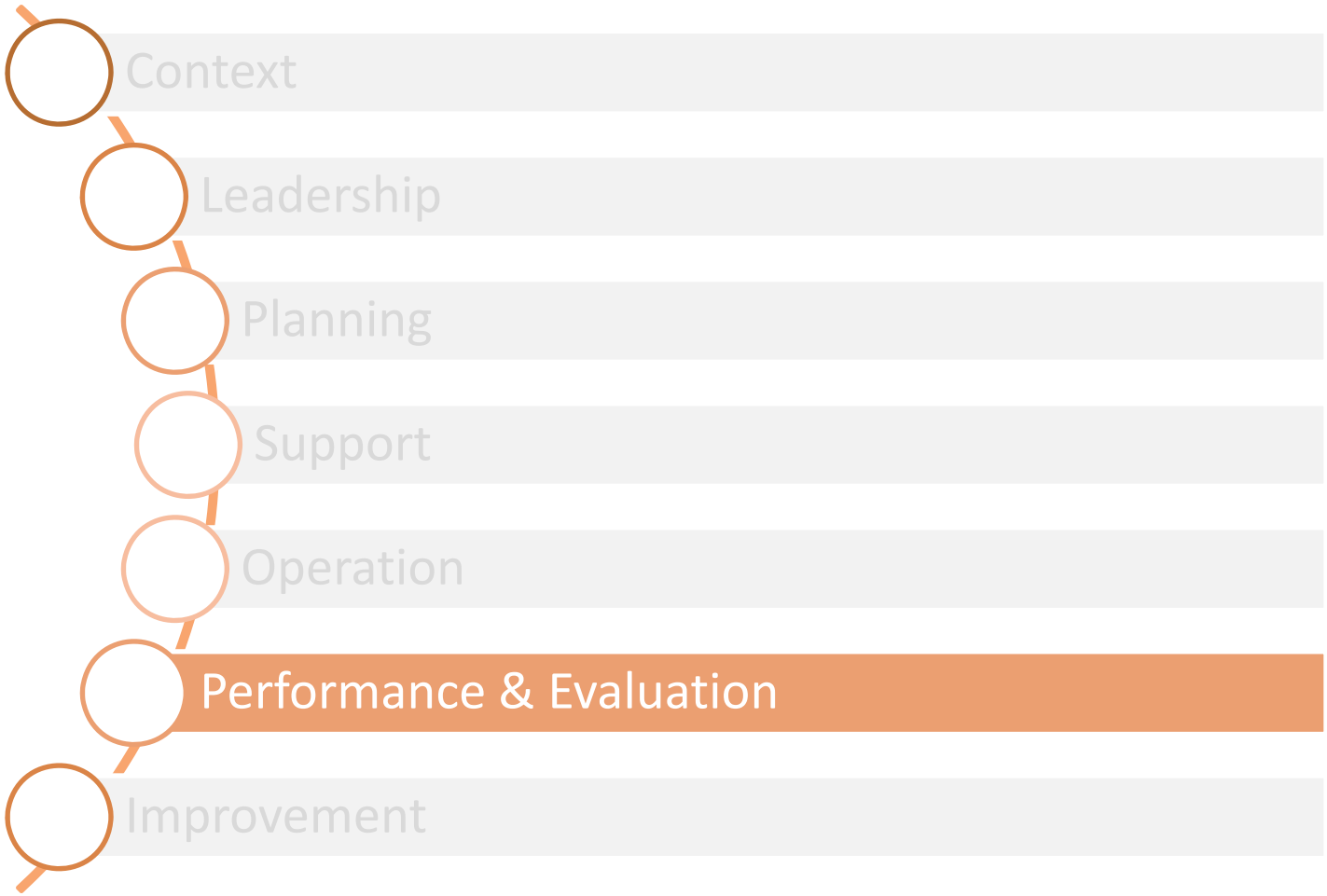

Where does Automation Meet ISO?

Performance & Evaluation

Summary:
Evaluation and Performance sits in its own category

“how do you build a constant feedback loop from your operations to ensure that you are saying what you do, and doing what you say?”

