

Navigating Leadership: Fostering Continuous Improvement and Total Quality Management to Drive Organizational Excellence

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Speaker



Jennifer Mascioli-Tudor, MBA

With over two decades of dedicated industry experience, [Jennifer](#) has established herself as a seasoned leader in the fields of Quality and Regulatory within the pharmaceutical and medical device industries. Throughout her career, she has successfully led diverse global teams, demonstrating a strong understanding of industry requirements and trends.

Her extensive background encompasses a wide range of responsibilities, including strategic quality, regulatory initiatives, regulatory compliance management, and operational excellence practices. Jennifer has a proven track record of implementing robust quality systems, ensuring adherence to stringent regulatory standards, and driving continuous improvement across organizational processes.

Her leadership style is characterized by a commitment to fostering a culture of excellence, collaboration, and innovation within teams. Through effective communication and mentorship, she empowers her colleagues to excel in their roles and deliver exceptional results.

Jennifer has progressed through several roles of increasing leadership responsibility working for companies such as Johnson and Johnson, Kyphon, Medtronic, Nevro, Boston Scientific, Outset Medical and GE Healthcare.

She is now Founder and CEO of JMT Compliance Consulting, LLC. (www.jmtcompliance.com) where she is focused on partnering with small, emerging growth Medical Technology companies to drive Business/Quality/Regulatory strategy and Operational excellence initiatives.

Jennifer is passionate about building energized, diverse, and inclusive teams who are motivated by a shared mission to transform healthcare.

She holds a B.S. in Physiology/Chemistry and French from Eastern Michigan University and an MBA, Global Management from the University of Phoenix. Jennifer is an Instructor at UC San Diego, teaching courses to support the Regulatory Affairs for Medical Devices certificate program that is offered.



Learning Objectives

In this session, we will

focus on the following
learning objectives:



Developing a Total Quality Culture to Drive Organizational Excellence:

- Equip participants with actionable strategies and fundamental concepts essential for cultivating and nurturing a culture of Total Quality Excellence within the organization.



Promoting Continuous Improvement through Leadership Practices:

- Explore effective strategies for leaders to assess organizational dynamics and implement continuous improvement initiatives aimed at enhancing performance and driving positive change.



Empowering Teams through Quality Initiatives and Strategic Planning:

- Explore strategies to engage and inspire employees by fostering a culture of learning and development and change management.

What level are you currently at in your organization?

- ☐ Entry-level
- ☐ Mid-level
- ☐ Senior-level
- ☐ Executive-level

Navigating Your Leadership Journey: Fostering Continuous Improvement and Total Quality Management to Drive Organizational Excellence



Driving Organizational Excellence



Promoting Continuous Improvement



Driving Organizational Excellence



Organizational excellence is defined as the *ongoing efforts to establish an internal framework of standards and processes* intended to *engage and motivate employees* to deliver products and services that fulfill customer requirements within business expectations. It is the achievement by an organization of *consistent superior performance*—for example, outputs that exceed meeting objectives, needs, or expectations.

Reference: <https://asq.org/quality-resources/organizational-excellence#:~:text=It%20is%20the%20achievement%20by,objectives%2C%20needs%2C%20or%20expectations.>

Driving Organizational Excellence



An organization
is a group aggregated and
combined under specific
leadership to function as a
single entity for a
particular purpose.



Excellence
is a measure of consistently
superior performance that
surpasses requirements and
expectations without
demonstrating significant
flaws or waste.

Organizational excellence continues the progress established by a foundation such as total quality management, in which all levels of the organization participate in continual improvement.

Driving Organizational Excellence



Driving Organizational Excellence



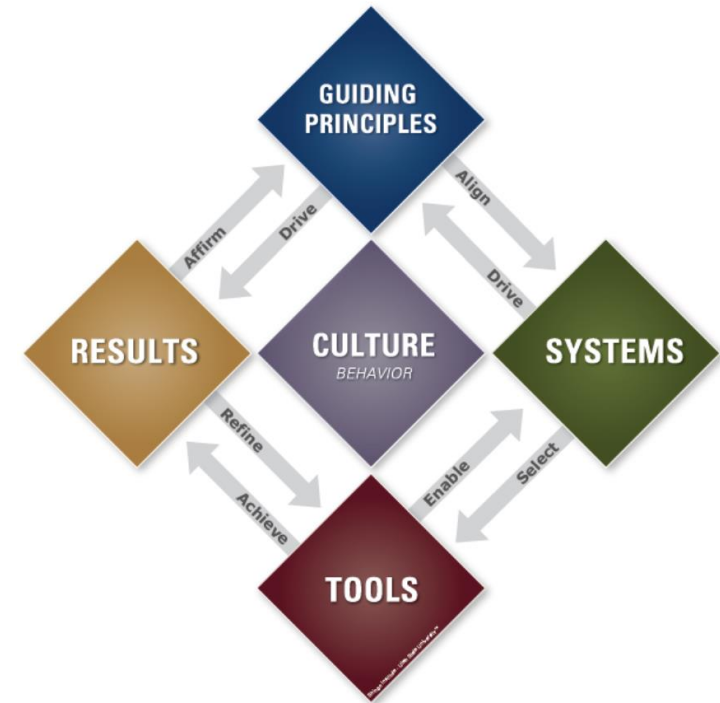
Driving Organizational Excellence

The shingo Model™

Principles: The *Shingo Guiding Principles* are the basis for building a sustainable culture of organizational excellence. In the Guiding Principles diamond, the principles are divided into three dimensions: *Cultural Enablers, Continuous Improvement, and Enterprise Alignment*.

