Why are we doing this?

• Many firms identify the need to develop, improve, and sustain quality culture.
• Some of these firms need a playbook to make these changes.

• We offer an approach:
  • This is a set of practices, not the set of practices.
  • Firms can choose to follow this playbook exactly or to pick parts that suit specific needs.
  • Other approaches and playbooks exist; they may lead to equally successful results.
The rules of the road

1. Quality culture is enterprise-wide. All functions – from R&D, to operations, to HR – drive quality

2. Quality culture is top-down and bottom-up. It starts with leadership commitment to quality and practices that assure that all staff understand and drive quality

3. Quality culture is inward and outward facing:
   - Successful companies measure and show quality achievements to staff and leadership
   - Successful companies make it easy for stakeholders to see quality culture and its impact

Sample Quality Statements

- Fostering a quality mind-set with the objective of developing, manufacturing, and providing products and services with zero defects that are trusted and preferred
- Complying with relevant laws and regulations
- Challenging ourselves to improve the quality management system to guarantee product safety, prevent quality incidents, and eliminate defects
- Encouraging participation and promotion of quality responsibilities through standards, education, training and coaching, supervision, and effective communication
What is quality culture and why do we value it?
Quality Culture Overview

What
• Quality culture is the beliefs and practices within a firm that drive quality in areas including product development, production, and distribution.
• Every employee – from front-line staff to senior leaders – is responsible for quality culture.

Why
• Quality culture enables a firm to be a trusted partner for its stakeholders, living up to their expectations and upholding the firm’s mission.
• Quality culture makes good business sense.

How
• Drive behaviors that promote patient safety, quality awareness, and compliance.
• Provide information and education about:
  ▪ Products and their use; and
  ▪ Compliance and quality requirements.
• Show employees how their performance impacts product, service, and process quality.
• Recognize and reward behaviors that promote quality awareness and compliance.
• Promote a blame-free culture and clear expectations for behavior.
Quality culture is effective when it spans the value chain.

Supplier → Company → Patient
Quality culture impacts product lifecycle

Organizational Quality Culture
Quality culture makes good business sense.

- Across the medical device industry, the direct cost of quality equals $26 billion to $36 billion annually. (McKinsey & Co, *Capturing the Value of Good Quality In Medical Devices*, April 2017)

- With better quality practices, the range of recoverable costs is $6 billion to $11 billion per year. A key driver of industry improvement is quality culture maturity. (McKinsey & Co, *Capturing the Value of Good Quality In Medical Devices*, April 2017)
Quality Culture: The Four Behaviors
Quality culture ties to a company’s mission and vision.

Example: one company tied quality to its mission and vision by highlighting four behaviors to help employees across the business understand expectation for their behavior:

“Imagine what we can do for patients when each of us exhibits these behaviors:

• Accountable: We all are accountable to deliver on our commitments.
• Courageous: We all speak up when we notice something wrong, in a blame free environment.
• Patient Focused: We all understand how our actions affect patients.
• Preventive: We all share and implement ideas to continuously improve processes and procedures.

We will be successful when the organization’s quality culture becomes a competitive advantage . . . .”
Quality Culture Overview: Behavior and “I” statements

Our quality behaviors come to life in “I Statements.”

Accountable:

We are all accountable for quality outcomes. We all are accountable to deliver on our commitments. We need to understand and follow our processes. We must resolve quality issues. We all contribute to getting the job done right.

- I understand and follow the processes that are in place.
- I follow through on making decisions based on facts and data.
- I work to resolve identified quality and compliance concerns.
- I will not take shortcuts when it comes to the quality of my work.
- I do what I say I will do.
Courageous:

We are courageous when we share quality issues and their potential for a mistake. We help improve our internal processes. We increase our ability to attain and sustain quality excellence. We all speak up when we notice something wrong, in a blame-free environment.

• If I see something that doesn’t seem right, I say something.
• I share quality concerns and issues when I see them, and I encourage others to do the same.
• I share examples of things we have done well and areas for improvement in my group.
• I share ideas for improvement.
• I suggest product or process improvements that would improve quality even when there are roadblocks to those improvements.
Patient-Focused:

We are patient-focused. The safety and quality of our products for patients and clinicians is our priority. We understand how our actions affect patients.

