Quality Culture: Tools for a Stronger Organization

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Pharmaceutical Regulatory Science Team
Dublin Institute of Technology, Ireland
What Do We Mean by Cultural Excellence?

Transforming the Cultural DNA of the Pharmaceutical Industry

Envisions a genetic re-engineering of the cultural DNA of the pharmaceutical industry from a compliance-led culture to an excellence-led culture of quality.

The evolution towards a culture of quality will require a re-ordering of the DNA sequence to build a double helix, strengthened from a combination of patient focus and excellence.

Promoting, coaching and leading specific desired behaviours while identifying and preventing specific undesired behaviours.
An Overview of ISPE’s Cultural Excellence sub-teams activities

...to improve capability in shaping cultural excellence.
Leadership and Vision Team

Erika Ballman Team Lead
Leadership and Vision

• Purpose: Identify best-practices and leader-led behaviors most directly linked to positive culture transformation.

• *Shaping Excellence* Interviews captured shared stories, successes and learnings in leader’s own words, with a specific focus on improving Pharmaceutical Quality.

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**Shaping Excellence - Leader Interviews**

<table>
<thead>
<tr>
<th>Section 2: Leader SV's (Vision, Values, Voice, Visibility, Vigilance)</th>
</tr>
</thead>
<tbody>
<tr>
<td>L1 How do you define a culture of excellence? What do you look for? What do you measure?</td>
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<tr>
<td>L2 What leadership traits are most attributable to cultural transformation?</td>
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<td>L3 How do you describe your leader style?</td>
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<td>L4 Do you have a clear stated Vision within your organization?</td>
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<td>L5 How was (and is) the Vision communicated?</td>
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<td>L6 How do you ensure leaders deliver consistent messages congruent with the company Vision?</td>
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<td>L7 What have you learned about leadership over time? Has your approach or style changed? How?</td>
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<td>L8 What are the most dangerous inactions of a leader?</td>
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<tr>
<td>L9 What are the most important actions a leader can take to foster positive culture?</td>
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<tr>
<td>L10 Did (do) you have a mentor? Do you mentor or coach other leaders? Formally or Informally?</td>
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</tbody>
</table>

**Section 3: Leader Influence on Mindsets and Behavior**

<table>
<thead>
<tr>
<th>B1 Do you formally or informally assess employee engagement? How? What is the frequency? Can you share any metrics?</th>
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<tbody>
<tr>
<td>B2 Do you have a “speak up” culture? Do employees raise concerns and provide feedback?</td>
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Interview method was one-hour teleconferences focused on a set of 15 core questions.

> Generated 100+ written transcript pages and > 11 hours of audio. *Findings were presented June 2016 (ISPE/PQRI Quality Manufacturing Conference)*
Leader 5V: Leader Influence on Culture

5V’s of Leader Influence on Culture

- **Vigilance**: Accountability, Follow-through, Grit
- **Vision**: Strategy, Unifying Goals, Plan, Mantra
- **Visibility**: Presence/GEMBA, Priority, Actions and Reactions
- **Values**: Ethics, Model Behaviors, Humility
- **Voice**: Passion, Credibility, Clarity, Motivation
Next Steps

Article:

• *Shaping Excellence: How Leader Actions and Behaviors Influence Quality Culture – Target November 2016.*

Support for Quality Culture Guidance Document (Fall 2016) with other dimension teams.

Share leader self assessment tools within the guide (self and team-based assessments) and in-depth findings from “Shaping Excellence” interviews.
Attitudes and Mindsets

Team

Matt Pearson
Team Lead
Shaping Quality Cultural Excellence: Attitudes & Mindsets

**Attitudes & Mindsets drive performance....**

*Performance Model*

- Attitudes
- Mindsets
- Behaviors
- Actions
- Results
- Performance

- **Attitudes drive mindsets...**
- **Mindsets drive behaviors...**
- **Behaviors drive actions...**
- **Actions drive results...**
- **Results drive performance**

....so our ability to monitor & shape mindsets matter!!
Shaping a Quality Mindset Using Experience Based Approach

**Accountability**
- Participation in multiple successful Kaizen (quality improvement) events
- Belief that I can and should directly improve quality in my area
- Active identification of quality improvements and acting upon them
- Continuous incremental improvement to processes and performance

**Ownership**
- Direct experiences with their leader empowering and supporting their decision making within their area
- Belief that I can and should make decisions and own quality in my area
- Decisions are made promptly by those closest and knowledgeable to issue
- Increased ownership, quicker decision making and problem solving