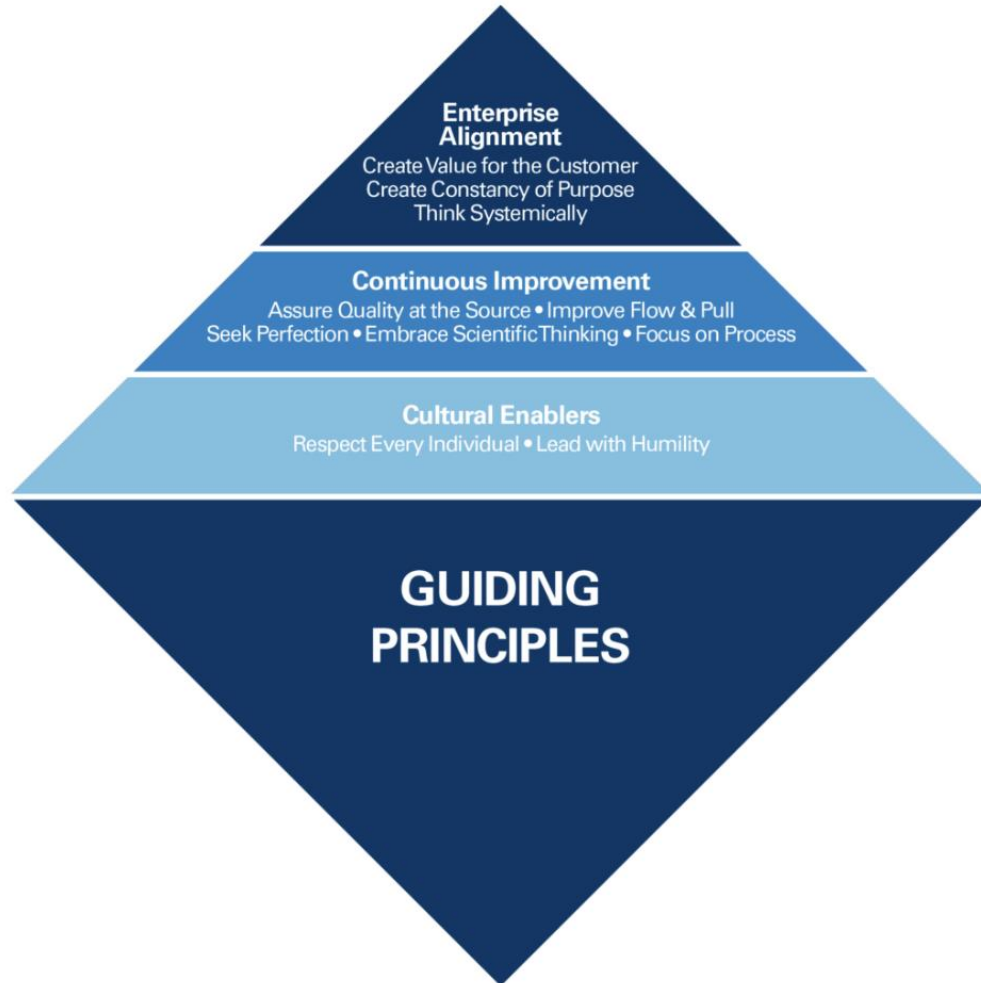
Tools: One common mistake made by organizations is focusing too heavily on a specific tool-set as the basis for improvement efforts. Tools do not answer the question “why,” they only focus on “how.” *But knowing the “how” without understanding fully the “why” often leaves team members waiting for instructions, powerless to act on their own.*

Reference: <https://shingo.org/shingo-model/>



Driving Organizational Excellence

The shingo Model™



Shingo Guiding Principles

Click on each principle for a detailed explanation.

[Respect Every Individual](#)

[Lead with Humility](#)

[Seek Perfection](#)

[Embrace Scientific Thinking](#)

[Focus on Process](#)

[Assure Quality at the Source](#)

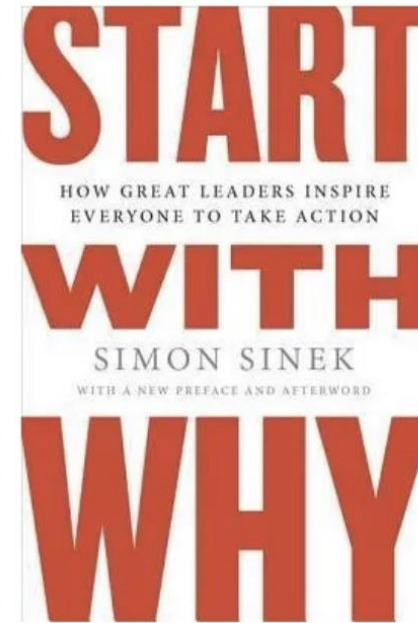
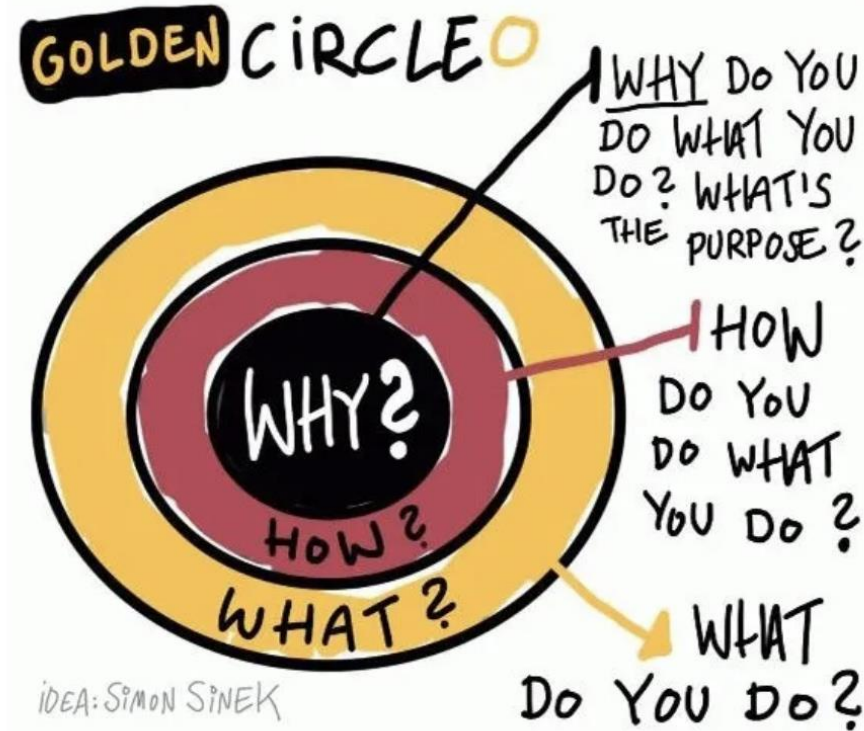
[Improve Flow & Pull](#)

[Think Systemically](#)