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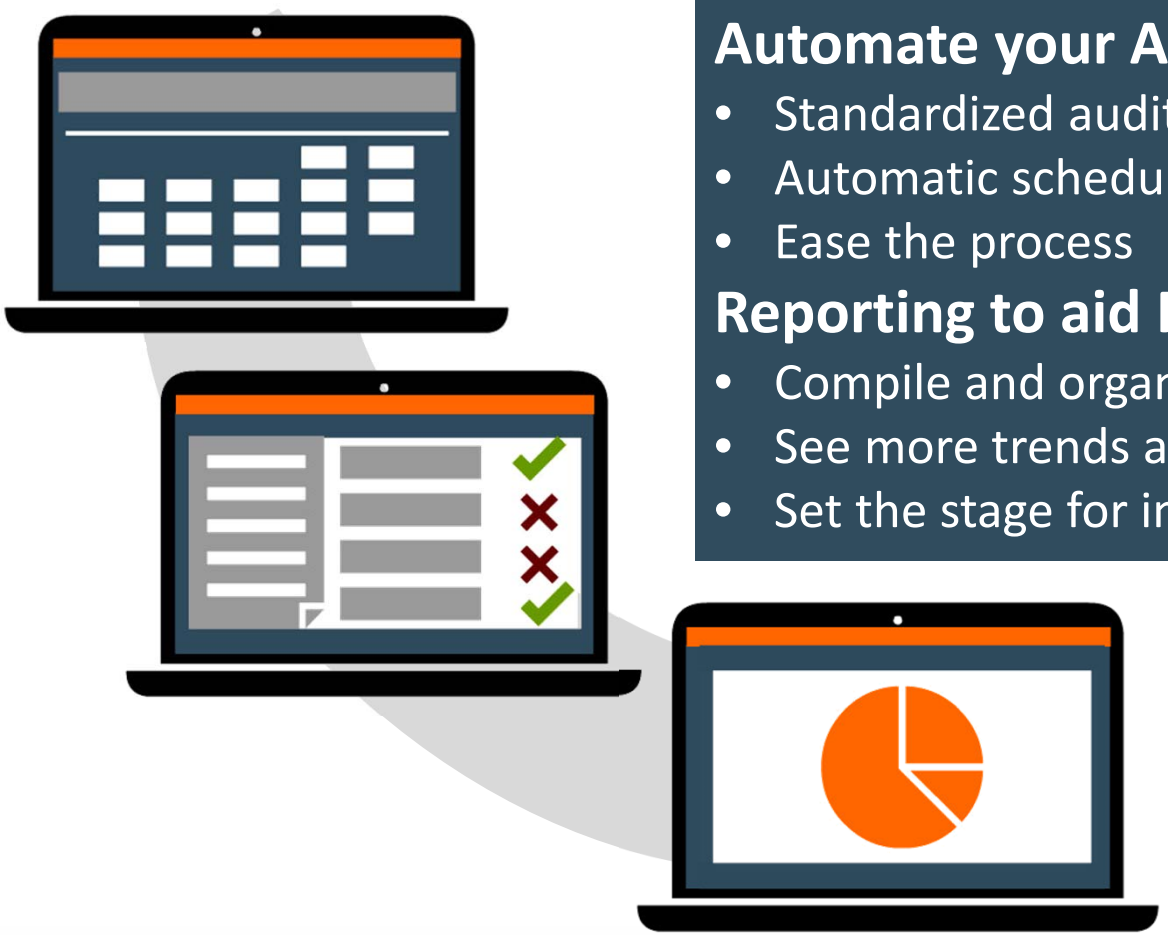
Performance & Evaluation

Technology Consideration:



Automate your Auditing

- Standardized audits – process-based!
- Automatic scheduling, templating
- Ease the process

Reporting to aid Reviews and Decisions

- Compile and organize data
- See more trends across the entire operation
- Set the stage for improvement activities

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Performance & Evaluation

For instance:

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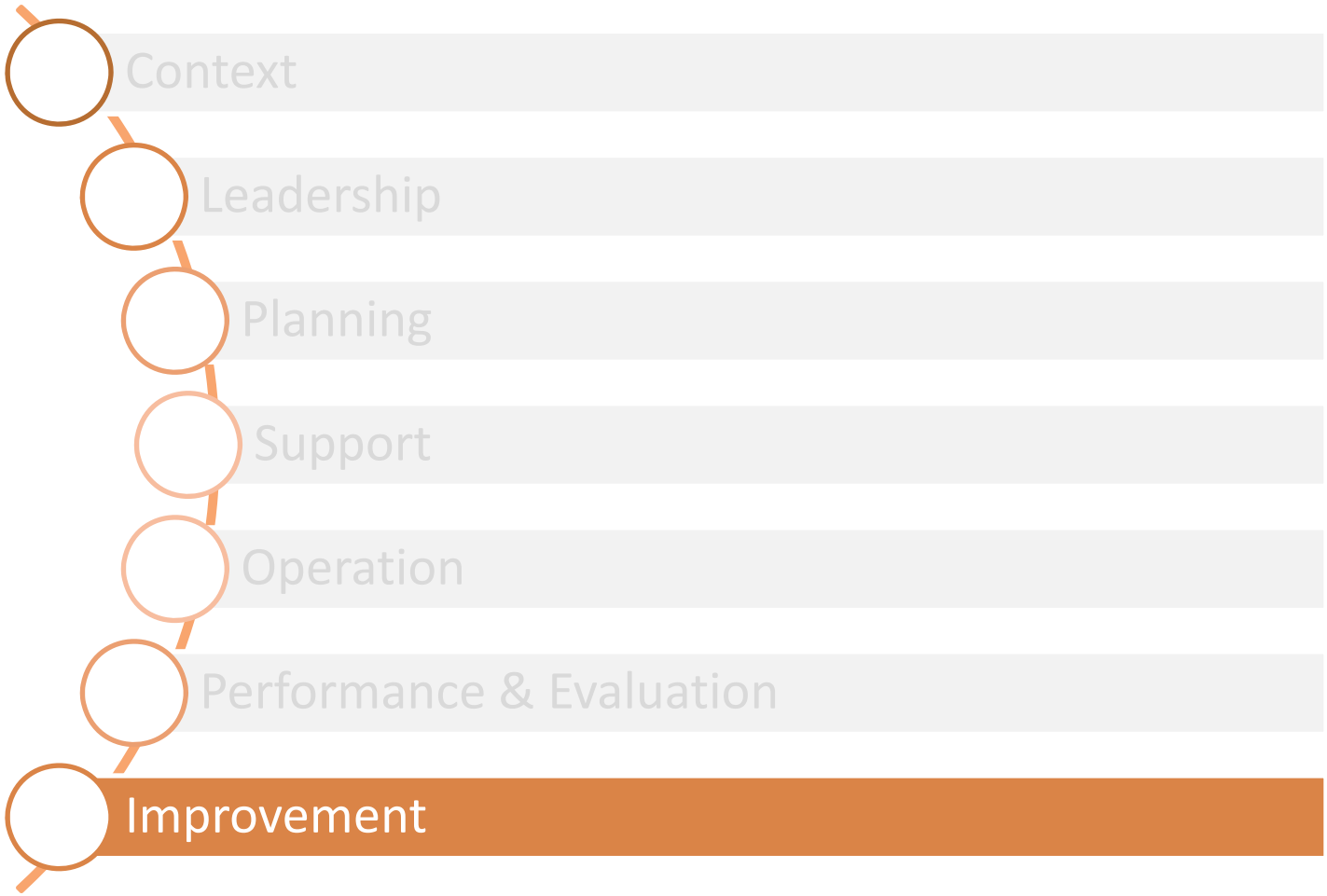

Where does Automation Meet ISO?

Improvement

Correction and improvement:

Covers Nonconformities and Corrective Action, but much broader in scope

Key concept: commitment to customer, to improvement, to companywide involvement

Focus on “how do we foster overall improvement”

Where does Automation Meet ISO?

Improvement

Technology Consideration:

Nonconformance Management

- Ease data entry through integration
- Adverse Event Tracking – based on type of event
- Build-in Risk management tools to filter by risk

Launch Corrective Actions

- Direct from adverse event - traceability
- Inherit information, create a full “story”

Initiate Change

- Reporting helps to initiate a change management workflow process – close the loop!