• I strive to understand the needs of our patients and my role in meeting those needs.
• I always put the safety of patients first.
• I do not make compromises when it comes to the quality of my work.
• I report any patient complaints, no matter where I am when I hear them or what level/position I have in the company.
Quality Culture Overview: Behavior and “I” statements

Our quality behaviors come to life in “I Statements.”

Preventive:

We attain and sustain quality by preventing issues. We improve our processes before problems happen to save the business from costly mistakes and corrections. We make sure that we provide the highest quality products and services when they’re needed.

- I take the time needed to do my work right the first time.
- I think back on what I have learned to prevent future mistakes.
- If a mistake does happen, I make sure we improve our process so it doesn’t happen again.
- I share and implement ideas to continuously improve processes and procedures.
The Five Workstreams: Operationalizing the Behaviors
## Quality Culture Overview

### Five Work Streams

<table>
<thead>
<tr>
<th>Quality Culture Work Streams</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Awareness</strong></td>
</tr>
<tr>
<td>Develop an enhanced understanding of our products – the conditions they treat; how, where, and when the products are used; and the potential consequences to patient safety if a product does not function properly.</td>
</tr>
</tbody>
</table>

### Communication

Develop ongoing structured communications to ensure that clear, consistent, and impactful messages reach the target audiences. Connect to the minds and hearts!
Quality Culture Work Stream: Communication

**Why**
- Connect to the minds and hearts.
- Promote quality behaviors and tie behaviors to patients.
- Build awareness and understanding of quality culture.
- Share good practices and lessons learned.

**How**
- Leadership communication and support
- Videos, posters, digital signage
- Quality/patient forums and events
- Goal setting, huddles, 1-on-1 meeting
- Employee engagement

**What**
- Formal programs and broad communications
- Structured interpersonal/ongoing communications

Pledge wall signing by employees
Quality Culture Work Stream: Product Awareness

Why
To help employees understand the impact their work has on products and services

How
• Structured and effective product education
• Patient/clinician experiences and stories from using products
• Quality/patient forums and events
• Design for reliability and manufacturability

What
• Clinical use education on products
• Patient and customer experiences
• Understanding internal and external customer requirements (critical to quality understanding)
Quality Culture Work Stream: Visual Management

Why
• Metrics show the health of the business: Are we on track to hit our goals? Are there issues that require our help to improve?
• This enables detection of problems immediately and solutions before they become larger issues.

How
• Policy deployment/Hoshin Kanri
• Communication boards
• Lean-Sigma tools (i.e., 5S)

What
• Clearly defined metrics/measurements
• System/process to cascade metrics/measurement through the organization
• Visual work
Quality Culture Work Stream: Continuous Quality Improvement

**Why**
- To educate and ensure all employees understand:
  - The company's approach to quality and compliance;
  - The balance between quality and quantity; and
  - The importance of effective “closed-loop” problem solving (proactive and reactive).

**How**
- Structured and effective quality and compliance training
- Structured problem solving approach e.g., PDCA, A3
- Lean Methodology
- 5 Why’s

**What**
- Quality and compliance awareness
- Problem solving
- Lessons learned
Quality Culture Work Stream: Recognition

**Why**
- Harnesses the energy and capability of the entire workforce to identify positive work
- Promotes teamwork and creates positive momentum towards quality culture

**How**
- A structured recognition program
- Informal and formal peer-to-peer recognition
- Global recognition
- Team meeting, town hall meetings

**What**
- Peer-to-peer recognition
- Manager-to-employee recognition
- Leadership-to-team recognition
Principles Of Quality Culture

- Understand quality behaviors.
- Develop and deploy workstreams that support quality behaviors.
- Point out examples of quality behaviors in action.
- Model quality behaviors in your day-to-day work.
- Recognize others for exhibiting quality behaviors.
Deploying a Quality Culture Initiative
# Action Plan: Workstream Implementation

## Gap Analysis And Planning

<table>
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<th>2</th>
<th>3</th>
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</thead>
</table>

1. **Gap assessment:** What already exists in our work and environment that supports a quality culture?

2. **Where is the most opportunity for progress?**

3. **Which workstreams can be implemented in the long and short term?**
Quality Culture Work Stream: Communication

Expectation: formal broad communications

Why: Develop ongoing structured communications to ensure clear, consistent, impactful messages to reach the target audiences. Connect to the minds and hearts!