[Create Constancy of Purpose](#)

[Create Value for the Customer](#)

Driving Organizational Excellence



“The Golden Circle” concept, as defined by Simon Sinek, is a communication and leadership framework that instructs leaders to start by clearly defining and communicating their **WHY**, followed by recruiting those who can strategize the **HOW**, and then using **WHAT** they do as proof of their why. *This concept is how the best leaders and companies achieve success through a common phenomenon.*

5 WAYS TO HELP CREATE PSYCHOLOGICAL SAFETY



1. MAKE
it an explicit
priority.



2. FACILITATE
everyone
speaking up.



3. ESTABLISH
norms for how
failure is handled.



4. CREATE
space for new ideas
(even wild ones).



5. EMBRACE
productive
conflict.



Center for Creative Leadership®

Building a Culture of Excellence



- Psychological safety means feeling safe to take interpersonal risks, to speak up, to disagree openly, to surface concerns without fear of negative repercussions or pressure to sugarcoat bad news.
- Psychological safety nurtures an environment where people feel encouraged to share creative ideas without fear of personal judgment or stepping on toes.
- In this kind of environment, it feels safe to share feedback with others, including negative upward feedback to leaders about where improvements or changes are needed.
- It is OK to admit mistakes, to be vulnerable, and to speak truth to power.

Reference: <https://www.mckinsey.com/featured-insights/mckinsey-explainers/what-is-psychological-safety>

Which leadership style do you find most effective in your organization?

- ☐ Transformational
- ☐ Transactional
- ☐ Servant Leadership
- ☐ Democratic
- ☐ Executive-level

Building a Culture of Excellence



The Benefits of Psychological Safety:

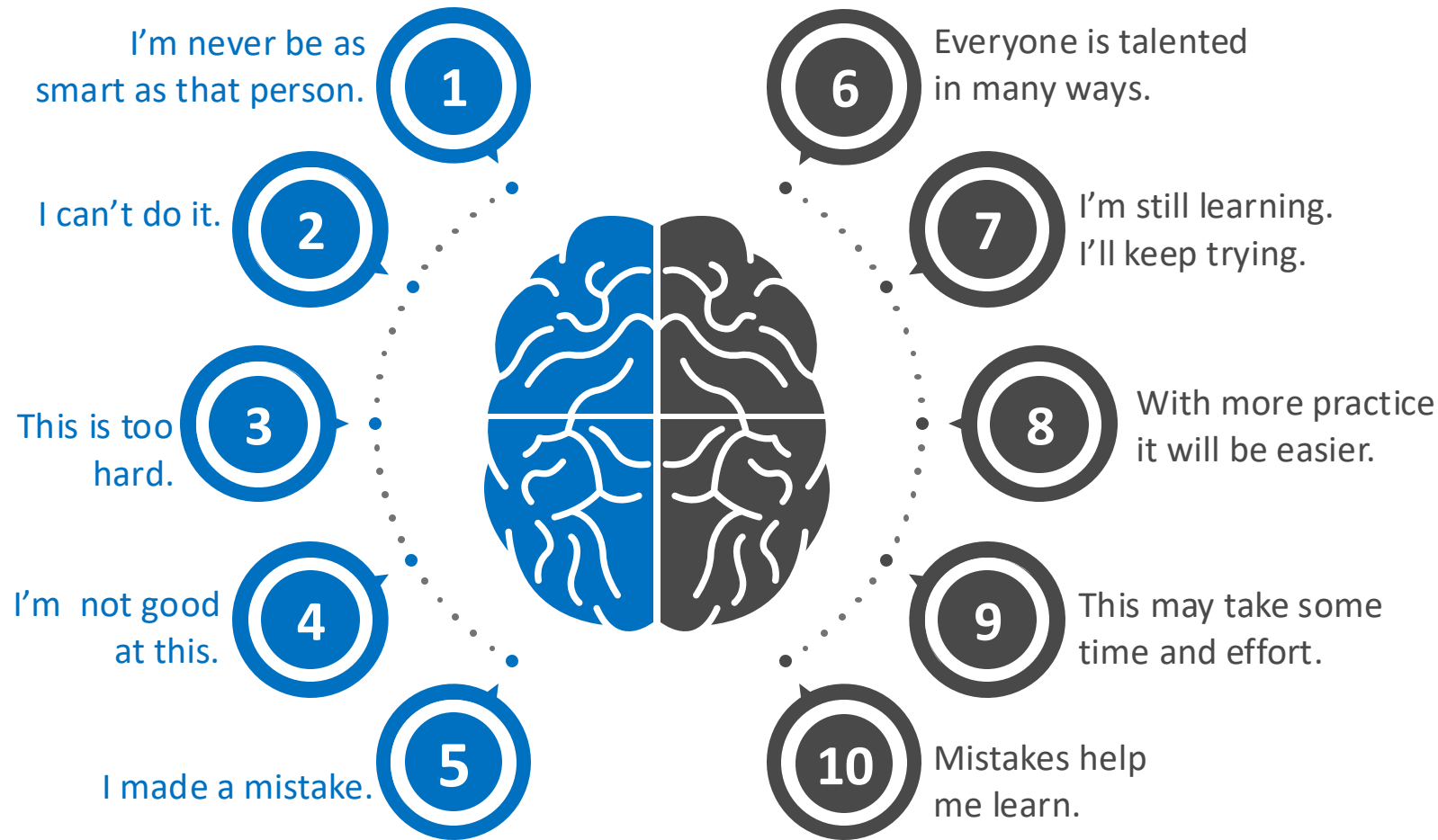


Reference: <https://www.linkedin.com/pulse/fostering-psychological-safety-catalyst-inclusive-teams-patton/>

Navigating Your Leadership Journey: Fostering Continuous Improvement and Total Quality Management to Drive Organizational Excellence



Promoting Continuous Improvement



In her book, "Mindset," renowned Stanford psychologist Carol Dweck says that *it's not intelligence, talent or education that sets successful people apart. It's their mindset, or the way that they approach life's challenges.*

Promoting Continuous Improvement



- Organizational transformation hinges on the idea that *we can better ourselves and our organizations*.
- The continuous improvement process (*Plan, Do, Check and Act or PDCA*), is an investment in an organization's future to reach their full potential.
- It is deliberate process that requires observation, analysis, planning, and action.
- Continuous improvement is the process of making small incremental changes that add up to significant results based on deliberate observation of current processes.
- The main idea behind continuous improvement is that no process is perfect and there is always room for improvement.
- The goal is to eliminate waste, optimize resources, and empower employees to make changes that improve the company's bottom line.
- **Question: How does your organization drive Continuous Improvement projects?**

Promoting Continuous Improvement

WHAT IS KAIZEN?

