Developing and Sustaining a Quality Culture in Medical Device and Life Science Industries

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Beth Crandall is a respected leader who brings over 15 years of experience in the life sciences industry specializing in the regulated medical device market. Ms. Crandall also possesses a strong background of leading large quality system programs and implementing changes to related policies, procedures, and systems. She uses organizational change techniques to maximize productivity while achieving business and compliance objectives.

Ms. Crandall earned a Bachelor of Arts degree from the College of St. Thomas in Business Administration, Human Resource Management. A certified Project Manager (PMI PMP), Ms. Crandall has presented at several medical device conferences and published “A Blueprint for Quality” in MD&DI magazine.
Objectives

By the end of this presentation, our goal is for you to:

- Understand and recognize the distinct elements of a Quality Culture.
- Be able to identify the sub-cultures impacting your overall Quality Culture.
- Be able to assess the status of influential sub-cultures, in order to evaluate the effectiveness of your overall Quality Culture.
- Generate ideas for developing or sustaining your Quality Culture.
What is a Quality Culture?
What is a Quality Culture?

**Quality**

- Is a standard as measured against something of a similar kind.
- Indicates the degree of excellence.
- In the Medical Device and Life Science industries, Quality is typically associated with compliance. It also pertains to ensuring a product, process or service meets specifications, standards, regulations or other expectations.

*Quality is the degree of excellence of the process and the outcome as it pertains to applicable specifications, regulations or standards.*
What is a Quality Culture?

Culture

“That complex whole which includes knowledge, belief, art, morals, law, custom and any other capabilities and habits acquired by man as a member of society.”

E.B. Taylor, English anthropologist and founder of cultural anthropology

Culture is the combination of factors that drive behavior of individuals within groups, and within larger organizations.
What is a Quality Culture?

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.”

*Harvard Business Review article “Creating a Culture of Quality” April 2014*

An individual’s behavior is impacted by the expectations, behavior and actions of those around them. It assumes they have effective quality guidelines to follow, and that there are effective incentives driving the activities, discussions and behavior of those around them.
Quality Sub-Cultures

Behavior is shaped by the expectations of all the groups with whom you interact.

Individuals are part of multiple groups:
- Company-wide Peers
- Business Unit Peers
- Management/Supervisor
- Regulatory Agencies
- Internal Customers
- External Customers
- Peers
- Company-wide Peers

Each group has separate Sub-Culture

The Quality Sub-Cultures impact the overall company Quality Culture.
Sub-Culture Example

What happens if sub-cultures are not aligned?

**Scenario:**
- There is a compliant, documented process for a task.
- Your manager told you on your first day to follow the documented process, and has said in meetings that quality is important.
- Management has not:
  - Followed up to confirm you were trained on the process.
  - Asked to see evidence you are following the process.
- Your department peers:
  - Do not follow the process.
  - Give you a hard time when you use the documented process.

**Result:**
The individual is not experiencing an effective Quality Culture.
- Management sub-culture isn’t driving behavior.
  - The Manager is “talking the talk” but not “walking the walk.”
- The peer sub-culture is driving the behavior more than the Manager expectations or what is written in the procedure.
Why it Matters...

Business benefits of an effective Quality Culture

- More efficient utilization of limited resources
- Less waste, scrap and re-work
- Improved speed to market
- More likely to stay on the market

An effective Quality Culture enables resources to align & achieve company objectives.
Are you part of a Quality Culture?

Let’s rephrase the question....

Are you part of a group with

*multiple factors* in place that

*drive positive behaviors* of individuals within the group to

follow *defined processes* and *produce outcomes*

with a *high degree of excellence* as it pertains to applicable

*specifications, regulations or standards*?
## Quality Culture Elements

<table>
<thead>
<tr>
<th>Quality Culture Element</th>
<th>Examples</th>
</tr>
</thead>
</table>
| **Multiple factors that drive positive behaviors of individuals** | • Peer award and recognition program  
• Regular meetings with management where results are presented and immediate consequences and actions needed identified  
• Visible reprimand and consequences for individuals not complying to processes or expected quality behavior  
• Regular discussion and follow up actions by leadership on issues regarding processes or behaviors |
# Quality Culture Elements