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<td>Incorporate quality into existing regular updates from business leadership to the team/site, i.e. standing agenda time for quality updates including patient stories, product awareness or case studies in quarterly all-team/site meetings; sharing prepackaged content such as excerpts from global town hall or content from quality website in town hall-type meetings, leadership messages, or newsletters. Request feedback.</td>
<td>Personalize quality updates from leadership in regular, broad communications channels (quarterly meetings, leader newsletter); less reliance on prepackaged content and updates are more specific to the business. Create original content -- feature team members, using case studies, personal patient stories, product awareness or recognition. Create opportunities for broad all-team/all-site visibility to quality recognition programs.</td>
<td>Quality messaging is driven and owned by business leaders and shared among all leaders. Quality is a regular topic among all levels of team meetings; team leaders regularly formally recognize employees for quality during team meetings. Team members drive quality topics and share feedback without solicitation. Create opportunities for all-team/site visibility of employee quality recognition, leverage all broad channels (posters, websites, digital signage, status boards).</td>
</tr>
<tr>
<td>Content delivered by the business leaders, not the quality leader.</td>
<td></td>
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<tr>
<td>Quality culture signage is visible in public areas (signage, e-billboards, etc.)</td>
<td></td>
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</tr>
<tr>
<td>Quality Event</td>
<td>Host a dedicated annual quality event for all employees with the objective of educating employees, building awareness, and enhancing understanding of quality culture. Creativity encouraged.</td>
<td>Quality Event</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Expand quality events to longer, more in-depth and more frequent events featuring personalized content, i.e., recognition of quality activities among the team, personal patient stories, business-specific case studies. Educate employees about the ways that quality culture is visible in the team/organization’s work.</td>
</tr>
</tbody>
</table>
Quality Culture Work Stream: Communication

**Expectation:** interpersonal communications

**Why:** Creating two-way dialog between managers and team members focused on quality allows everyone to internalize quality behaviors and surface opportunities for quality improvement. Each employee understands how they contribute to improving patient safety, product/service quality, and business goals.

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<td>Managers create the opportunity for the team to internalize what quality means in their work and to discuss the quality behaviors.</td>
<td>Managers encourage team members to surface problems through a continuous and open dialog around quality impact and problem solving.</td>
<td>Team members incorporate quality and problem solving into their daily dialog. Take ownership of discussing, evaluating and improving quality.</td>
</tr>
<tr>
<td>Employees and managers discuss their teams’ unique contribution to quality during onboarding, learning about their roles.</td>
<td>Managers learn to coach team members to better see opportunities for quality improvement. Team meetings, 1-1's, etc. all include coaching dialog around quality improvement.</td>
<td>Managers regularly visit the places where value is created and engage in dialog with team members that helps to surface issues that could impact quality and opportunities for improvement. Interactions are no longer &quot;scheduled&quot; and happen routinely where the work occurs.</td>
</tr>
</tbody>
</table>
Quality Culture Work Stream: Product Awareness

Mission: Expectation: product use and patient experience

Why: Develop an enhanced understanding of our products and services – the conditions they treat; how, where, and when they are used; and the possible consequences to patient safety if they do not function properly. Help employees understand the impact their work has on the products and services provided to the patient so they can continue to drive improvements in quality: "You touch the product, you touch the patient."

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<tr>
<td>Education is provided by specialists to team members on the products and services they touch throughout the value stream. Education includes the product's function or therapy, use by the customer/patient, and impact to patient outcomes.</td>
<td>Management creates regular mechanisms and forums for ongoing learning about products and for contact with patients. Systems are created for team members to bring forward and share their personal stories and experiences with products and services.</td>
<td>Team members are the experts on product usage and how each work step impacts product quality and patient experience. They seek out ways to mistake-proof their work and provide improvement suggestions across the value stream (i.e., supply, quality, design, delivery). Patient-focus is central to everyday decision making within the work process: &quot;You touch the product, you touch the patient.&quot;</td>
</tr>
<tr>
<td>Team members have access to patient stories related to the use of products and services.</td>
<td></td>
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</table>
Quality Culture Work Stream: Product Awareness

Expectation: understanding internal and external customer requirements

Why: To help employees understand the impact their work has on the products and services to patients so they can continue to drive improvements in quality: "You touch the product, you touch the patient."