Kaizen is a strategy where employees at all levels of a company work together proactively to achieve regular, incremental improvements to the manufacturing process. In a sense, it combines the collective talents within a company to create a powerful engine for improvement. Kaizen is also referred to as Continuous Improvement.

Kaizen is part action plan and part philosophy.

- As an action plan, Kaizen is about organizing events focused on improving specific areas within the company. These events involve teams of employees at all levels, with an especially strong emphasis on involving plant floor employees.
- As a philosophy, Kaizen is about building a culture where all employees are actively engaged in suggesting and implementing improvements to the company. [In truly lean companies](#), it becomes a natural way of thinking for both managers and plant floor employees.

Kaizen works hand-in-hand with [Standardized Work](#). Standardized Work captures the current best practices for a process, and Kaizen aims to find improvements for those processes. Note the emphasis on current; Standardized Work is living documentation (it continually evolves through Kaizen).



PHILOSOPHY

Developing a culture where all employees are actively engaged in improving the company.

ACTION PLAN

Organizing events focused on improving specific areas within the company.

Promoting Continuous Improvement



What Is a SWOT Analysis?

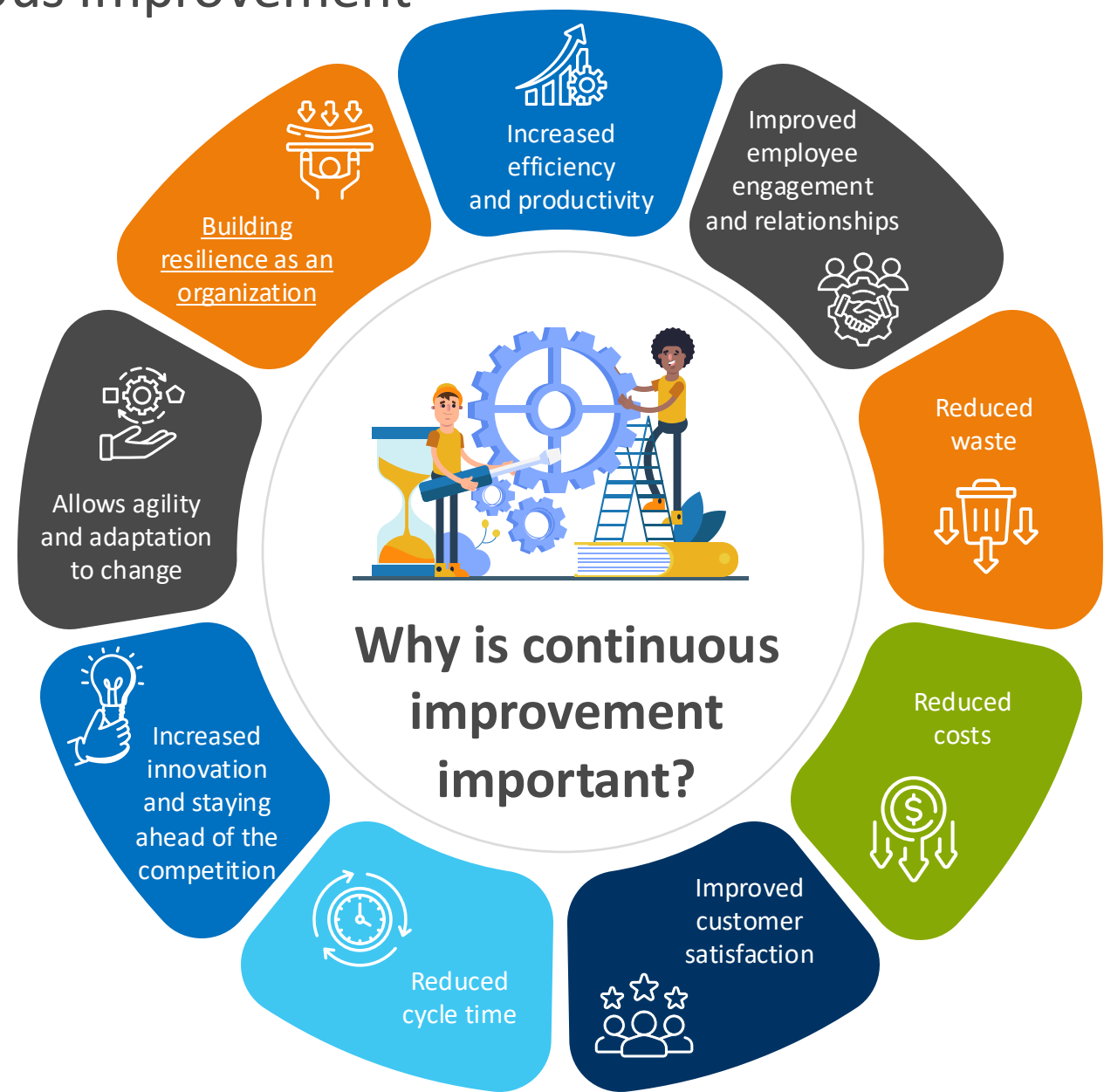
SWOT stands for Strengths, Weaknesses, Opportunities, and Threats, and so a SWOT analysis is a technique for assessing these four aspects of your business.

What is the objective of a SWOT analysis?

The primary objective of a SWOT analysis is to help organizations develop a full awareness of all the factors involved in [making a business decision](#). Albert Humphrey of the Stanford Research Institute created this method in the 1960s during a study conducted to identify why corporate planning consistently failed. Since its creation, the SWOT analysis has become one of the most useful tools for business owners to start and grow their companies.

