Quality culture matters: Increasingly companies believe that culture matters; this is also reflected in their efforts to work on it!!

Yes, culture matters! What is your culture?

Do You Have a Quality Culture?
Perspectives on the value of creation and assessment of quality culture
By David Keeling, Paul Rutten and Vanya Telpis, McKinsey & Company
Oct 17, 2017

Measuring quality culture is essential to improving mindsets and behaviors in pharma companies. The challenges to measuring culture are significant, but our research demonstrates that they can be overcome. While there is no ultimate metric for culture, good measures are available, each with proven correlation to quality outcomes. Indeed, companies with a strong quality culture are distinguished by their ability to measure culture and apply those insights to culture improvement efforts.
Data supports: Quality outcomes are strongly correlated with quality culture.
Quality performance is communicated clearly, regularly monitored and reinforced through robust metrics, governance and incentives.

All employees especially “shop floor” ones understand and follow the SOPs/guidelines even when “no one is watching”.

Managers spend time on the shop floor to observe operations (“gemba”), effectively identify quality improvements, coach employees and reinforce the importance of quality.

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

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

**What is quality culture: Five (5) pillars of strong quality culture**

1. Quality as top priority
2. Employees own quality
3. Open dialogue
4. True resolution of problems
5. Leadership role models
Culture can be measured reasonably well!!

Combination of measures

Quality culture survey (on annual basis) to measure intangible culture elements

- 5 elements
  - Leadership
  - Governance
  - Capabilities
  - Integrity
  - Mindset

- Monthly/quarterly pulse check survey to measure progress on 5 elements

Tangible culture indicators

- CAPAs with preventive measures
- Planned maintenance rate
- Employee turnover rate
- Human error deviations
- Deviations w/o assigned root cause
- CAPA effectiveness (retraining)
- Recurring deviations
4. You can build quality culture: You don’t need a lifetime – shift in culture can be demonstrated in 4-6 months!!

Are you too busy to improve?

No thanks!

We are too busy

Created by Håkan Forss @hakanforss http://hakanforss.wordpress.com
How: Three steps to build quality culture

A. Diagnose
- 4-6 weeks
- Identify opportunities and baseline

B. Design
- 6-8 weeks
- Leverage influence model to identify interventions

C. Deliver
- Rapid implementation in 3-4 months
- Sustain and improve thereafter
Use a combination of survey, practices, tools and data

- Culture survey (30,000+ responses)
- Focused Group Discussions / Deep Structured Interviews (400 + data points)
- Targeted Analysis (POBOS)

Rapid opportunity/issue identification
Common observations from firms that have challenging quality culture

1. Leadership’s lack of understanding and denial – failure to acknowledge that problems exist and a false sense of self – “we know-it-all”

2. Failure to consistently demonstrate “Quality first behavior” in decisions and actions (not just talk) – “implicit delivery focus”

3. There has been progress but systems for raising quality issues and identifying continuous improvement opportunities remain inadequate

4. Gaps between practice and procedure at Shop/ lab floor – “Tick the box mindset”

5. Gaps in Investigation – Unable to identify root cause of issues and put in place robust CAPAs

6. Limited understanding of metrics with ineffective governance

7. Weak planning system and limited cross functional collaboration

8. Training ≠ Capability building
Culture transformation model – “Influence model”

**4-part culture-transformation framework**

**“I will change my behavior if…”**

**Fostering true understanding and conviction**

- I know what is expected of me – I agree with it, and it is meaningful
- I am committed to change and action

**Role-modeling**

- I see superiors, peers and subordinates behaving in the new way

**Reinforcing with formal mechanisms**

- New ways of working are reinforced through structures, processes and systems, communication and rewards

**Developing talent and skills**

- I, (both existing and new employees), have the skills and competencies to behave in the new way
### 4-part culture-transformation framework

**“I will change my behavior if…”**

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<thead>
<tr>
<th>Fostering true understanding and conviction</th>
<th>Reinforcing with formal mechanisms</th>
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<tbody>
<tr>
<td>Openness and change leadership program</td>
<td>Effective quality governance - right metrics, robust governance processes including notification to management</td>
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<tr>
<td>Multi channel, 2-way communication</td>
<td><strong>Rewards &amp; Recognition</strong> to encourage good quality outcomes</td>
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<tr>
<td>Formal platforms to raise issues</td>
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<tr>
<th>Role-modeling</th>
<th>Developing talent and skills</th>
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<tr>
<td>Gemba - Senior leaders role modeling quality in day-to-day behaviors</td>
<td>Technical, managerial &amp; behavior skills across levels (e.g., Investigation capabilities)</td>
</tr>
<tr>
<td>Symbolic acts by leadership team that further establish importance of quality</td>
<td><strong>Digital &amp; analytics</strong> for quality improvement &amp; capability building</td>
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**Illustrative actions from successful case examples**