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<tr>
<td>Customer requirements are defined for all products/services.</td>
<td>Management deploys processes and systems that elicit regular engagement and feedback from customers in product/service design and delivery.</td>
<td>Customers become an extension of the value stream. Time is regularly spent in their environment to gain deep understanding and appreciation for how they use the product/service and to uncover improvement opportunities. Employees in all areas in the value stream partner with customers to drive improvement in every facet of their work.</td>
</tr>
<tr>
<td>Employees closest to the value stream are educated on the product and process critical-to-quality elements.</td>
<td>Customer requirements are translated into tighter controls in the work process, i.e., robust systems are in place for the detection of conditions that might lead to the creation of a product/service that is outside of the customer specification.</td>
<td>Team members understand how every work step in their process impacts quality. They are empowered to stop their work whenever a condition exists that might impact quality.</td>
</tr>
<tr>
<td>Customer complaint and product performance data from patients and clinicians is shared with employees.</td>
<td>Team members know the most commonly-occurring customer complaints and understand how their work steps can prevent these issues.</td>
<td>Customer complaints and product performance data are integrated with systems to evaluate potential new risks to quality.</td>
</tr>
</tbody>
</table>
Quality Culture Work Stream: Visual Management

Expectation: clearly defined metrics

Why: All employees should understand how their work impacts business performance and goals, see actual performance vs. target, and help improve performance. Metrics show the health of processes and make performance gaps visible. Look for gaps to drive improvement; no gaps means no improvement.

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<td>Define critical few metrics for quality, service, cost, safety and employee engagement for the entire organization and begin to cascade the metrics down to the workflow level.</td>
<td>Metrics are rationalized, aligned, and understood through all layers of the organization. Metrics are made visible. Regular cadence of cross-functional review occurs and problem solving occurs to close gaps.</td>
<td>Ownership of the metrics (activities to update, achieve, manage, and improve) resides with the employees for their own workflows. Management &quot;manages&quot; by providing support to hit targets, e.g., by removing barriers in the work process, versus managing to the metric.</td>
</tr>
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**Quality Culture Work Stream: Visual Management**

**Expectation: visual work**

**Why:** Visual work and workplace creates an environment that enables us to detect problems immediately and solve them before they become larger issues.

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<td>Define work processes and understand performance and maturity.</td>
<td>Engage team in defining a standard work method and establish agreement in the work team to pursue the standard. Organize the physical and electronic workplace to make things easy to see and find. Create visual methods to show the health of the workflow.</td>
<td>Make the work easy to see and the workplace visually intuitive so that problems can be immediately detected. Establish an expected response when problems are found (Stop and Fix; See Something, Say Something) that feeds into structured Problem Solving.</td>
</tr>
</tbody>
</table>
Quality Culture Work Stream: Continuous Quality Improvement

Expectation: quality and compliance awareness

Why: All employees should clearly understand and comply with applicable business, regulatory, and product-quality standards. All employees are empowered to solve problems and drive continuous improvement in all facets of the company to ensure products and services deliver positive patient outcomes. Each employee understands the company's approach to quality and the importance of personal responsibility and compliance to all regulations in order to make a safe and effective product.

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<td>Uphold the minimum standard to ensure compliance to regulations.</td>
<td>Management creates standard business practices that continually engage employees in internalizing why quality and compliance is critical to create customer value. Empowers employees to &quot;See Something and Say Something&quot; when issues arise.</td>
<td>Quality and compliance built into the work and employee development is focused on empowering employees to own and improve their work process towards better meeting customer needs (above and beyond compliance).</td>
</tr>
</tbody>
</table>
Quality Culture Work Stream: Continuous Quality Improvement

Expectation: problem solving

Why: Detecting small problems during the work process prevents them from becoming bigger problems. Solving problems with a standard methodology (e.g., A3 DMAIC) ensures that employees and leaders can solve problems together as well as identify and solve the root cause of problems so they do not recur. Key to problem solving is having a deep understanding of work process and how it connects to the customer and patient

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<td>Deploy common problem solving methodology, moving toward a standard approach.</td>
<td>Management creates standard business practices involving problem solving. Stronger alignment of strategy and improvements</td>
<td>Everyone, everyday uses well-defined, structured problem solving in their work. The focus shifts from a few individuals owning larger improvements projects to everyone solving many small problems quickly and thoroughly.</td>
</tr>
<tr>
<td>Define work processes and understand performance and maturity.</td>
<td>Drive stability and predictability into processes to achieve quality, service, cost, and engagement</td>
<td>Continuously strive to improve flow of value to the customer through your process</td>
</tr>
<tr>
<td>Understand your work’s connection to the flow of value of products and services to the patient.</td>
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# Quality Culture Work Stream: Continuous Quality Improvement

**Expectation:** lessons learned

**Why:** Customers and regulators expect the highest level of quality. A problem or issue that has been resolved in one part of a company may be faced by another.