S STRENGTHS	W WEAKNESSES	O OPPORTUNITIES	T THREATS
<ul style="list-style-type: none">Things your company does wellQualities that separate you from your competitorsInternal resources such as skilled, knowledgeable staffTangible assets such as intellectual property, capital, proprietary technologies etc.	<ul style="list-style-type: none">Things your company lacksThings your competitors do better than youResource limitationsUnclear unique selling proposition	<ul style="list-style-type: none">Underserved markets for specific productsFew competitors in your areaEmerging need for your products or servicesPress/media coverage of your company	<ul style="list-style-type: none">Emerging competitorsChanging regulatory environmentNegative press/media coverageChanging customer attitudes toward your company

Promoting Continuous Improvement

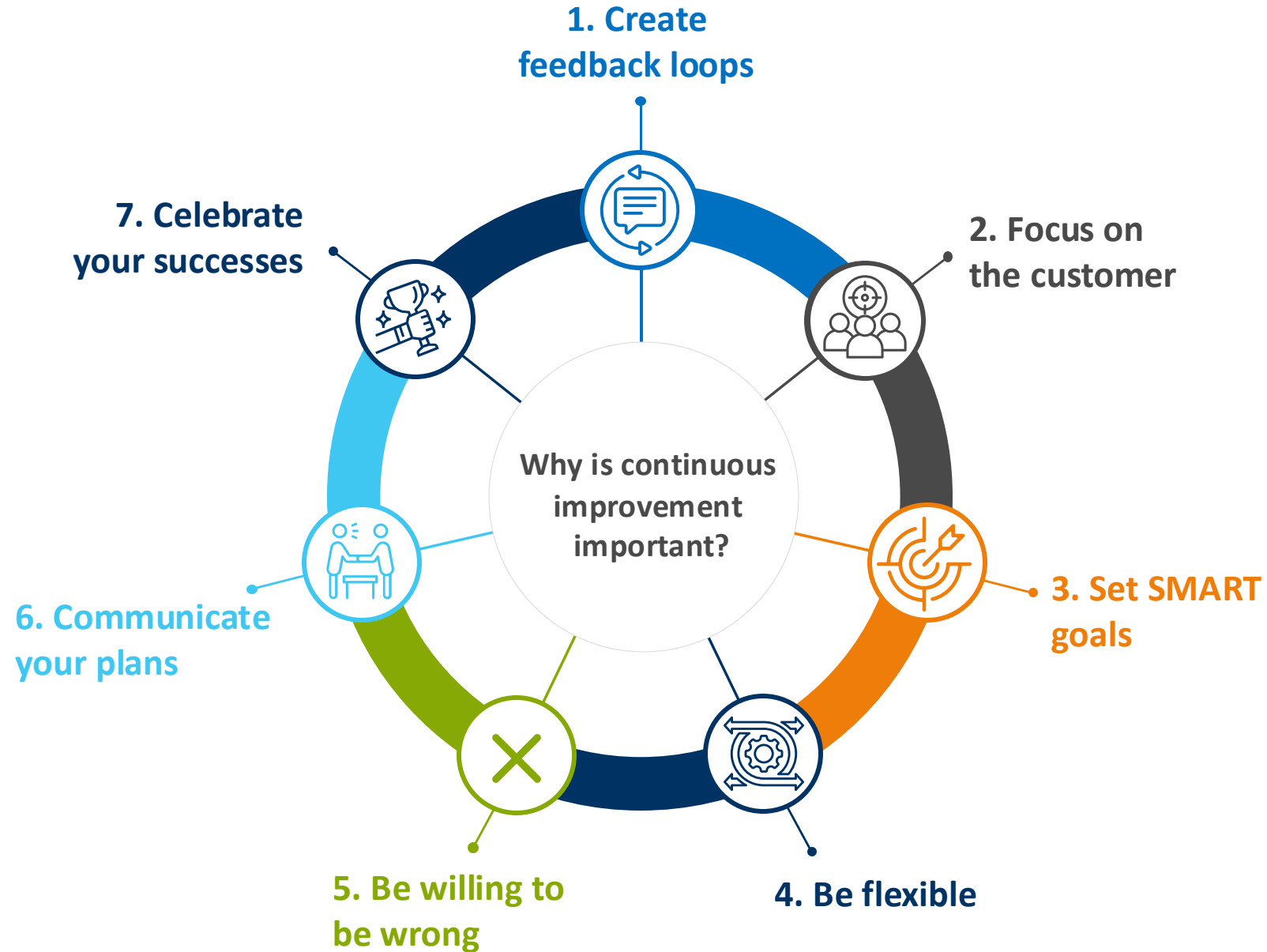


References: <https://www.betterup.com/blog/continuous-improvement#what-is-continuous-improvement?>

How do you feel about changes in the workplace?

- ☐ I embrace and adapt to change quickly
- ☐ I take time to adapt but eventually do
- ☐ I find change challenging and stressful
- ☐ I resist change whenever possible