**Action Oriented**
- Participation in multiple facilitated risk assessment events
- Belief that I can and should identify and communicate risks to management
- Active communication of risks and mitigation actions and decisions
- Improved proactive communication and mitigation of risks as part of daily activity

**Speak Up**
- Direct experiences with their leader encouraging and acknowledging speak up
- Belief that I can and should admit mistakes, raise issues and recommend improvements
- Concerns and issues are raised immediately to supervisor
- Improved prevention and speed in addressing issues and driving improvements
# Cultural Excellence Mindset Shift

<table>
<thead>
<tr>
<th>Lower Maturity</th>
<th>Vehicle</th>
<th>Higher Maturity</th>
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</thead>
<tbody>
<tr>
<td><strong>Quality is a Guidance</strong></td>
<td><strong>Accountability</strong></td>
<td><strong>Quality is a Devotion</strong></td>
</tr>
<tr>
<td>I abide by the rules because we have to in order to remain in business.</td>
<td>Quality is built in to everything I do because it is the right thing for our patients, my colleagues, and the organization</td>
<td></td>
</tr>
<tr>
<td><strong>Observer</strong></td>
<td><strong>Ownership</strong></td>
<td><strong>Owner</strong></td>
</tr>
<tr>
<td>I observe quality in my area — It is interesting, but it doesn’t have anything to do with me. I do what’s asked and follow the simple instructions</td>
<td>I am responsible for quality in my area. I don’t assume that an error will be caught by someone else.</td>
<td></td>
</tr>
<tr>
<td><strong>Reactive Orientation</strong></td>
<td><strong>Action Orientation</strong></td>
<td><strong>Proactive Orientation</strong></td>
</tr>
<tr>
<td>I spend most of my time responding to and fixing problems that arise to keep up with production schedules</td>
<td>I spend most of my time identifying issues proactively and intervening to minimize any potential negative impacts on quality &amp; compliance</td>
<td></td>
</tr>
<tr>
<td><strong>Passive Communication</strong></td>
<td><strong>Speak Up</strong></td>
<td><strong>Active Communication</strong></td>
</tr>
<tr>
<td>When I come across a quality risk, issue or an opportunity to improve it, I may or may not call it out.</td>
<td>I speak up, bring up quality issues, and regularly challenge status quo for improved quality</td>
<td></td>
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A Look Ahead at More to Come....

**Quality Culture Maturity Tool**

21 Question Behavioral Assessment Tool

### Recommended Action Options

1. Ensure employee job descriptions reflect the importance of quality work, upholding CGMPs and continual improvement.

2. Have quality culture goals built into yearly objectives for business and employees.

3. Ensure reward and recognition program is aligned to support employee ownership of quality and quality culture behavior demonstration.

4. Deploy common continuous improvement methodology training and support within the organization (e.g. Lean/Six Sigma, Quality Risk Management, Knowledge Management)

### Recommended Action Options

1. Develop and implement a formal GEMBA process with defined schedule, frequency and participation.

2. Develop GEMBA guides to help participants develop good dialogue.

3. Visible status tracking of identified continuous improvement opportunities (on a whiteboard in the area or other easily accessible place).

4. Provide coaching to leaders how to do an effective GEMBA walk.

....to enable assessment and improvement in cultural excellence
The GEMBA team has developed a Best Practice Guide for...

- WHY to do a GEMBA walk
- What a GEMBA walk is and what it isn’t
- Management and customer involvement
- Frequencies for the various levels of management involved in GEMBA walks
- “HOW TO” recommendations including a set of questions to prepare and perform GEMBA walks
- Defining agreed actions and how to best track them

All recommendations are based on practical experiences of team members companies
The GEMBA Best Practice recommendations are supported by ...

- A case study from a volunteer site to demonstrate how the concept can be adapted based on the maturity of a site and the site strategy and priorities

- Lessons learned from implementing GEMBA in the laboratories of 50+ pharmaceutical manufacturing sites in US, Canada, Europe and Asia describing tangible results, watch-outs, and surprises
Our conclusions are ...  

- GEMBA is a key program to enhance the Quality Culture of a site by
  - Creating visible management commitment to change
  - Engaging all employee levels of the organization
  - Enhancing communication of priorities, objectives and desired behaviors
  - Engaging customers to allow people to see “the bigger picture”

- GEMBA in itself is not enough to drive culture change but it is the most immediate and direct intervention that a site can implement

Implementing GEMBA is the boldest move to make a visible change
Leading Quality Indicators (LQIs)

Dr. Nuala Calnan
Team Lead
Most “quality” metrics do not gauge quality; rather, they are process measures that capture compliance. The only true measures of quality are the outcomes that matter to patients.