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<td>Processes are put in place to capture learnings and mechanisms are developed to share the learnings with appropriate audiences in the work group.</td>
<td>Management creates standard business practices to share learnings across the organization.</td>
<td>Employees work is designed to include quick learning cycles using problem solving. Lessons from experiments are broadly shared across the organization (and beyond) and incorporated into improvements.</td>
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</table>
Quality Culture Work Stream: Recognition

Expectation: Peer to Peer Recognition

Why: Recognize and reward employees for exhibiting desired behaviors. Harness the energy and capability of the entire workforce to identify positive work efforts. Promote teamwork and create positive momentum towards quality culture.

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<tr>
<td>Employees are beginning to appreciate blame-free culture and are willing to provide feedback to colleagues on their performance. Limited peer-to-peer recognitions</td>
<td>Employees feel comfortable giving and receiving positive and not-so-positive feedback to their colleagues. Often, employees recognize their colleagues for demonstrating quality culture behaviors.</td>
<td>There is a sense of implicit trust among employee. This is manifest in reflexive actions to do the right things for patients. Recognizing peers for going an extra mile for patients’ sake is a norm.</td>
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### Quality Culture Work Stream: Recognition

**Expectation: Manager to employee recognition**

**Why:** Individual recognition from one's manager engages and inspires employees to continue high levels of achievement and reinforces quality behaviors.

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<td>Managers are beginning to appreciate the power of positive reinforcement. They are looking for opportunities to recognize employees for desired behaviors and outcomes.</td>
<td>Managers are in the work areas, providing timely recognition and feedback to employees. Employees take the feedback in the right spirit and strive to improve in a collaborative way.</td>
<td>Public recognition of employees is how the organization functions. Employees are proactively asking for feedback and ways to improve performance.</td>
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**Expectation: Leadership to team recognition**

**Why:** Leadership recognition is critical to engaging and inspiring employees to attain higher levels of achievement and sets the tone for the broader organization for what is valued.

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<td>Leaders are beginning to recognize the need to appreciate employees for going above and beyond and by positively impacting organizational performance.</td>
<td>Few employees have been nominated for higher level (at BU/Group level) recognition. Employees feel valued.</td>
<td>Leadership recognitions have created patient-centric organization where employees feel connected to organization mission. Every employee can articulate the value they create and its impact on every stakeholder.</td>
</tr>
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</table>
## How do we track our progress: sample metrics