Promoting Continuous Improvement

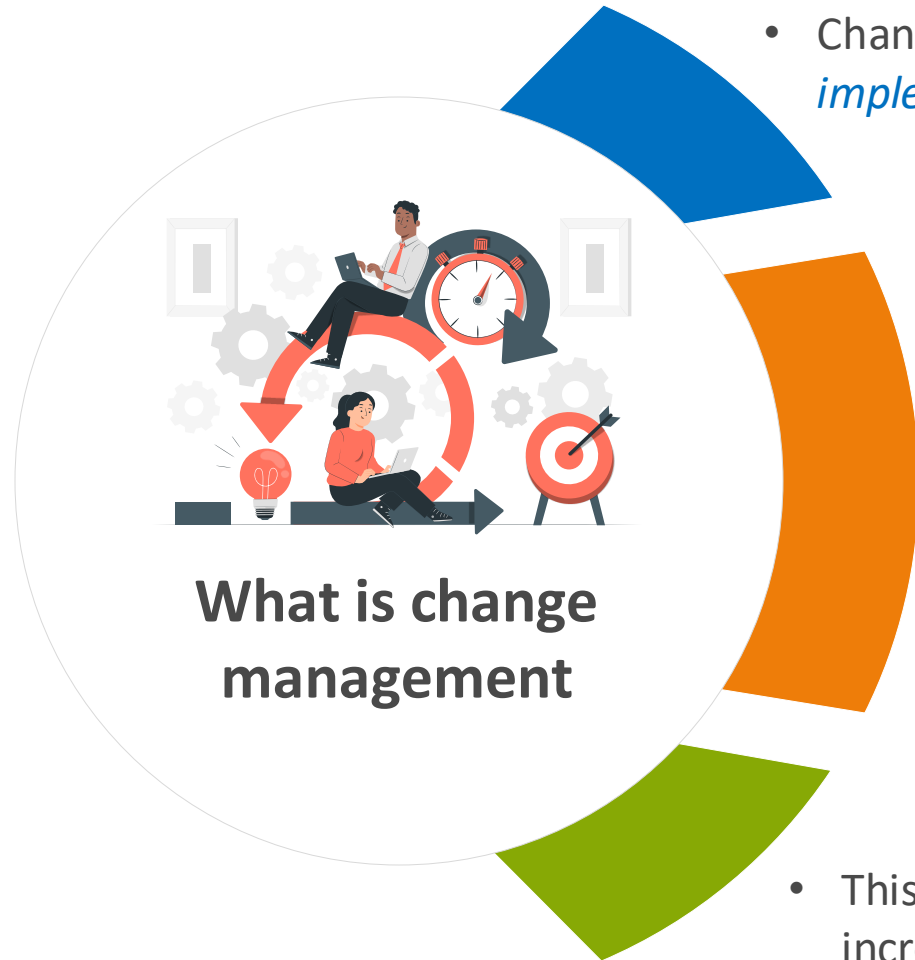


References: <https://www.betterup.com/blog/continuous-improvement#what-is-continuous-improvement?>

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Leading Change for Organizational Excellence



- Change management is the *process that businesses and organizations use to implement changes* through *building and delivering effective change strategies*.
- It *includes* reviewing *reasons for change, implementing changes, and helping people adapt to these changes*.
- This could be staff structure, introducing new technology, reducing costs, increasing profits, or a combination of these to reach a desired goal.



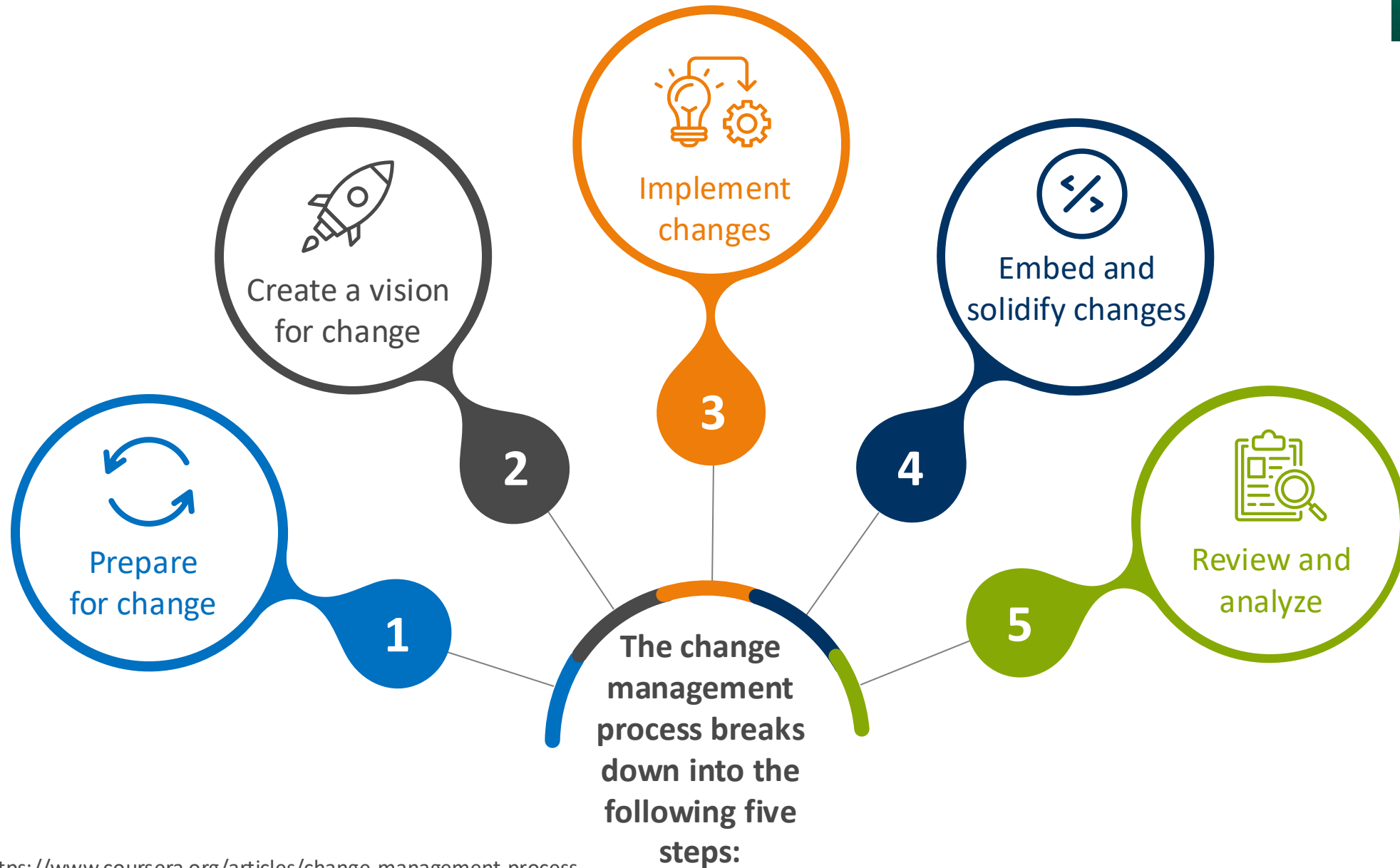
What is change management

Situations that require a change management process

We need change management in an organization for a number of reasons. Common situations include:

- Implementing new technology
- Leadership or management turnover
- Change in work culture
- Mergers and acquisitions
- Current processes are not working
- Changes in staff and structure
- A time of crisis

