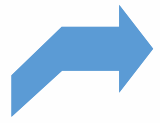


Quality Culture



Agenda

 What is Quality Culture

 Understanding Quality Culture

 Leader's role in Quality Culture

 Metric's role in Quality Culture

 Systems and Processes in Quality Culture

 People's role in Quality culture

Quality

Quality Metrics

What we see and usually
attempt to address

Mindsets and beliefs

Fear

Retaliation

Unbiased

Delivery vs
Quality
focus

50000 Ft
working

CI / Ideas

Work
management

Metrics

Stress
management

Complex and
impractical
documents

Complex
systems

Rewards how

Review
process

Actions /
Reward &
Recognitions

Approachable

Pressure

Culture

“True Quality Culture – an environment in which employees not only follow quality guidelines but also consistently see others taking quality- focused actions, hear others talking about quality, and feel quality all around them”

From Harvard Business Review April 2014: Creating a Culture of Quality.

“Leadership, vision and values make up the foundation for a culture of quality...An organization’s culture - the way it does things, the way it “lives”- has a direct impact on how well its processes and people operate.”

Clues About Culture, Amanda Hankel, Quality Progress, August 2014

“Financial incentives don’t reduce errors. Employees must be passionate about eliminating mistakes.”

Ashwin Srinivasan and Bryan Kurey of CEB

“Positive Quality culture is the atmosphere in the organization, where (1) each employee owns their responsibilities towards quality (2) each employee escalate issues (3) each employee works joyfully (4) each employee participates in continuous improvement (5) Leaders role models (6) problems are resolved to its root and (7) has a system in place ensure that the above becomes the default environment and is not dependent upon individual employee”

Vikram Shukla, Vice President, Pfizer

7 pillars for Positive quality culture

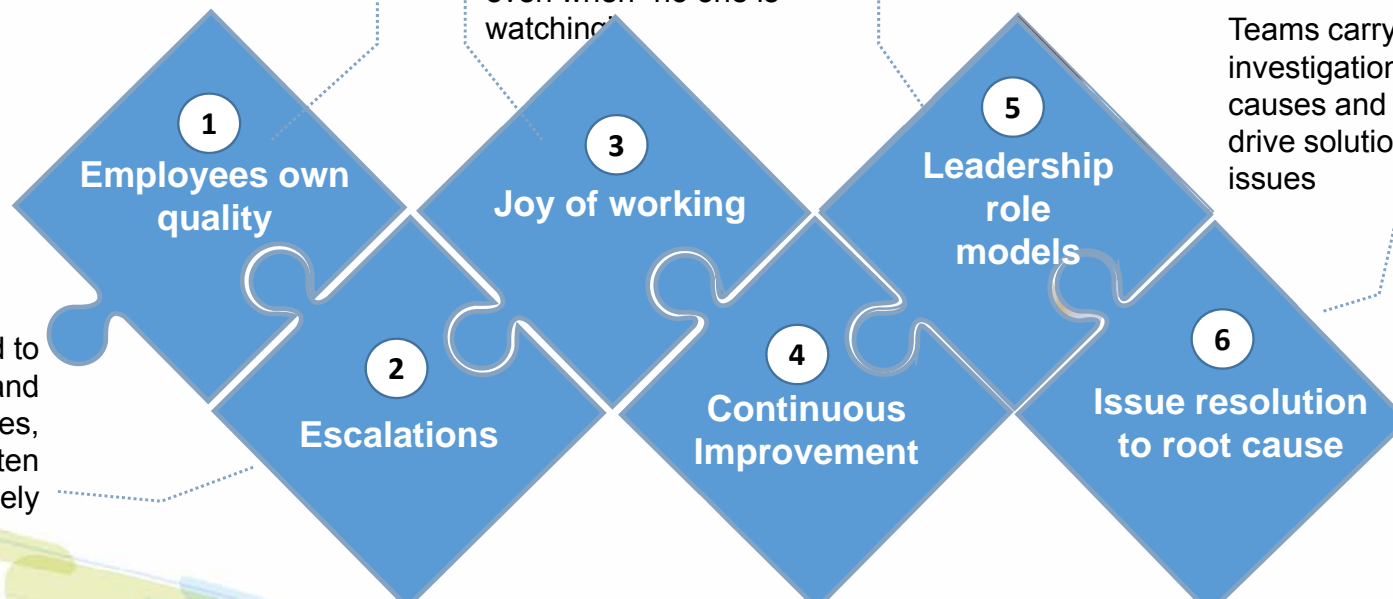
Quality performance is regularly monitored and reinforced through robust metrics, governance and incentives. **Impact on quality is considered before taking any decision**