- I will change my behavior if…
Leadership change journey

**Phase – UNDERSTAND & COMMIT**

1. Present a change story and establish a group commitment to have an open mindset.
2. Present fact base on quality outcomes compared with POBOS.
3. Align on leadership role/responsibility/expectation and overall commitment to quality improvement.
4. Decide the “goal.”
5. Present fact base on current mindset/behaviors.
6. Develop and align on desired behaviors.
7. Leverage simulations to demonstrate current vs. desired behaviors and impact on quality outcome.
8. Personal commitment to drive actions.
9. Concrete actions around Gemba walks, investigations, and performance management to drive behavior change.
10. Role model behavior change.
11. Communicate.
12. Monitor progress, reward behavior changes, and reinforce.

**Phase – IMPLEMENT & REINFORCE**
True capability building goes far beyond traditional 2-3 day classroom training.

**Traditional ‘training’**

- **Building ‘capabilities’**
  - Need identification
    - Assessment to prioritize skills & expectations for the participants
    - Developing content around addressing the need
  - Classroom training to learn theory & study case examples
  - Live case study: Practice skill solving a live case study
  - Breakthrough project: Apply combination of multiple skills to deliver impact & reinforce skill
Use digital tools to scale & sustain individually customized capability building

**Key Features**

- Based on principles of gamification
- Easily accessible on-the-go through smartphones
- Customized to an individual’s needs

- **Quiz:** Multiple choice questions to test understanding
- **Knowledge nuggets:** Theory on subject to ‘read & learn’
- **Challenge:** Users challenge each others for a time trial
Use advanced Analytics; it helped identify ~10% of tests likely to contribute to ~60% of future invalid OOS; 35% reduction in OOS within 1 month of implementation

<table>
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<tr>
<th>How it was done?</th>
<th>Details</th>
<th>Impact?</th>
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<tr>
<td>Hypothesis generation</td>
<td>50+ hypotheses generated based on CFT workshops, historical data (e.g. logs, exit interviews) &amp; expert inputs</td>
<td>~9-12% of product-test combinations identified which account for ~60% of potential invalid OOS in the next month</td>
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</table>
| Validation of hypotheses against data | 35+ data sources leveraged:  
- Digital data from central systems (e.g., LIMS)  
- Manual data (e.g., exit interview notes)  
- External data (e.g., date-wise weather patterns) | 35% reduction in overall OOS within 1 month of implementation |
| Decision tree to identify reasons | Created and tested 3,500+ univariate features and 10K+ multi-variate features | |
| Recommendations on allocation of rules | | |
Continuously improve investigations with best practice feedback loops – Simplified

**Pre-investigation process**
- Incident logged
- Risk based classification
- Initial impact assessment
- Investigator assigned

**Investigation process**
- Investigator
- Reviewer (QA)

**After investigation**
- Report revised/finalized
- Logged into the system

- Investigation quality scores measured at each node/point
- Feedback provided (role modeling), to improve investigations

**Internal SME/third party review**
- Corporate Quality Head
- Site Quality Head

(All reports)
(on sample basis)
THANK YOU

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Quality culture survey, focused group discussions and interviews identified the mindset shifts for a client and the impact was measured through monthly pulse check.

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<th>Approach to quality culture assessment</th>
<th>4 behavioral shift finalized</th>
<th>Impact</th>
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<tbody>
<tr>
<td>1 Quality culture survey</td>
<td>From Achieving delivery target is the top most priority</td>
<td>To Achieving high quality is more important than delivery targets</td>
</tr>
<tr>
<td>2 Focused group discussions</td>
<td>From Quality Is not my responsibility</td>
<td>To I am responsible for Quality</td>
</tr>
<tr>
<td>3 Deep structured interview</td>
<td>From I am not empowered to drive quality outcomes</td>
<td>To I have the authority/power to drive quality outcomes</td>
</tr>
<tr>
<td>4 Underlying causes identified</td>
<td>From I am not confident when asked tough questions by the auditor</td>
<td>To I am fully confident about our processes and can face an auditor anytime</td>
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