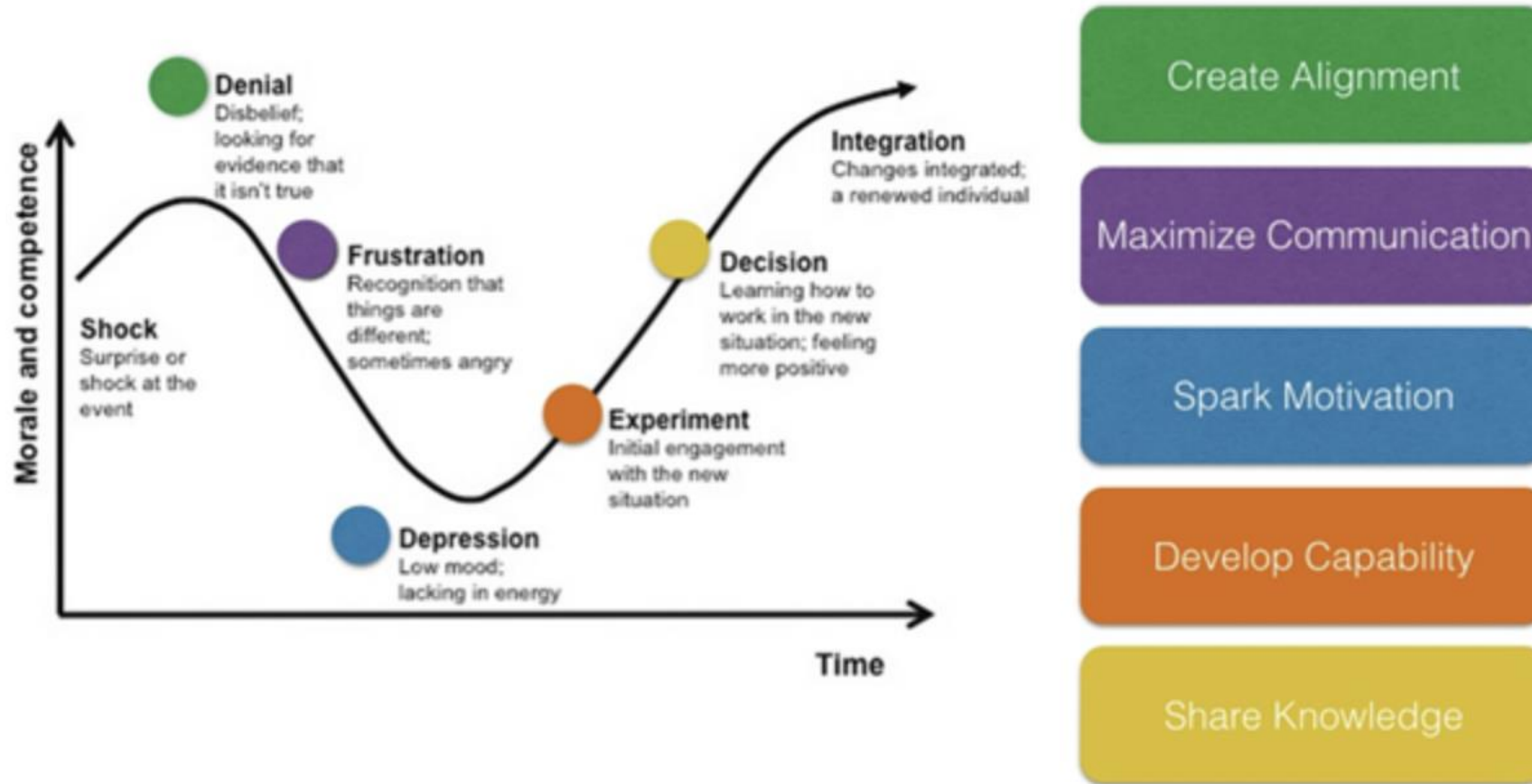
Leading Change for Organizational Excellence



References: <https://www.coursera.org/articles/change-management-process>

Leading Change for Organizational Excellence

The Kübler-Ross change curve



Leading Change for Organizational Excellence

Common Rea

- **Denial:** If a c
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- indivi
- **Acce**
- invol
- occur



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References: <https://www.coursera.org/articles/change-management-process>

Navigating Change in the Workplace

- 1 What change did you encounter in the workplace?
- 2 How did you initially feel about this change?
- 3 How was the change communicated to you and your colleagues?
- 4 Was the communication clear and sufficient? Why or why not?
- 5 How did you adapt to the change personally and professionally?
- 6 What strategies or actions did you take to manage your adaptation process?
- 7 What were the biggest challenges you faced during this change?
- 8 How did you overcome these challenges?
- 9 What did you learn from this experience about handling change?



Leading Change for Organizational Excellence



References: <https://management30.com/blog/navigating-organizational-change-a-model/>

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Wrap Up



Wrap Up



Building a culture of excellence *requires a shared vision and core values* to serve as the foundation, *with leaders modeling the behaviors* throughout the organization;