All employees experience joy and feel motivated especially “shop floor” ones understand and are capable in the relevant SOPs and guidelines, and follow them even when “no one is watching”

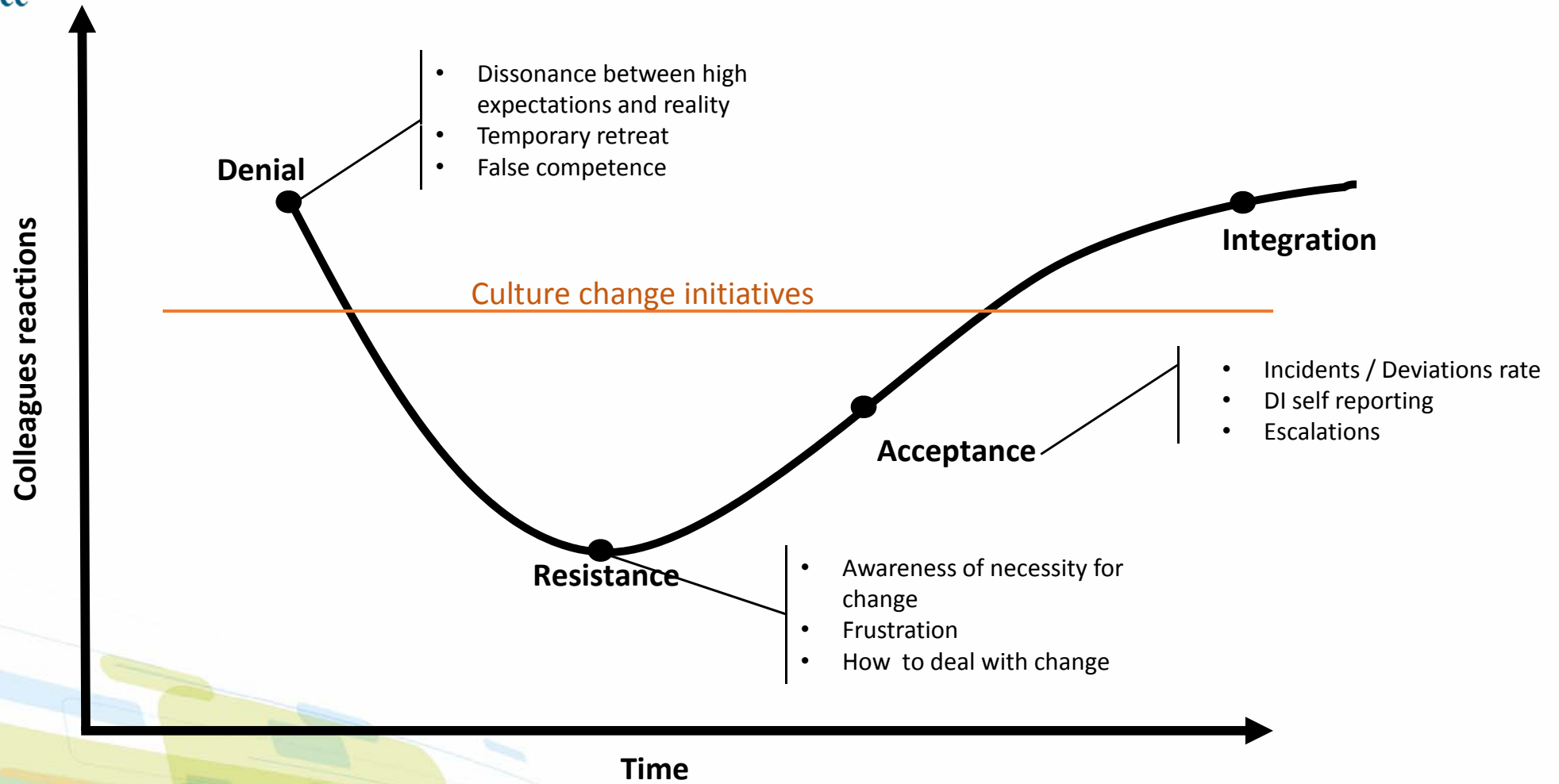
Managers spend time on the shop floor to observe operations (“gemba”), effectively identify quality improvements and coach employees and works on development of people. **They reinforce importance of quality in day-to-day behaviors**

Teams carry out rigorous, high-quality investigations to identify the right root causes and preventive actions and drive solutions to avoid recurrence of issues

Employees are not afraid to raise quality issues and proactively flag issues, whereupon leaders listen and act appropriately