<table>
<thead>
<tr>
<th>Line Item</th>
<th>Work stream</th>
<th>QBWM Expectation</th>
<th>Assessment Question</th>
<th>Assessor’s Standard Work</th>
<th>Getting Started (1)</th>
<th>Accelerating (2)</th>
<th>Institutionalizing (3)</th>
<th>Preventive</th>
<th>Courageous</th>
<th>Patient Focused</th>
<th>Accountable</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong> Communication</td>
<td>Formal mass communications</td>
<td>How is the QBWM program being communicated across the value chain, functions, and key stakeholders?</td>
<td>Site has formal process to communicate and educate employees in all functions and levels on the intent, behaviors, and expectations of &quot;Quality Begins with Me&quot; (QBWM). Various communication methods are used through shop floor observations and interviews with management and shop floor employees.</td>
<td>Inconsistent and/or informal communication with employees about the QBWM program with limited understanding amongst employees about the program.</td>
<td>Formal communication programs educate all employees on QBWM. i.e., Video Posters, Newsletters, Digital Signage, Videos, Town Hall Meetings, etc. All managers articulate the program intent, but limited understanding of the program. Some employees are aware of the program and understand the intent.</td>
<td>Who/What/where is invoicing of major tasks and services?</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>2</strong> Communication</td>
<td>Formal mass communications</td>
<td>What is the level of understanding of the 4 &quot;Quality Begins with Me (QBWM)&quot; Behaviors and expectations across different levels within the organizational structure?</td>
<td>Understanding of the QBWM is low between levels through Focus Group feedback and interviews with managers and shop floor employees. Additional opportunities for employees and managers to observe and demonstrate QBWM behaviors.</td>
<td>Limited number of employees can articulate the 4 key QBWM Behaviors and how they implement them in their jobs.</td>
<td>Most of the employees can articulate the 4 key QBWM Behaviors through various examples on how they personally impact quality.</td>
<td>All employees can articulate the 4 key QBWM Behaviors through various examples on how they personally impact quality.</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td><strong>3</strong> Communication</td>
<td>Formal mass communications</td>
<td>How does the site promote a &quot;Blame-Free&quot; Culture?</td>
<td>Through Focus Group and shop floor interviews, most employees view the &quot;Blame-Free&quot; environment as a reality.</td>
<td>Some employees are uncomfortable in responding to leadership questions on &quot;Blame-Free&quot; culture. Most PCA (Plant Coaches) are &quot;People-focused&quot;. Employee feedback indicates a lack of support of &quot;Blame-Free&quot; culture.</td>
<td>Managers understanding of employees of what a &quot;Blame-Free&quot; Culture is with limited &quot;See Something, Say Something&quot; example provided. Most PCA (Plant Coaches) focused on the process not the people. Leadership not supportive of &quot;Blame-Free&quot; culture.</td>
<td>Most employees can explain &quot;See Something, Say Something&quot; and can provide examples of &quot;Blame-Free&quot; culture. Employees are comfortable reporting the process and the culture in the environment. Managers in a position to make decisions made.</td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td><strong>4</strong> Communication</td>
<td>Interpersonal Communications</td>
<td>How are Managers engaging employees on a frequent basis?</td>
<td>Video call/weekly Team meetings, informal 1:1s, informal feedback, during interaction with shop floor employee. Add/Focus Group and shop floor employee feedback on the following: Do they listen to you? What do you do about mistakes? Do they develop you on the shop floor? Do they communicate?</td>
<td>Web of leadership is monitored as workable because: a) when something goes wrong (accidents, breakdowns, or quality issues)</td>
<td>Most of the leadership has structured small group meetings (e.g., &quot;Town Halls&quot;, debriefs, etc.) with specific topics and &quot;closed loop&quot; follow-up with the employees. Employee feedback on the engagements is favorable.</td>
<td>Leadership have structured small group meetings on a larger basis. Mailing list: all shifts. Visibility across all shifts if applicable. Leadership promotes interaction with employees to seek improvement ideas, feedback, feedback, feedback. Employees can provide excellent examples of small group meetings. Employees feel like they are respected and listened to.</td>
<td></td>
<td></td>
<td>X</td>
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<td>2</td>
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How do we track our progress: sample metrics (cont.)

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<th>Patient Focused</th>
<th>Accountable</th>
<th>Score</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Product Awareness</td>
<td>CTQ Understanding</td>
<td>SCORING</td>
<td>Place an “X” in one of the boxes to the right that most closely aligns with current state processes.</td>
<td>X</td>
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<td>1.9</td>
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<tr>
<td>2</td>
<td>Product Awareness</td>
<td>Understanding Internal &amp; External Customer Requirements – Critical to Quality (CTQ) Understanding</td>
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<tr>
<td>3</td>
<td>Continuous Quality Improvement (CQI)</td>
<td>Quality and Compliance Awareness</td>
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<td>4</td>
<td>CQI</td>
<td>Problem Solving</td>
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<td>5</td>
<td>CQI</td>
<td>Problem Solving</td>
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<tr>
<td>6</td>
<td>CQI</td>
<td>Problem Solving</td>
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</table>

Note: Question only applies to functions where CTQs are applicable, e.g., Ops, Service Distribution, Contact, E2E.