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Improvement

For instance:

“The History of an Event”

It is still “Plan, Do, Check, Act”

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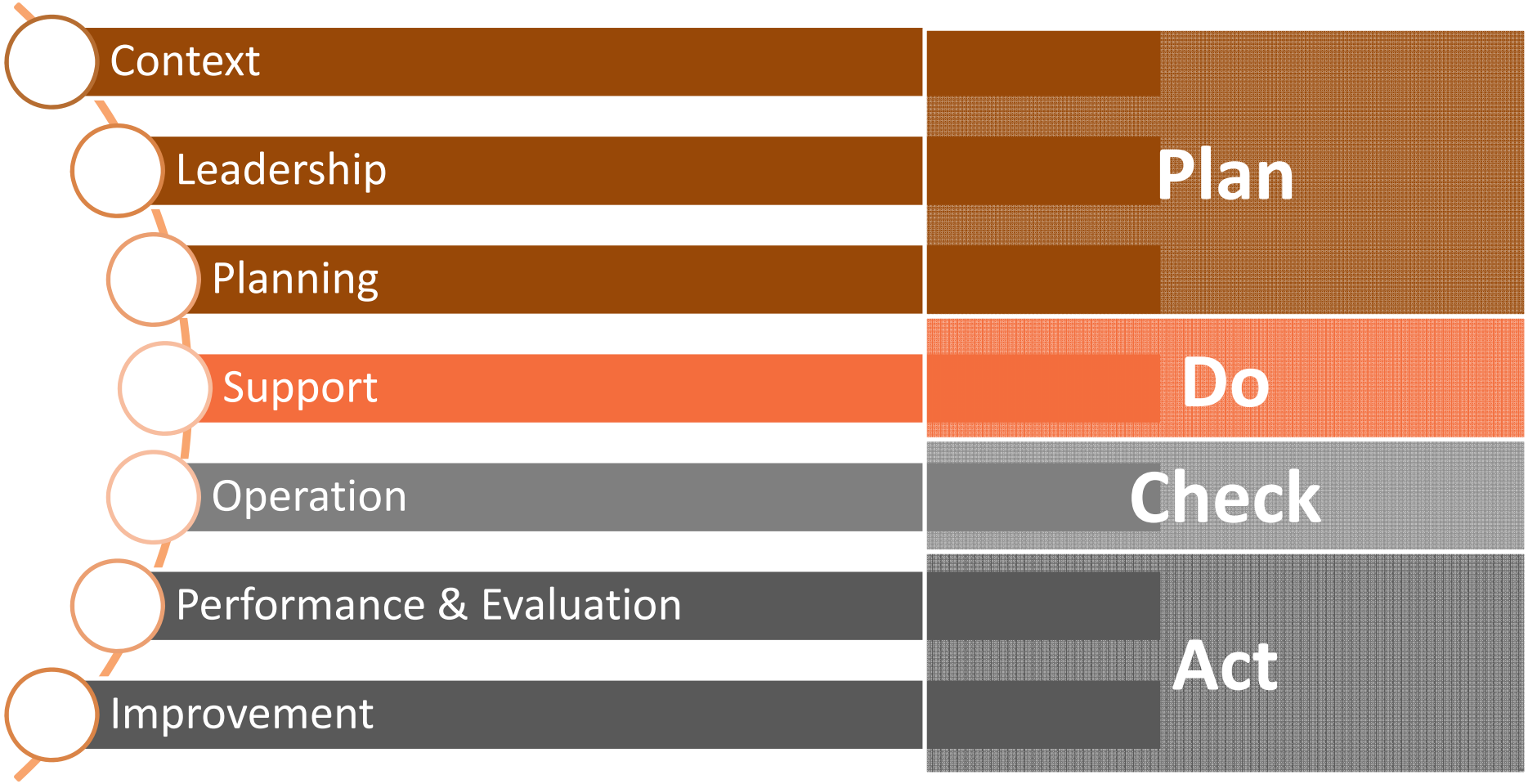