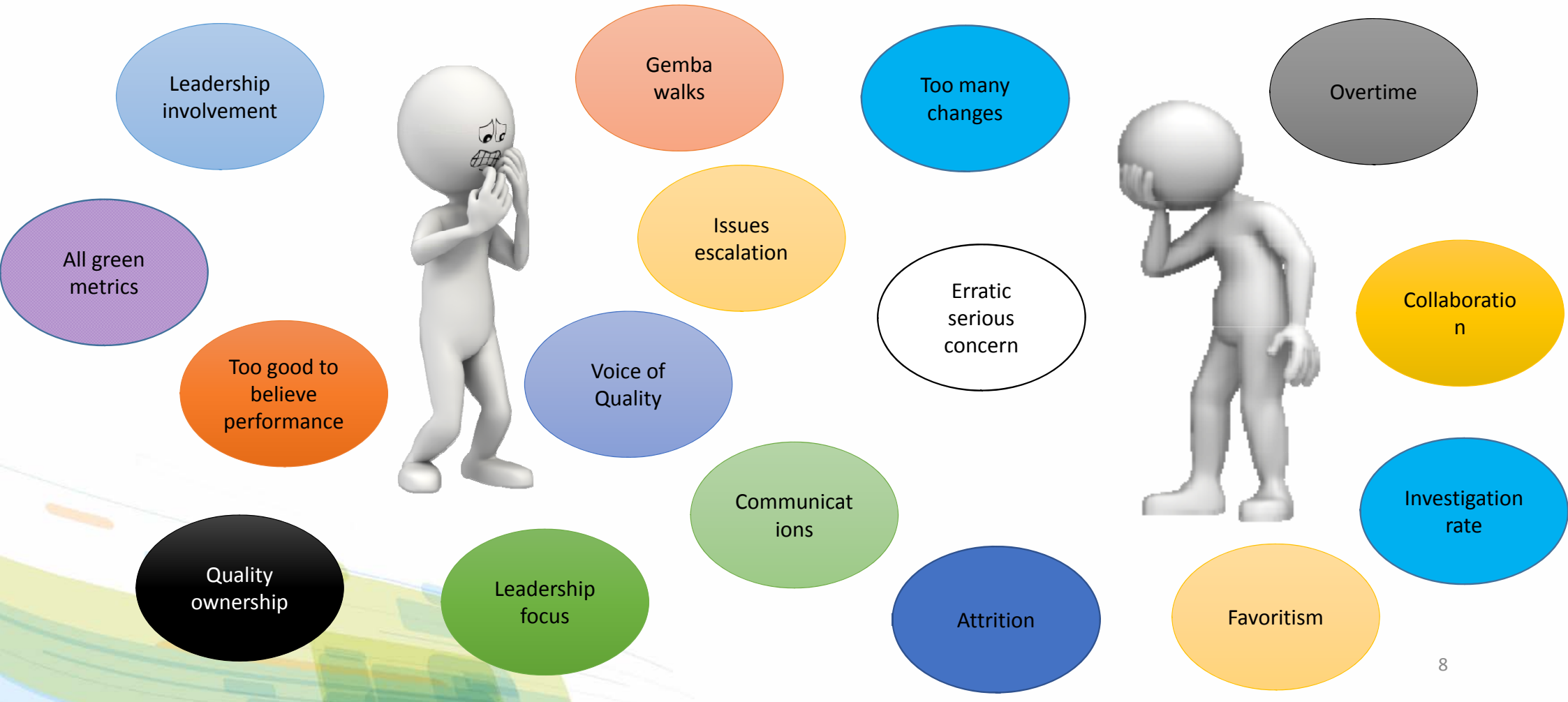


Quality Culture Change Stages



Understanding the Culture

Culture Indicators



Measurement of culture

1 **Quality, culture & capability survey** to identify key gaps across multiple-dimensions of culture

2 **Focus Group Discussions (FGDs) & Deep Structured Interviews (DSIs)** across cohorts to identify limiting behaviors & root causes related to the identified gaps