<table>
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| Defined processes with a high degree of excellence as it pertains to applicable specifications, regulations or standards | • Completely documented Quality Management System  
• Evidence of successful assessment or detailed audit of processes (for adherence to standards and regulations)  
• Results of focus groups or usability studies, confirming the Quality system is user friendly  
• CAPAs with high percent of successful Verification of Effectiveness (VOE)  
• Continuous improvement program, with metrics                                                                                                                                                  |
# Quality Culture Elements

<table>
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| Defined **outcomes with a high degree of excellence applicable specifications, regulations or standards** | • Clear product inspection processes, with evidence that the inspection techniques are utilized and are effective (such as validated inspection test methods, with results proving errors are caught)  
• Procedures that clearly list the required elements of a document deliverable (such as the minimum content required for a Report, with evidence that reports are routinely produced in compliance with those specifications)  
• Procedures that clearly indicate requirements for manufacturing equipment qualification, and evidence that the equipment qualifications were conducted in compliance with those requirements |
## Examples: Outcomes & Inspection Criteria

<table>
<thead>
<tr>
<th>Quality System Area</th>
<th>Example Outcomes or Deliverables</th>
<th>Example Inspection Criteria</th>
</tr>
</thead>
</table>
| **Production & Process Controls** | o Finished Goods  
o DMR | o Product Specification  
o Finished Goods Inspection procedure with detailed criteria  
o Procedure listing specific expectations for DMR approval |
| **Complaint Handling** | o Complaint record  
o Investigation evidence | o Procedure with detailed criteria for complaint record, used in approval of the complaint record  
o Procedure with detailed information about expectations for investigation evidence |
| **CAPA** | o CAPA record  
o Root Cause Analysis results | o Procedure with detailed criteria for CAPA record, used in approval of the CAPA  
o Procedure with detailed information regarding Root Cause Analysis evidence |
Determining if you have a Quality Culture
Quality Culture Score Card

Create a Quality Culture score card:

- Include a column for each influential sub-culture group applicable to your situation.
- Objectively review the status of the Quality Culture elements for each sub-culture.
- Assign “+” or “-” to indicate if the element exists or is missing.
- Identify areas where the Quality Culture needs development or further attention.
- Identify areas where the Quality Culture is effective, and should be sustained.

<table>
<thead>
<tr>
<th>Quality Culture Element</th>
<th>Department Peers</th>
<th>Immediate Mgmt.</th>
<th>Direct Reports</th>
<th>Business Unit</th>
<th>Company Wide</th>
<th>External Customers</th>
</tr>
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<tbody>
<tr>
<td>Multiple factors that drive positive behaviors of individuals</td>
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## Quality Culture Elements

<table>
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<tr>
<th>Quality Culture Element</th>
<th>Do you have it?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Recognition programs (with meaningful rewards)</td>
</tr>
<tr>
<td></td>
<td>Visible Metrics that indicate if processes are being utilized</td>
</tr>
<tr>
<td></td>
<td>Visible metrics that indicate outcomes meet specification</td>
</tr>
<tr>
<td></td>
<td>Tangible consequences if processes not utilized</td>
</tr>
<tr>
<td></td>
<td>Tangible consequences if outcomes do not meet specification</td>
</tr>
<tr>
<td></td>
<td>Positive Peer attitude toward utilizing processes</td>
</tr>
<tr>
<td></td>
<td>Positive Peer attitude toward outcomes meeting specification</td>
</tr>
<tr>
<td></td>
<td>Visibly engaged leadership</td>
</tr>
<tr>
<td></td>
<td>Evidence of leadership attention to positive and negative behaviors and outcomes</td>
</tr>
</tbody>
</table>

*Multiple factors that drive positive behaviors of individuals*
## Quality Culture Elements

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| Defined processes with a high degree of excellence as it pertains to applicable specifications, regulations or standards | - Processes assessed and confirmed to be compliant with applicable regulations and standards  
- Processes evaluated by end users to determine usability and effectiveness  
- Evidence of process effectiveness  
- Evidence of effective continuous improvement for processes |
# Quality Culture Elements

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| **Defined outcomes with a high degree of excellence applicable specifications, regulations or standards** | - Documented clear and objective specifications for outcomes or deliverables* confirmed to be compliant with applicable regulations and standards  
- Clear and objective inspection criteria to determine if outcomes or deliverables meet specifications |

*Deliverables include any tangible or intangible object produced that is intended to be delivered to a customer (either internal or external). Examples include: products, software systems, equipment, reports, records, engineering specifications, etc.
Example Scenario

Determining if there is an effective Quality Culture...