Question:
How can we design leading indicators of quality to measure outcomes that matter to our patients?

Answer:
Focus on driving the “desired” behaviours through Key Behaviour Indicators (KBIs).
Changing Behaviours, Measuring Results

- The ABC model holds that *Antecedents* lead to *Behaviours*, which lead to *Consequences*.

- Antecedents are events that precede behaviours and are triggers to what people say and do. They are enablers to behaviours however they do not motivate behaviours.

- It is the consequences that motivate by either reinforcing or discouraging the behaviours, i.e. consequences determine whether desired or unwanted behaviours occur.

Feedback in the form of Reinforcement... not Enforcement
Use of the IMPACT Tool* for development of a set of Leading Quality Indicators (LQI) or Leading Behavioural Indicators LBI’s

Outlines how to design quantitative measures of the behavioural changes which enable the delivery of enhanced quality regulated products.

These measures target behavioural change across the key operational areas of

*Patient, People, Places, Prevention and Performance*
## Pinpointing High Impact Behaviours

### PATIENT IMPACT

<table>
<thead>
<tr>
<th>LQi Category</th>
<th>Patient</th>
<th>LQi Category</th>
<th>Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>(I) Identify Goal</td>
<td>Consistent delivery of high quality medicinal products</td>
<td>(M) Measures to deliver Goal</td>
<td>Increase the number of batches which are Right First Time</td>
</tr>
<tr>
<td>(P) Pinpoint Behaviours</td>
<td>Enhanced attention to detail where 'Quality is everyones Job'</td>
<td>(AC) Activate &amp; Consequate</td>
<td>'Celebrate' / acknowledgment of each RFT batch by leadership/ local management. Use of visual management for motivation on progress.</td>
</tr>
<tr>
<td>(T) Transfer Knowledge and Skills to sustain change</td>
<td>Learning Teams using problem solving tools to identify incidents, activate early intervention, implement PA's</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leading Quality Indicators (LQi)</td>
<td>% RFT Batch Approvals / Investigation for Lots</td>
<td>% RFT Batch Records</td>
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<tr>
<td></td>
<td># Suggestions Successfully Implemented</td>
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### PEOPLE IMPACT

<table>
<thead>
<tr>
<th>LQi Category</th>
<th>People</th>
</tr>
</thead>
<tbody>
<tr>
<td>(I) Identify Goal</td>
<td>Consistent delivery of high quality medicinal products</td>
</tr>
<tr>
<td>(M) Measures to deliver Goal</td>
<td>Reduce the number of deviations attributed to Execution Error</td>
</tr>
<tr>
<td>(P) Pinpoint Behaviours</td>
<td>Enhanced attention to detail where 'Quality is everyones Job'</td>
</tr>
<tr>
<td>(AC) Activate &amp; Consequate</td>
<td>Encourage transparency. Institute a 'no blame' approach to ensure early surfacing of errors and mishaps when they arise. All functions included in shop floor morning meetings to proactively review paperwork completion and address 'near miss' events root causes</td>
</tr>
<tr>
<td>(T) Transfer Knowledge and Skills to sustain change</td>
<td>Share the Near Misses in Lunch and Learn sessions</td>
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<tr>
<td>Potential Leading Quality Indicators (LQi)</td>
<td>Publish Campaign Lessons</td>
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<td></td>
<td>Learned and review at APQR</td>
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<tr>
<td></td>
<td>% campaign reviews completed</td>
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Triggers

Monitoring For Risks in the Manufacturing Network

### Part I – Leadership Interview and Discussion
(Assessor / Site Leadership/Management)

<table>
<thead>
<tr>
<th>Topic</th>
<th>Comments / Documentation / Evidence</th>
<th>Risk Rating</th>
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</thead>
</table>

#### 1. Organization and Management

- **1.1. Company / Site Organization**
  - Obtains organizational chart:
    - How is the Quality Department organized and is it independent? (yes/no)
    - How many layers of management are in the organization and who is the top level of control at each level?
    - What is the ratio of Quality to total personnel? (is this considered low/high?)
    - What is the reputation of the Quality team? Are they known for providing high-quality services?
    - What kind of feedback or complaints have been received regarding Quality services?
    - What kind of training or development opportunities are available to Quality personnel?