3 **Periodic assessments** to closely evaluate and measure quality culture

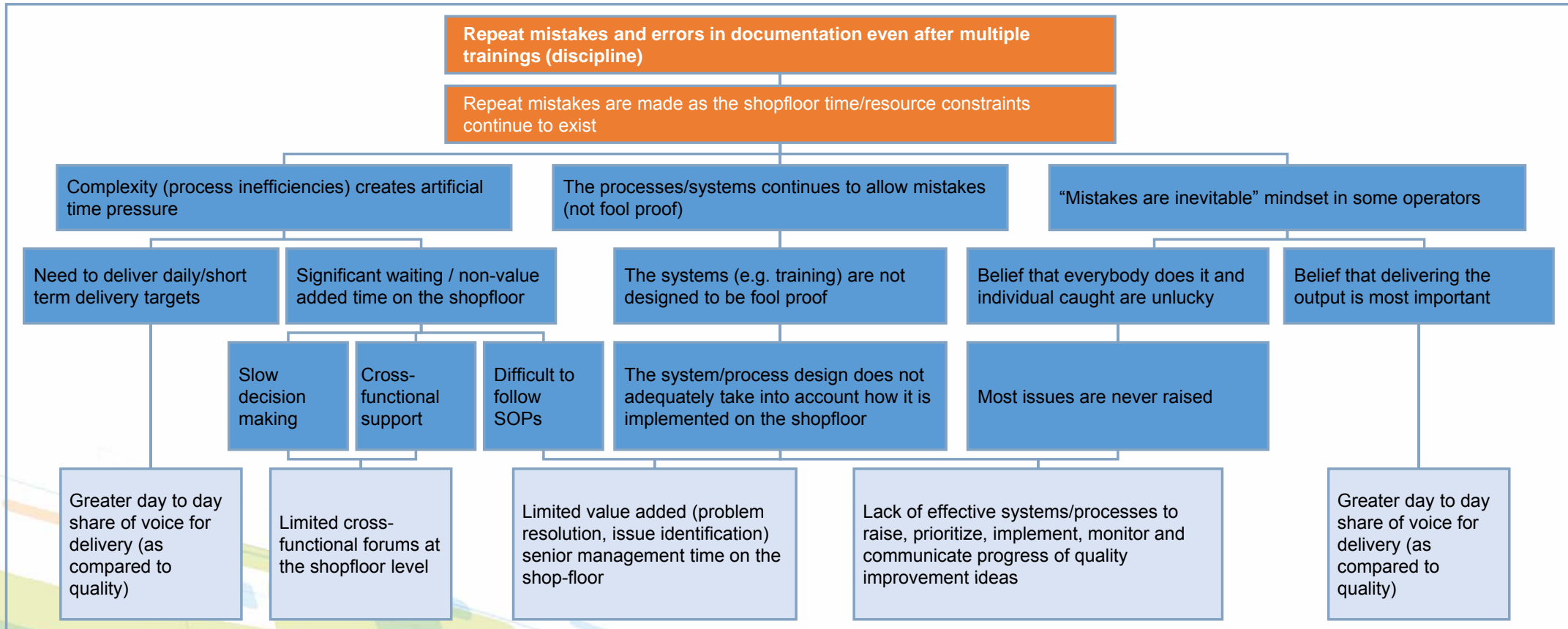
Instruction: Of the four statements in each question, select one where you think the company's performance is best and one where you think the company's performance is the worst. Do not select the same issue for both best and worst performance

Question	Statement	Best performance	Worst performance
Q1	My supervisor / manager is approachable, and provides sufficient support & coaching to help resolve quality related challenges I may be facing	<input type="radio"/>	<input type="radio"/>
	People I work with do not look for short cuts, which may have an impact on quality & compliance, to improve productivity	<input type="radio"/>	<input type="radio"/>
	We carry out robust investigations to identify and resolve the exact rootcause of issues rather than just providing band aid fixes	<input type="radio"/>	<input type="radio"/>
	The company genuinely recognizes and celebrates colleagues with high Quality achievements	<input type="radio"/>	<input type="radio"/>
Q2	We have regular and open discussion on quality related issues on the shop floor with our supervisor/manager	<input type="radio"/>	<input type="radio"/>
	There is frequent communication (through posters, videos, town halls etc.) from the site leadership to reinforce the importance of quality & compliance	<input type="radio"/>	<input type="radio"/>
	The trainings I attend are adequate to ensure Quality in my duties	<input type="radio"/>	<input type="radio"/>
	People I work with do not look for short cuts, which may have an impact on quality & compliance, to improve productivity	<input type="radio"/>	<input type="radio"/>
Q3	The trainings I attend are adequate to ensure Quality in my duties	<input type="radio"/>	<input type="radio"/>
	My supervisor / manager is approachable, and provides sufficient support & coaching to help resolve quality related challenges I may be facing	<input type="radio"/>	<input type="radio"/>
	The company gives me ways to report quality issues without any concern for potential negative consequences	<input type="radio"/>	<input type="radio"/>
	We carry out robust investigations to identify and resolve the exact rootcause of issues rather than just providing band aid fixes	<input type="radio"/>	<input type="radio"/>

