



Cultural Excellence Report

Cultural Excellence Report

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Introduction

Background

Quality culture is a feature of organizational design that fosters cross-functional ownership of quality. It treats quality not as a hindrance for success, but as a necessity that allows the company to make decisions that best benefit patients. [1] Culture can be described using many different terms, but the key is to define, emphasize, and support the demonstration of desired behaviors and results. Quality culture refers to the expressed and implied ways in which an organization operates, affects quality performance and supply chain excellence, and ensures patient-focused outcomes.

Culture determines quality outcomes, because it affects the organization's ability to identify and act upon near-miss shortages, assure transparent problem escalation, and strive for operational excellence. A healthy quality culture requires management ownership and accountability, performance metrics that promote continual improvement, and a strong risk-management framework. All are key to the proactive identification and prevention of poor quality outcomes. Finally, quality culture is driven by leadership example.

While no regulations currently describe expectations for a quality culture, there is growing regulatory interest [6][7] in promoting quality more broadly within the context of culture. During ISPE's April 2015 conference on quality metrics, Dr. Janet Woodcock, Director of the US Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, described her intent to move both industry and the FDA along the "continuous improvement pathway" by adding metrics and a quality management system to the agency's risk-based approach. [3][4]

The focus on metrics as a vehicle to assess quality performance has driven an interest in understanding and measuring an organization's quality culture. This signals a shift from reliance solely on regulatory compliance to an emphasis on continuous improvement in which there is deep understanding throughout an organization of the elements critical to product quality.

Quality culture can play a central role in preventing drug shortages* and should not be adversely affected or overtaken by immediate business needs. Reality often differs from policy, however, and people may make decisions that undermine quality. [3]

Each organization's quality culture exists in a different context, based on organizational ownership, supply chain configuration, maturity, product mix, and regional influences. Understanding this context is critical in assessing the influence and current health of the culture within a given organization.

This report shares insights on quality culture improvement across six key dimensions and outlines a series of practical and powerful approaches, practices, and tools to support implementation of the cultural excellence framework and promote behavioral change that will ultimately benefit the patient and the business.

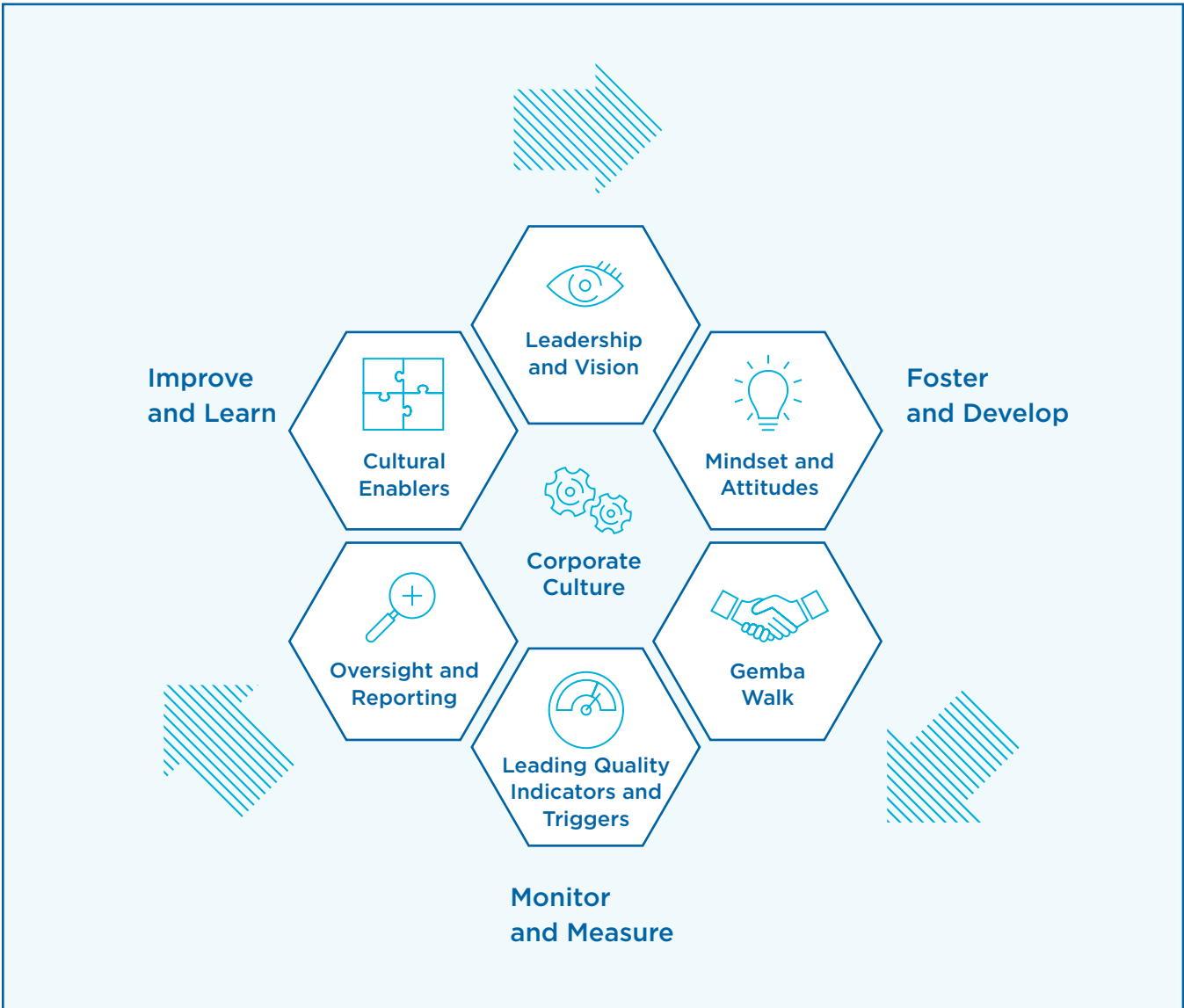
* Speaking at the April 2015 conference, Woodcock also noted that "fear of reporting problems internally within an organization and fear of negative repercussions from reporting them to the agency drives behaviors that are not just nonproductive, but anti-productive."

