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 Culture

Quality

What we see and usually attempt to address

Mindsets and beliefs

Quality Metrics

Fear
Retaliation
Unbiased
50000 Ft working

Delivery vs Quality focus
Work management
Metrics
CI / Ideas

Complex and impractical documents
Stress management
Actions / Reward & Recognitions
Complex systems
Rewards how

Approachable
Pressure

Review process

Approachable
Pressure

50000 Ft working

Unbiased

Delivery vs Quality focus
Work management
Metrics
CI / Ideas

Complex and impractical documents
Stress management
Actions / Reward & Recognitions
Complex systems
Rewards how

Approachable
Pressure

Review process

“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.”

“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

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

2. Escalations

3. Joy of working
   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.”

4. Continuous Improvement

5. Leadership role models
   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.

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

7. All employees experience the overall environment demonstrative above behaviors and are not dependent management initiatives, individual employee’s and leaders push
Quality Culture Change Stages

Indian Pharmaceutical Alliance

Quality Culture Change Stages

- Denial
  - Dissonance between high expectations and reality
  - Temporary retreat
  - False competence

- Resistance
  - Awareness of necessity for change
  - Frustration
  - How to deal with change

- Acceptance

- Integration
  - Incidents / Deviations rate
  - DI self reporting
  - Escalations

Culture change initiatives

Colleagues reactions

Time
Understanding the Culture
Culture Indicators

- Leadership involvement
- Gemba walks
- Too many changes
- Overtime
- All green metrics
- Issues escalation
- Erratic serious concern
- Too good to believe performance
- Voice of Quality
- Collaboration
- Investigation rate
- Leadership focus
- Communications
- Attrition
- Favoritism
- Quality ownership
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
### Quality, culture & capability survey

**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.

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

Repeat mistakes are made as the shopfloor time/resource constraints continue to exist

Complexity (process inefficiencies) creates artificial time pressure

Need to deliver daily/short term delivery targets

Significant waiting / non-value added time on the shopfloor

Slow decision making

Greater day to day share of voice for delivery (as compared to quality)

Cross-functional support

Limited cross-functional forums at the shopfloor level

Limited value added (problem resolution, issue identification) senior management time on the shop-floor

Difficult to follow SOPs

Limited value added (problem resolution, issue identification) senior management time on the shop-floor

The processes/systems continues to allow mistakes (not fool proof)

The systems (e.g. training) are not designed to be fool proof

The system/process design does not adequately take into account how it is implemented on the shopfloor

"Mistakes are inevitable" mindset in some operators

Belief that everybody does it and individual caught are unlucky

Belief that delivering the output is most important

Most issues are never raised

Lack of effective systems/processes to raise, prioritize, implement, monitor and communicate progress of quality improvement ideas

Greater day to day share of voice for delivery (as compared to quality)
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.
Leaders Role in Culture Development

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.

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.

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

Provide
Provide structural enablers to support organizational improvement and inspire an environment of continual learning.
Leader’s communication

Communication

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

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

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

- **VISION**
  - Strategy, unifying goals, game plan, company mantra or credo, the desired state

- **VALUES**
  - Guiding principles, ethical conduct and expectation, humility, empathy, patient focus

- **VOICE**
  - Passion, credibility, authenticity, and clarity, as well as the ability to articulate the vision, and inspire and motivate others

- **VIGILANCE**
  - Ability to drive accountability, determination, grit, focus, discipline, and follow-through

- **VISIBILITY**
  - Leader presence, what he/she gives priority/time to, what he/she reacts and responds to
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

The systems are so complex and its so difficult to get things done

Let me see how I can bypass the system

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
Cultural Enablers

Leadership & Vision

Foster & Develop

Attitudes & Mindsets

LQI’s & Triggers

Gemba Walk

Oversight & Report

Monitor & Measure

Improve & Learn
Thanks you