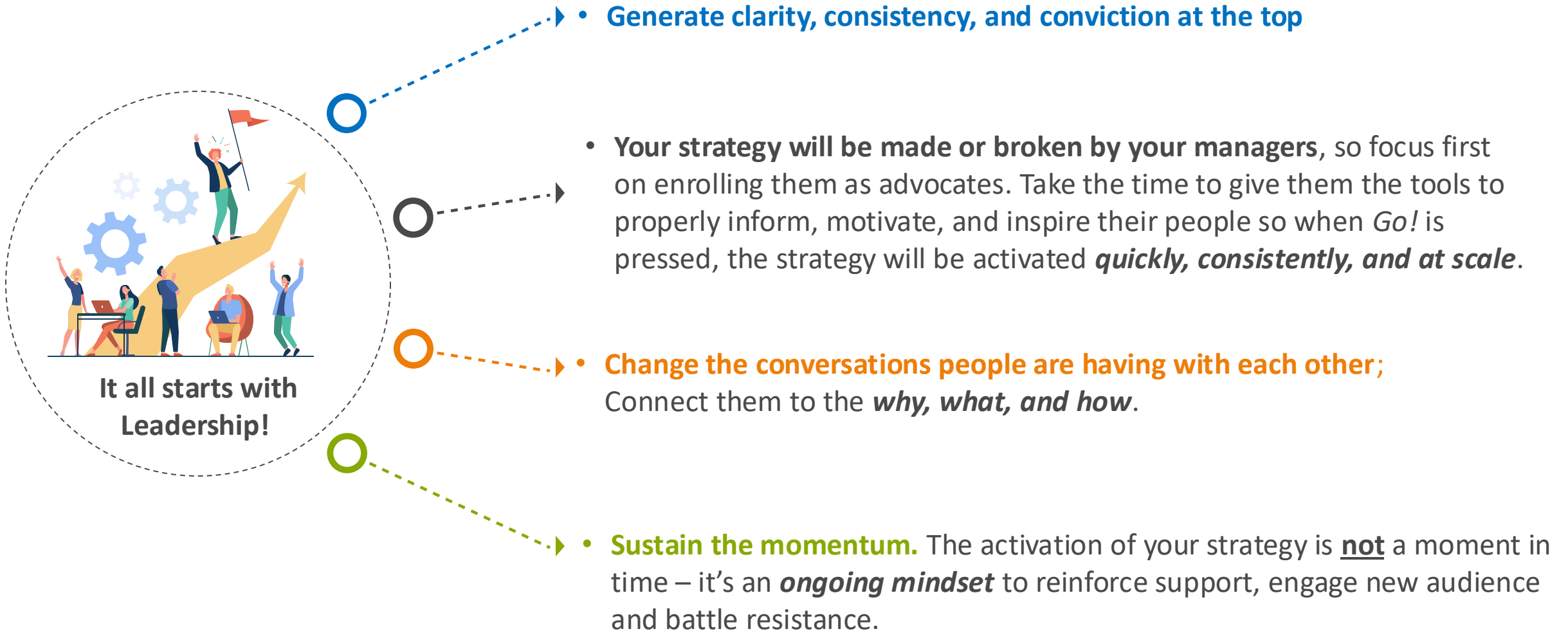


It is a *deliberate effort and commitment from leadership and employees* alike.



By defining clear values, fostering collaboration, promoting continuous improvement, implementing strong change management practices and providing support and recognition, *organizations can create a culture where excellence thrives.*

Promoting Continuous Improvement



References: https://www.hr.com/en/magazines/all_articles/it-all-starts-with-your-leadership_lceghfn2.html

About ComplianceQuest



About ComplianceQuest

Transform to a fully connected business with a next-generation AI-Powered Product Lifecycle, Quality and Safety management platform, built on Salesforce.

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1000+
Customer Sites

125M+
Active Records being
Managed

1000+
Man years
Domain Expertise

Award
Winning
Solution

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Direct and Partner
locations

INSIGHT
PARTNERS

\$36M in 2019

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AICPA SOC 2
ISO 27001
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2023 QMS Market Guide

ComplianceQuest Named a Leader on Frost & Sullivan's Frost Radar™ for its EQMS Platform

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5 STAR USER REVIEWS

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SPRING 2022 TOP PERFORMER Quality Management Software

SUMMER 2022 TOP PERFORMER EHS Management Software

Inc. 5000 LIST 2019-2022

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Lifescan

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CANON MEDICAL

YKK

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a smiths company

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TELADOC

3M

QORVO

Financially Strong

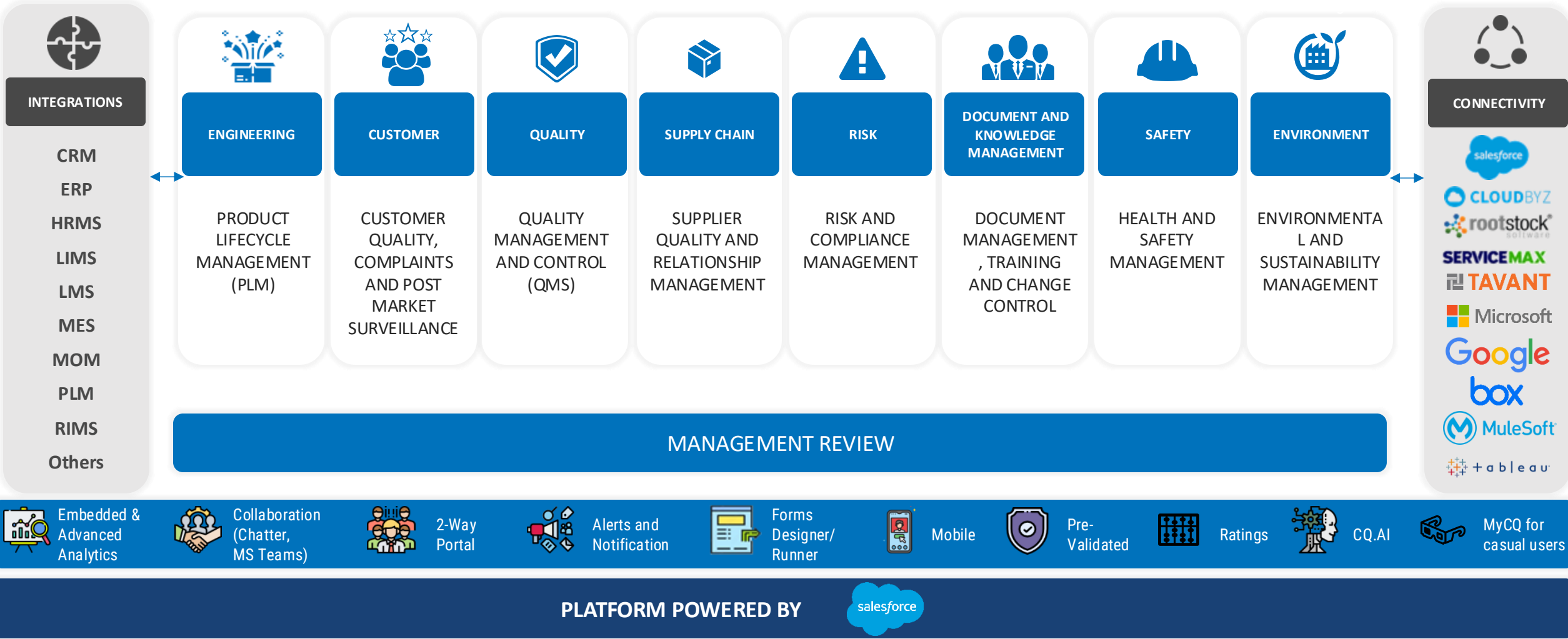
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CQ intelligently automates operations from product innovation to customer success



THANK YOU



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