

Quality Culture: Incorporating Quality Principles Across Your Organization

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Agenda

What does it mean to develop a “quality culture”?

- How is it different than traditional QA?

What are the key elements?

- Employee Ownership & Empowerment
 - Defining core quality principles
- Continuous Improvement
- Credible Leadership Support

Q&A

What is a Cultural Value?

Cultural Values are more than what you hope to achieve

- Values are central beliefs deeply understood and *shared by every member of a company/organization.*
- Values *guide the actions* of everyone in the company or organization.
- Values *focus the energy* of the company/organization, *drive decision-making* and are the anchor points for all its plans.



Quality as a Function



Traditionally, quality was a function

- QAU audits studies to ensure compliance with GLP regulations
- QC Inspectors measure manufactured goods to ensure compliance with engineering drawings

This approach is **reactive**—errors are found and addressed *after* they occur

Creates an “us vs. them” mentality where QA polices rules and employees are afraid to speak up

Quality as a Cultural Value

Holistic approach

- Quality is everyone's responsibility
- Not a function (what someone does), it's a philosophy (how/why they do it)

Supports all aspects of business operations

- Administrative, Technical, Personnel Development, Client Satisfaction

Provides flexibility for changing business needs

- Focusing on principles of quality empowers employees to apply them to a wide range of situations and requirements

Increases employee satisfaction and retention

Quality Culture: Key Elements

Must include

- Employee ownership and empowerment
 - **Ability to apply quality principles to variety of situations**
 - Open dialogue without fear of retribution/penalty
- Continuous Improvement
- Credible leadership support
 - Talk the talk, walk the walk



Employee Ownership & Empowerment

Onboarding/Training should include an introduction to QA principles

- Defined by your organization
- Broad enough to be applied across all organizational functions
 - Competency
 - Documentation
 - Data Management
 - Equipment/Infrastructure



Competency

Does the employee have the appropriate experience and training to execute the task to which they are assigned?

- Education, Experience, On-The-Job Training

Why is it important?

- Reduces errors
- Provides employee with the tools for success, builds confidence
- Satisfies regulatory requirements

Competency should be discussed openly, candidly, and regularly between employee and manager/supervisor

- Evaluate current level, develop plan for future growth



Image Source: Stone Environmental

Documentation

How should the task be performed?

- SOPs, Instructions, Manuals, Checklists, Forms

Why is it important?

- Reduces reliance on institutional knowledge
- Addresses safety concerns (PPE, SDS, etc.)
- Protects equipment from misuse
- Establishes consistent methodology between individuals
- Training tool
- Satisfies regulatory requirements



Image Source: Stone Environmental

Data Management

How will you capture data and prevent unwanted changes?

- Handwritten log sheets, Excel spreadsheets, electronic field forms, text messages...

Why is it important?

- Traceability to source
 - Establishes integrity for technical data
- Supports other processes and reports
 - Expense report receipts and timesheets support invoicing clients
- Provides context and reasons for changes
- Satisfies regulatory requirements

Equipment/Infrastructure

Is the equipment/infrastructure reliable and appropriate for use?

- Calibrated, Maintained, Cleaned
- Used by trained staff
- Inventory/storage

Why is it important?

- Provides assurance that data collected is accurate
- Enables efficient processing
 - The right tool for the right job