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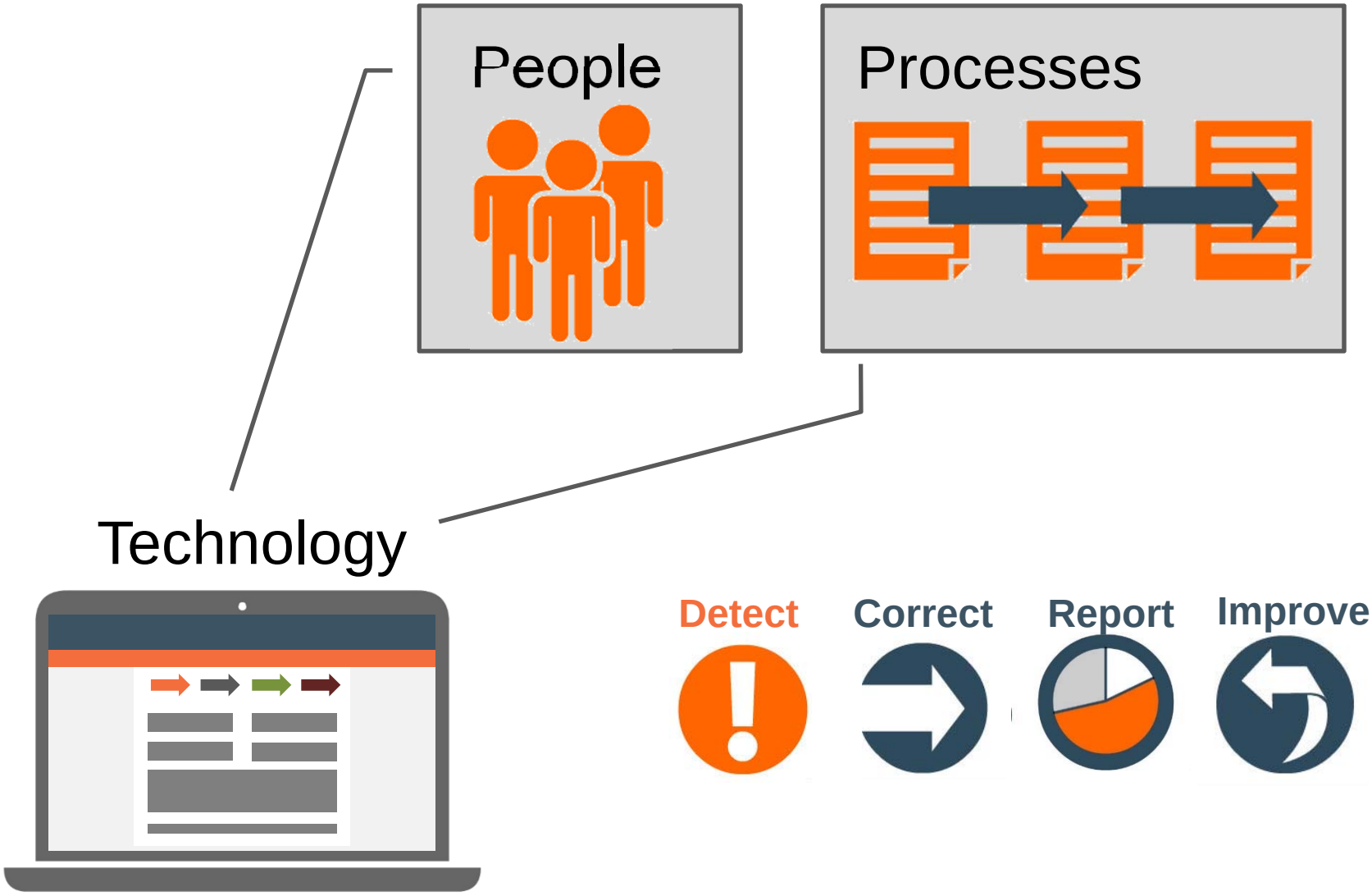
People
Processes
Technology
Detect
Correct
Report
Improve

Cheat Sheet

Section	Summary	Technology Considerations
4: Context	How you will manage Quality in a process-Based QMS ?	**Flexibility:** Needs to meet your unique business processes Adaptation: Map the solution to YOUR QMS
5: Leadership	Quality is a company-wide commitment, driven by many leaders, not just one person	**Centralization of QMS:** Single Holistic Place for managing control/visibility **Document Control:** Single source for fostering collaboration on processes
6: Planning	Shift to Risk Management – identification AND Control of risks	**Risk Management and CAPA:** leveraging risk methods to identify hazards, but also tools, embedded into the process that assess risk integrate with actions (CAPA, etc.)
7: Support	Focus on People and Infrastructure	**Document Control, Integrated with Employee Training**
8: Operations	Traceability on how you design, source, plan and measure	**Integrated Processes:** Building a seamless, traceable process, with one process integrated to the next.
9: Evaluation	Build a feedback loop and track Customer feedback, Audits, and Management Reviews	**Complaint/Adverse Event Tracking:** **Auditing:** **Reporting and Analytics:**
10: Improvement	Fostering a commitment to company-wide improvement	**Nonconformance Tracking:** **Corrective Action:** **Reporting & Change Management:**

Cheat Sheet

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