FGDs & DSIs



■ What
 ■ Why (1to5)
 ■ Root cause



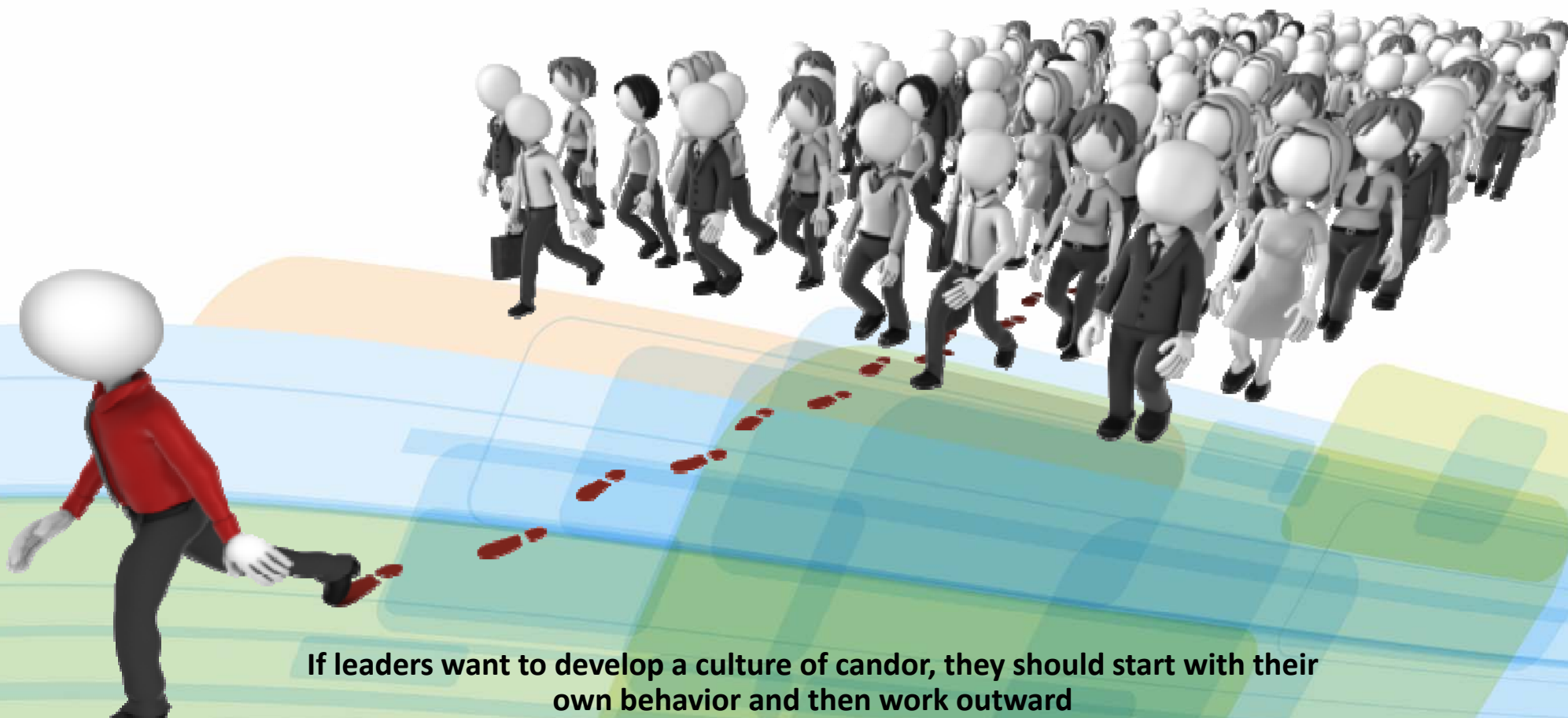
Understanding Culture

- Measuring site or corporate / company?
- How much time it takes to change the culture?
- Will all be on board on this journey?
- Its not measurable hence how to determine actions?
- Who owns this culture change process?
- Corporate driven actions?



Leadership

Culture change starts here...



If leaders want to develop a culture of candor, they should start with their own behavior and then work outward



Share vision

Share a vision that includes the importance of quality frequently and broadly within the organization.



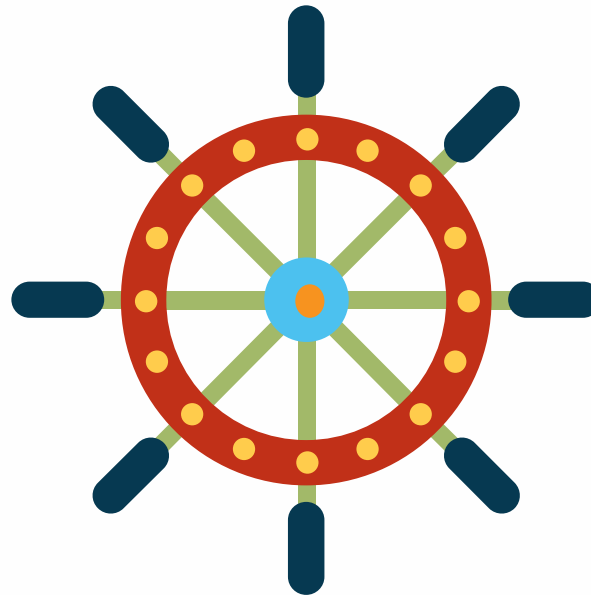
Demonstrate

Demonstrate decision-making and behaviors that align with the stated quality vision and value excellence above sole focus on regulatory compliance