Six Dimensions of Cultural Excellence

The ISPE Quality Culture Subteam, sponsored by the ISPE Quality Metrics Team and co-led by Dr. Nuala Calnan of the Dublin Institute of Technology and Matt Pearson of Genentech, are pleased to publish this comprehensive report on cultural excellence, based on the subteam’s work over the last 24 months.

The report focuses on the six dimensions of cultural excellence, a framework introduced at the ISPE Quality Metrics Summit in April 2015 (Figure 1) that facilitates a holistic assessment of those elements required to foster, develop, monitor, measure, learn, and ultimately improve an organization’s quality culture.

Figure 1: Six dimensions of cultural excellence framework



The six dimensions are:

1. **Leadership and vision:** Leaders establish and engender the vision for the organization. Their thoughts, words, and actions about quality are critical in establishing and maintaining a culture of operational excellence. Leadership and vision, therefore, play a key role in establishing the culture, either within a local manufacturing site or across the company.
2. **Mindset and attitudes:** These play a key role in driving cultural performance, although they can be difficult to define, observe, and measure. Leaders can assess, monitor, and develop the desired cultural excellence mindset and attitudes within their organizations, using the practical and powerful approaches outlined in this report.
3. **Gemba walks:** Management engagement on the floor is a powerful way to demonstrate quality commitment to all members of the organization. Gemba walks allow site leaders to communicate clear messages using open and honest dialogue, and provide a real indication of progress toward desired behaviors at all levels. Gemba walks also empower front-line employees by recognizing their contributions to site results and involving them in problem-solving and continuous improvement.
4. **Leading quality indicators and triggers:** There are inherent links between culture, behavior, and leading quality indicators (LQIs) that drive desired patient-focused behaviors. Monitoring and surveillance of key triggers and the design of LQIs are highly recommended practices to help shape cultural excellence.
5. **Oversight and review:** Management oversight and review practices that engage both management and employees support a healthy quality culture because they demonstrate transparency, facilitate dialogue, bring attention to issues so they can be addressed, and highlight best practices so they can be replicated.
6. **Structural enablers:** These support the desired behaviors, help speed the pace of change, and improve performance over time. [5] They include:
 - Develop a learning organization
 - Establish learning teams
 - Influence and recognize organizational change
 - Solve problems proactively
 - Identify true root cause

Assessment Criteria and Cultural Excellence Tool

Based on additional research and findings, the ISPE Quality Culture Subteam adapted the corporate culture gap analysis from the ISPE Drug Shortage Assessment and Prevention Tool [2] to determine a set of 21 desired key behaviors that support the six dimensions of cultural excellence. The result is the ISPE Cultural Excellence Assessment Tool (Appendix 1), designed to help organizations assess the maturity of these behaviors as part of their quality culture program.