Image Source: Stone Environmental

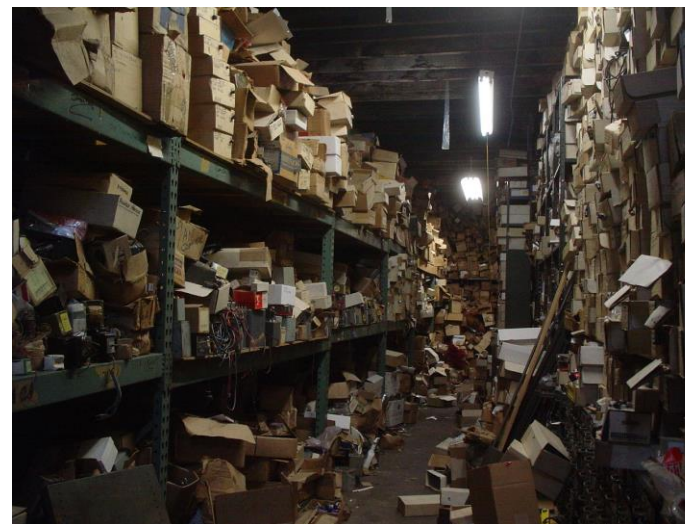


Image Source: Wikimedia Commons

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Continuous Improvement

Is a business strategy in addition to an important part of a culture of quality

Improves quality of services and products

Improves efficiency of processes

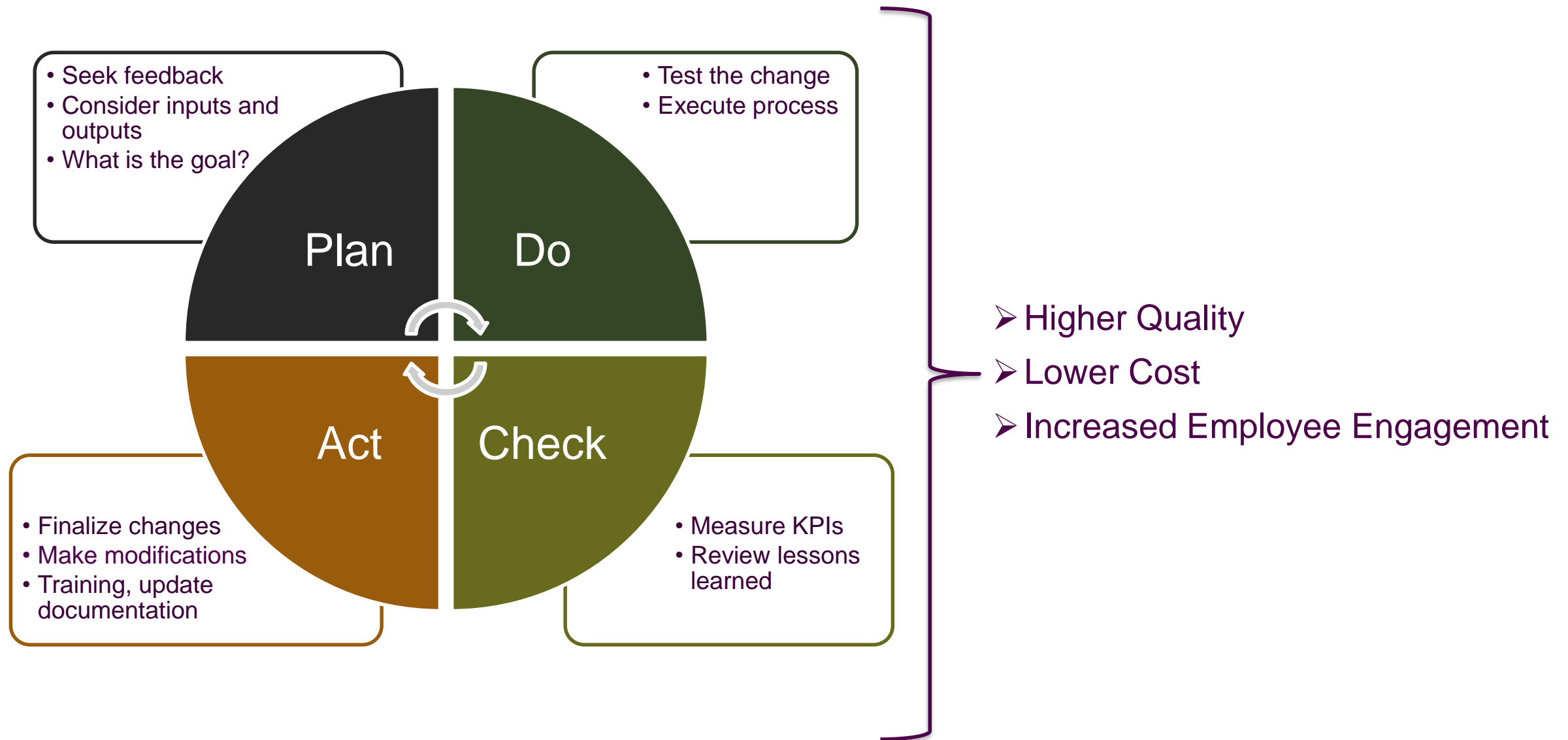
Provides mechanism for meaningful dialogue



“If you always do what you’ve always done, you’ll always get what you’ve always got.”

- Henry Ford

Continuous Improvement: PDCA



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Leadership Commitment

Establish structure that supports quality

- Clear company processes
- Clear communication channels
- Onboarding process to reinforce company values

Support employee training and development

Give and receive regular feedback

- Employees
- Clients



Summary

Quality as a cultural value is more meaningful than Quality as a job function

Quality Culture requires:

- Employee Ownership and Engagement
- Continuous Improvement
- Leadership Commitment

Quality Principles can be more universally applied across business operations than training to a standard/regulation

Quality Culture will drive higher quality results, higher client and employee satisfaction, and lower costs



*Who's responsible for Quality?
Everyone!*

Questions?

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