Shape

Shape employee experiences and mindsets through formal and informal quality discussions where site metrics are reviewed and quality issues can be raised



Gemba

Use Gemba as a best practice activity for the shop floor, laboratories, or other functional areas. Consider Gemba guidelines or checklists to aid the walk-through



Develop

Develop key site metrics and implement leading quality metrics and proactive measurements to drive continuous improvement



Provide

Provide structural enablers to support organizational improvement and inspire an environment of continual learning



Communication

I want you to meet the production target of 5 million this week without fail



Team Leader

Team

Impact of such a scenario

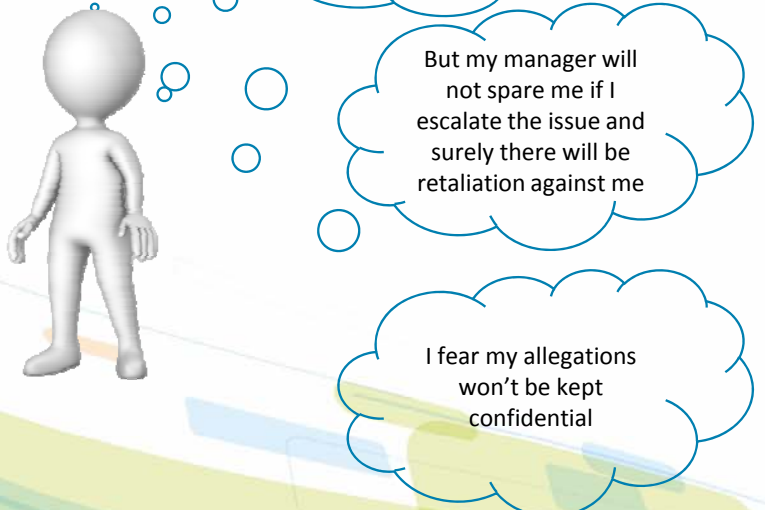
- Primary focus on achieving output and not on the process
- Focus only on what is to be done and not how it is to be done
- Colleagues to take short cuts as the expectations are not set properly
- No commitment of addressing problems through proper quality system as it is time consuming

How to overcome

- Reward & recognize the right behaviors
- Clarify expectations that goals and targets must be communicated in a manner that enables colleagues to recognize that the good results only matter if they are achieved the right way
- Production targets must be met with Quality, Compliance and Safety – regular reinforcement by leadership
- Make sure that leaders across different level in the organization support colleagues in addressing issues the right way
- Reinforce the expectations to all team members across levels using different communication platforms

Leadership Behavior

Scenario



My team members
are not working in
compliance.

I wish I could
escalate this issue to
the management.

But my manager will
not spare me if I
escalate the issue and
surely there will be
retaliation against me

I fear my allegations
won't be kept
confidential

Impact of such a scenario

- Real issues will never surface
- Management will not know the real situation at site
- Problem will not easily surface
- No one will speak up
- Management will get to hear only what they want to hear
- Issues won't be escalated
- Trust deficit at different levels in the organization
- Threats are recognized late by management
- Opportunities for course correction are lost
- Management will be surrounded by "Yes" men

How to overcome

- Foster an open and transparent culture
- Create Effective Communication Channels & Ongoing Communication Strategy:
 - ✓ a dedicated phone number for anonymous reporting,
 - ✓ drop box to collect colleagues feedback
 - ✓ regular town halls to communicate with colleagues
- Develop effective code standards and systems on raising concerns and on deterring retaliatory behavior
- Having an open door anti-retaliation policy and having visibility of this policy and its regular reinforcement
- Build and ensure a system that maintains confidentiality
- Proper checks and balances to be in place so that information is not leaked