Customer complaints and product performance data is shared between the Quality and Compliance department to identify any issues that affect customers. This data is then used to develop improvement initiatives for the organization.

| Continuous Quality Improvement (CQI) | Quality and Compliance Awareness | What processes or mechanisms in place to reinforce compliance awareness of employees? Is it effective? | | | | | | | | | 3 |
| Continuous Quality Improvement (CQI) | Problem Solving | How are different levels in the organization/site engaged in Continuous Improvement (CIP)? | | | | | | | | | 3 |
| Continuous Quality Improvement (CQI) | Problem Solving | How are quality behaviors being reinforced through various cultural drivers to proactively impact area performance? | | | | | | | | | 3 |

The Cultural Enhancement Initiative is a critical component of the organization's strategy. It aims to improve employee engagement and satisfaction by fostering a positive work environment. The initiative includes regular communication sessions, leadership workshops, and employee feedback mechanisms. The goal is to create a culture where employees feel valued and are motivated to contribute to the organization's success.

| Continuous Quality Improvement (CQI) | Problem Solving | How are quality behaviors being reinforced through various cultural drivers to proactively impact area performance? | | | | | | | | | 3 |

There is a structured governance around each initiative where data and other feedback methods are reviewed on a frequent basis to evaluate gap, opportunities, and monitor effectiveness. Improvement actions are owned and prioritized by the employees.
Showing Quality Culture
Firms must show quality culture to their customers (1 of 2)

• In addition to driving product and process improvements, strong quality culture distinguishes high-performing firms.
• To stand out, a firm must give current and potential customers clear and easily-understood metrics that show the firm’s quality culture.
• There is no single source of quality culture metrics. Firms can identify and apply metrics from multiple sources.

“Quality can . . . be expanded to create customer value and enhance brand image, thus serving as a competitive differentiator.” The ASQ Global State of Quality, Discoveries 2016
Firms must show quality culture to their customers (2 of 2)

• For example:
Appendix
DISCUSS THE FOLLOWING QUESTIONS AS A TEAM

1. What does quality mean to you and why does it matter?
2. How do you link quality to your company’s mission?
3. How are quality problems solved at all levels?
4. How are quality problems identified and communicated?
5. What does quality mean to you in your role to be accountable, courageous, patient-focused, and preventive?
6. How does your role impact patient outcomes?
7. How is quality of work measured in current environment?
8. How does our focus on quality make it exciting/important to do your best each day?
9. How do you recognize people demonstrating Quality behaviors?
## Leading firms build trust in society and solve important problems

<table>
<thead>
<tr>
<th>Culture</th>
<th>Values</th>
<th>Behaviors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adaptive self-learning focused on continuous improvement and sharing and deploying successful practices</td>
<td>Values (e.g., integrity, trust and accountability) vary across firms. Each firm’s values can be leveraged to drive culture improvement.</td>
<td>Like values, behaviors can vary in support of the mission and vision and drive culture (e.g., accountability, preventive, aware, adaptive, courageous, curious, collaborative).</td>
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<tr>
<td>Delivering Exceptional Patient Value</td>
<td>Share examples: “I statements for each function.” Be customer centric, patient centric, focus on exceptional quality.</td>
<td>What should this look like for our: customers, stakeholders, shareholders, functions: legal, ap, hr, ehs, customer service</td>
</tr>
<tr>
<td>Empowering our people</td>
<td>Examples: “case stories” of how if you touch the product, you touch the patient, and in other not product facing functions, you touch the process, you touch customer</td>
<td>Provide recognition to employees for exhibiting behaviors and values supporting a quality culture, patient or customer centric performance.</td>
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<tr>
<td>Leading by example</td>
<td>Top down-bottom up CEO, leadership and middle manager and frontline employees engagement</td>
<td>Survey results, correlation to KPIs, metrics, assessment results and continuous improvement</td>
</tr>
<tr>
<td>Sustainable profitable growth</td>
<td>Demonstrate how a culture of quality contributes to growth to investors, shareholders, key stakeholders, payers, and providers.</td>
<td>Tied to strategic initiatives and imperatives, supported by results, metrics, promoter scores.</td>
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<tr>
<td>Technology enabled</td>
<td>Bold ideas. Innovation, disruptive technologies, competitive advantages</td>
<td>Drive user unmet needs. Proactive customer centric engagement with KOLs, patients, key stakeholders</td>
</tr>
</tbody>
</table>
Additional Resources

  ▪ A framework to help companies identify costs related to poor quality and prioritize investments in good quality
- Background for the Cost of Poor Quality dashboard, available at
  http://mdic.org/cfq/resource-center-for-sustained-quality/
- McKinsey & Company, “Capturing the Value of Good Quality in Medical Devices,
  ▪ Shows the difference in quality-related costs between the leading and lagging performers in the medical device industry
  ▪ Identifies and measures the impact of emerging best practices that companies use to raise quality, including robust product and process controls, stronger operational maturity, mature quality systems, and robust quality culture and practices across the organization.