- The individual is a member of a business unit with multiple locations.
- The Quality System is established at the Business Unit level. There is no company wide Quality System.
- The Quality System procedures for their Business unit are compliant.
- There are no awards or incentives at the business unit level or below to drive behavior.
- There is a corporate wide recognition program with a “Quality” award.
- The department level processes are not fully documented.
- Management does not routinely review deliverables or evidence of process outcomes.
- The individual has documented processes for their direct reports.
- The individual does team level recognition at staff meetings.
# Example Quality Culture Score Card

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<td>+</td>
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**Comments:**

- The individual is not experiencing an effective Quality Culture, but is trying to establish one for their direct reports.
- The Business unit has compliant processes and outcomes, but the culture is breaking down at the department level.
- The external customers have incentives in place and have defined expected outcomes, but don’t have effective, defined processes.
- There are opportunities to improve the culture by focusing on factors that drive behaviors at the department and business unit levels.
Ideas to Develop and Sustain a Quality Culture
# Ideas to Develop & Sustain a Quality Culture

**Multiple factors that drive positive behaviors of individuals**

<table>
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<tr>
<th>Develop</th>
<th>Sustain</th>
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</table>
| - Establish recognition and award programs that reward desired Quality behavior | - Follow up with those who’ve been rewarded, confirm ongoing positive results  
- Refresh the program, ensure the recognition and rewards continue to be meaningful and valued |
| - Establish goals and objectives with measurable metrics; enforce tangible consequences regarding utilizing processes | - Continue to monitor and refresh metrics  
- Follow up on a sample of the tangible consequences, confirm having desired impact |
| - Establish metrics with tangible consequences regarding deliverables & outcomes | - Periodically conduct additional surveys or use other follow up mechanisms to track changes in peer attitudes |
| - Establish survey or other mechanism to assess Peer attitudes regarding utilizing processes and achieving quality outcomes | - Gather metrics regarding results of leadership performance objectives  
- Obtain 360 feedback on leadership engagement |
Ideas to Develop & Sustain a Quality Culture

Defined processes with a high degree of excellence as it pertains to applicable specifications, regulations or standards

<table>
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<th>Develop</th>
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<tbody>
<tr>
<td>❑ Assess processes to confirm compliant to applicable regulations and standards</td>
<td>❑ Conduct periodic assessments, including some “deep dive” assessments and spot checks</td>
</tr>
<tr>
<td>❑ Conduct usability assessments of processes with end users</td>
<td>❑ Conduct periodic assessments, including different combinations of processes, to ensure end-to-end process effectiveness and usability</td>
</tr>
<tr>
<td>❑ Establish and monitor metrics to measure process effectiveness</td>
<td>❑ Continue to monitor and refresh metrics</td>
</tr>
<tr>
<td>❑ Establish program for continuous process improvement, with focus on process usability and effectiveness, not just time and cost savings</td>
<td>❑ Monitor results of process improvements, include reporting on improvements to compliance, usability and effectiveness of quality processes</td>
</tr>
</tbody>
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Ideas to Develop & Sustain a Quality Culture

Defined outcomes *with a high degree of excellence applicable specifications, regulations or standards*

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<tbody>
<tr>
<td>- Document clear and objective specifications for outcomes or deliverables in all major areas of the Quality System</td>
<td>- Gather metrics and report status of documented specifications in all major areas of the Quality System</td>
</tr>
<tr>
<td>- Confirm documented specifications are compliant with applicable regulations and standards</td>
<td>- Periodically assess compliance against any changes to regulations and standards</td>
</tr>
<tr>
<td>- Establish clear and objective inspection criteria for all major outcomes or deliverables for all major areas of the Quality System</td>
<td>- Gather metrics and report status of documented inspection criteria for outcomes or deliverables in all major areas of the Quality System</td>
</tr>
</tbody>
</table>
Conclusion

Developing and Sustaining a Quality Culture

You should now be able to:

- Break down the elements of a Quality Culture into more practical pieces.
- Determine the sub-cultures with most influence on your Quality Culture, and determine if you have the factors needed for those sub-cultures to be effective.
- Apply specific ideas to develop or improving the Quality Culture elements.
- Achieve business benefits enabled by improved utilization of resources and more effective processes.
Q & A
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