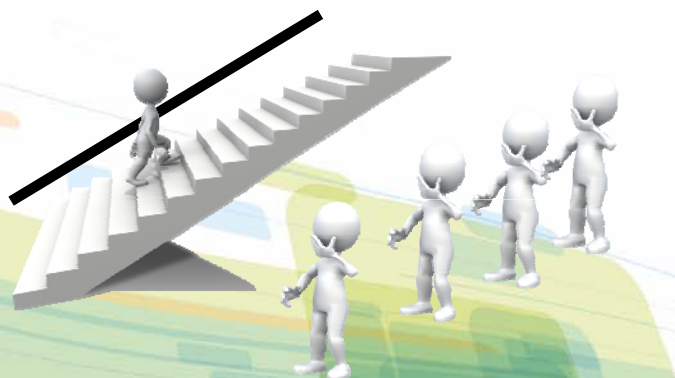
Leadership Behavior

Scenario

Let us pledge to hold the handrail for our own safety while on the stairs



Leader climbing without holding Handrail



Impact of such a scenario

- Colleagues will stop following leaders
- Colleagues lack trust on leadership and no one takes leader seriously
- Leader's impact on site is diluted
- Compliance and safety may be compromised leading to Data Integrity issues

How to overcome

Leaders should "walk the talk"

Leaders should be aware that "it is not what they say but what they do" which determines the Culture of the site



Role of Leader in influencing culture



Metrics



Colleagues behavior changes based on what gets monitored...

- There is **no single metric / indicator** that can help measure quality culture. Will need to have a **combination of indicators** to do so
- These indicators should comprise of both **Practices / Behaviors** demonstrated by the employees, and **Outcome Indicators** i.e. quality metrics / indices that capture performance
- Need to ensure that these indicators **do not incentivize incorrect behavior**, and rather encourage continuous improvement e.g., encouraging reduction in # of deviations may incentivize non reporting
- Indicators will need to be **tailored to individual company** based on the **quality / cultural challenges & issues**
- **All the selected indicators** for a particular company need to be monitored and improved upon (rather than measuring a composite index)

Quantitative metrics

Leading Indicators

- Number of people appreciated, rewarded or recognized
- Gemba numbers per leader
- Communication numbers
- Number of escalations
- Number of training completed
- Number of people trained on DMAIC process

Lagging Indicators

- People Turnover
- % human error

Qualitative metrics

- Effectiveness of Gemba
- Effectiveness of communication
- Effectiveness of rewards and recognitions
- Effectiveness of training
- Skip level meetings

Systems and Processes

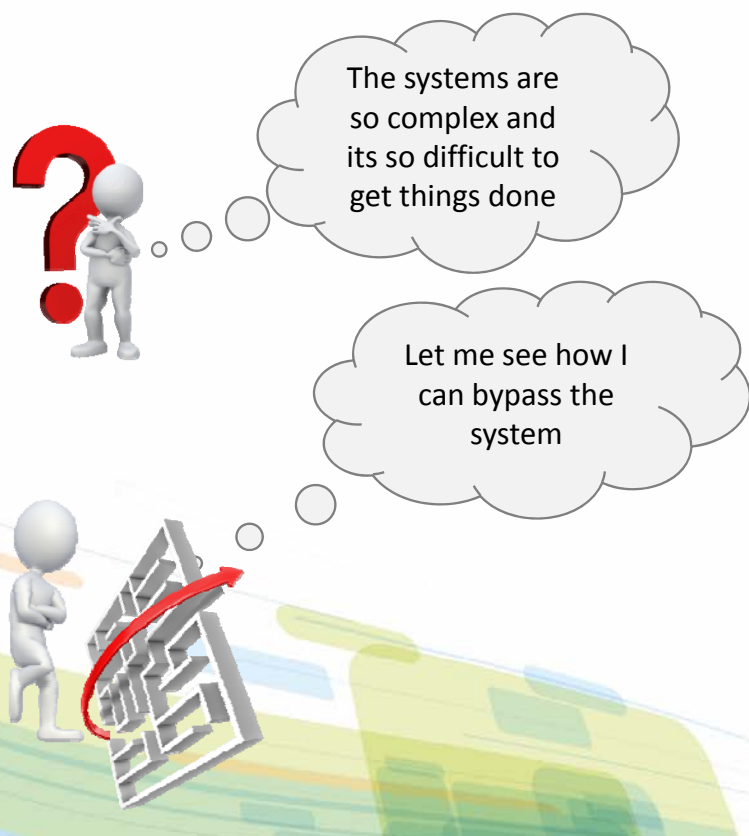
Complex systems or processes leads to wrong behaviors...

Reasons for complex systems

- Inputs from doers not taken or process owners
- SOPs are made by a dedicated documentation team
- Response to regulatory observations and commitments are not coming out of collaborative discussions
- “Duplication” as a measure of addressing issues
- Direction to implement a correction
- Process is a copy from other company!!