- **Temporary employees and consultants**:
  - Are temporary employees used? (yes/no)
  - Where are temporary employees utilized? (on site, off site, etc.)
  - What is the turnover rate for temporary employees? (number of employees hired per month)
  - Are temporary employees utilized in areas that are critical to Quality? (e.g., laboratory, manufacturing)

### Part II – Colleague/Employee interview and questionnaire
(Assessor / Employees from Operations)

<table>
<thead>
<tr>
<th>Topic</th>
<th>Comments / Documentation / Evidence</th>
<th>Risk Rating</th>
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#### 2. Organization and Management

- **2.1. Company / Site Organization**
  - What are quality decisions made? (corporate, local, etc.)
  - At what level are decisions made? Do colleagues have the authority to make important decisions on their own (e.g., on the shop floor and at the supervisors level) and are issues raised to the appropriate level at the appropriate time?

- **2.3. Management Commitment to Quality**
  - How is commitment to Quality defined and demonstrated by the management?
    - Is it clear how the Quality mission of the firm is defined?
    - To what extent does the Management provide training for employees to enhance Quality management?
    - Is there a formal policy for the identification and validation of documentation?
    - How does management resolve chronic quality problems (repeated audit observations, common causes affecting quality issues)?
Oversight and Review

Kira Ford
Team Lead
The Oversight and Review Heat Map Tool displays the output from the Quality Culture Behavior Maturity Assessment to enable the identification of best practices and area of opportunity.

### Shaping Quality Cultural Excellence: Oversight and Review

- Tool can be applied at either the macro (compare sites across the company) or micro (compare departments within a site) level.
- Horizontal view indicative of individual area performance. Vertical view indicative of cultural behavior performance across different areas.

<table>
<thead>
<tr>
<th>Site</th>
<th>Leadership &amp; Vision</th>
<th>Mindsets &amp; Attitudes</th>
<th>Assessment &amp; GEMBA</th>
<th>Monitoring &amp; Measurement</th>
<th>Management Oversight &amp; Reporting</th>
<th>Structural Enablers</th>
</tr>
</thead>
</table>
The **Oversight and Review Best Practices** highlights examples of different governance processes and approaches that foster leadership engagement in key areas that help reinforce a strong quality culture.

**Aligned Quality Objectives**

**Problem Identification, Problem Solving, Troubleshooting and Investigations**

**External Party Oversight & Reporting**

**Leadership Involvement**
Cultural Enablers

Tami Frederick
Team Lead
Shaping Quality Cultural Excellence: Cultural Enablers

Enabling All Dimensions of Cultural Excellence

Cultural Enablement Best Practices Guide:

- Cultural Enablement Best Practices Guide:
  - Assess Site using Quality Culture Maturity Tool
  - Develop Cultural and CI System roadmaps for role definition, KBI Expectations, Training and Support framework
  - Use System Improvement and Behavioral Accountability Template linking KPIs, with KBIs and system sustainability
  - Results indicate opportunities for improved maturity
  - Cultural Enablement Guide provides link between dimensions
## Shaping Quality Cultural Excellence: Cultural Enablers

### Cultural Enablement drives alignment and performance....

<table>
<thead>
<tr>
<th>Cultural Enablement Guide</th>
<th>Enablers Tool Examples</th>
<th>Leadership &amp; Vision (Dimension 1)</th>
<th>Attitudes &amp; Mindsets (Dimension 2)</th>
<th>Gemba Walks (Dimension 3)</th>
<th>LQI’s &amp; Triggers (Dimension 4)</th>
<th>Oversight &amp; Review (Dimension 5)</th>
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<td>Standard Approach in meeting or communication</td>
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<td>True Root Cause Analysis with Preventive and Corrective Action</td>
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- Toolkit enables employees at all levels in an organization
- Provides tools that can be used across the dimensions
- Best Practices Guide ties performance to behaviors
- Roadmap examples demonstrate how to implement

...enabling cultural excellence across all dimensions
How Do You Enable teams Culturally?

*Cultural Enablement Using the System Improvement/Behavior Accountability Model:*

- Assess your system for improvement
- Determine targeted Results
- Set Key Performance Indicators (KPIs)
- Set Key Behavior Indicators per role (KBIs)
- Set controls

... through Performance & Behaviors
**Cultural Enablement Key Learnings:**

- **Key Performance Indicators are tied to Key Behavior Indicators for each role in the organization (Leaders, Managers, Front Line)**
- **Roadmaps help to build accountability and cultural excellence**
- **Cultural Enablement tools span all Cultural Excellence Dimensions**
- **We own the collective Cultural Excellence of our Organization**
Publication Plans

• Publish a Comprehensive Six Dimensions of Cultural Excellence Report Early 2017

• Spring 2017 Conference on Developing and Promoting a Culture of Excellence
Thank You
nuala.calnan@dit.ie