Complex systems

Scenario



Impact of such a scenario

- Colleagues are forced to take short cuts to complete the task
- Taking short cuts leads to non compliance and Data Integrity issues
- Difficult to get things done
- Colleagues are unwilling to take up the task and pass it on to others

How to overcome



Take inputs from colleagues to simplify processes and procedures

Encourage Area owners/managers to look for simplification in their respective areas

Leaders to identify & review SOPs- pick 1 SOP at a time, read, understand and walk through it

Leaders must work towards implementation of simplification and removal of road blocks

People



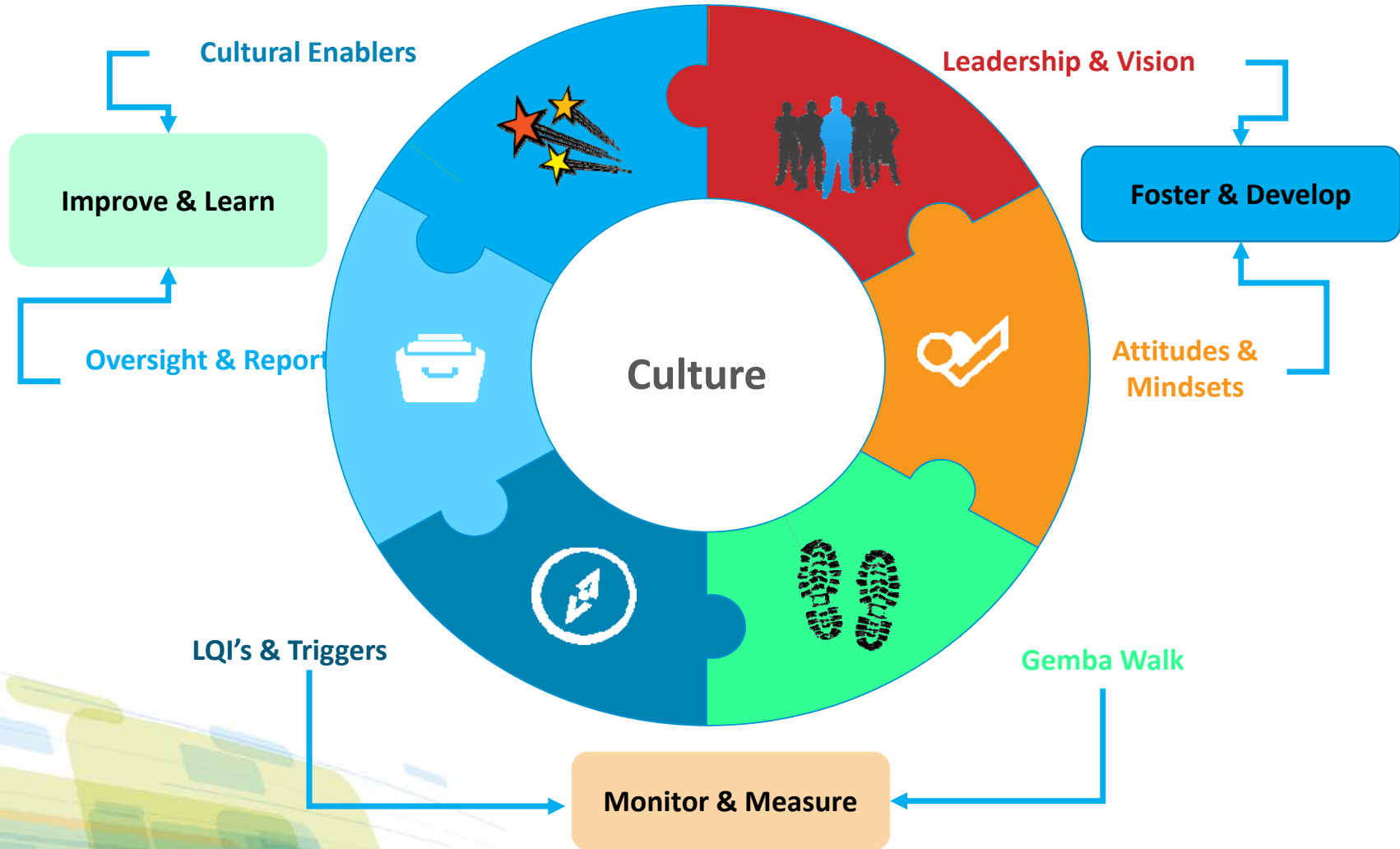
Please motivation, passion and courage is key to success

People

- Identify bad actors
- Perception of Biasness
- Skill building
- Capability building
- Ownership
- Work prioritization
- Collaboration
- Feeling of Joy
- Work stress
- Reward and Recognition for right behaviors



In summary



Thanks you