The Cultural Excellence Assessment Tool is the first of a suite of tools presented by the ISPE Quality Culture Subteam based on over two years of research, development, and sharing of best practices. It provides a behavior-based framework to understand, assess, and develop excellence in quality culture within organizations.

The tool uses a Likert-type scale,* due to its familiarity, ease of application, and minimal need for orientation (Table A).

Table A: Likert maturity rating scale

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5	LEVEL 6	LEVEL 7
Strongly disagree	Disagree	Slightly disagree	Neutral	Slightly agree	Agree	Strongly agree

Behavioral criteria associated with each of the six dimensions are described in their desired states, and the level of maturity is determined by the degree to which respondents agree or disagree with the statement presented. For behaviors with lower maturity scores, the tool also lists possible improvement actions to help develop and promote cultural excellence in those behaviors.

The tool is not designed to yield an overall cultural excellence score. Instead, it is intended to indicate specific behaviors and dimensions with lagging maturity. This comprehensive behavior-based approach to improving quality culture gives leaders and cultural excellence practitioners a practical and powerful means to shape cultural performance and deliver enhanced quality outcomes.

* A scale used widely in survey research, invented by American social psychologist Rensis Likert

Moreover, the tool is intended to provide ongoing utility for continuous improvement. Cultural excellence is a journey that takes time to cultivate and achieve the desired state. Companies and organizations that can shift maturity toward levels 6 and 7 on all dimensions should expect to see significant improvement in quality outcomes and employee engagement. Table B lists the 21 desired behaviors that are assessed across the six dimensions.

Table B: Cultural excellence: Desired states

	DESIRED BEHAVIORAL STATE
1	Leadership and vision
1.1	We regularly hear from management an emphasis on quality topics and the importance of quality.
1.2	When we have quality issues in conflict with business issues, both aspects are always considered by management before making a decision.
1.3	Leaders regularly provide sufficient support and coaching to line workers to help them improve quality.
1.4	Leaders always model the desired behavior of "doing the right thing" on issues of quality.
2	Mindset and attitudes
2.1	All employees consistently see quality and compliance as a personal responsibility.
2.2	Employees have sufficient authority to make decisions and feel trusted to do their jobs well.
2.3	Employees regularly identify issues and proactively intervene to minimize any potential negative impact on quality and compliance.
2.4	Employees are not afraid to speak up, identify quality issues, or challenge the status quo for improved quality; they believe management will act on their suggestions.
3	Gemba and shop floor engagement
3.1	There are both formal and informal processes in place to ensure management regularly visits the shop floor to observe, assess, listen, and coach the employees, such as Gemba walks.
3.2	There is evidence to confirm that the desired quality behaviors are routinely practiced on a day-to-day basis, for example, through Gemba walks. Opportunities for continuous improvements are routinely identified and implemented, as appropriate.
4	Monitoring and measurement
4.1	Quality metrics and goals are consistently designed and selected to promote/motivate desired quality behaviors.
4.2	Up-to-date quality metrics (right first time figures, excellence targets on defects, rejects) are regularly posted and easily visible near each production/work area.
4.3	All workers can routinely explain what quality information is tracked and why and outline their role in the achievement of quality goals.

	DESIRED BEHAVIORAL STATE
5	Management oversight and reporting
5.1	Quality goals and objectives are routinely established, linked, and aligned with organizational goals.
5.2	Management is regularly involved in reviewing and assessing product, process, and quality system performance.
5.3	The company's oversight and reporting capabilities are systematically applied to effectively manage external manufacturing performance within the supply chain.
5.4	Management regularly involves line workers in problem identification, problem solving, troubleshooting, and investigations.
6	Cultural enablers
6.1	Improvement opportunities and problems are acknowledged quickly, mistakes are formally reviewed, and company looks to share and learn from them.
6.2	Management enables employees at all levels within the organization to identify and communicate risks well across the organization.
6.3	We routinely recognize and celebrate both individual and group improvement achievements in performance quality.
6.4	Employees regularly receive training that effectively helps them ensure quality in their work fostering a learning organization.

Application

For organizations considering application of the ISPE Cultural Excellence Assessment Tool the following preparations should be considered:

1. Identify the organization, group, or team that you wish to assess.
2. Identify the representatives from the organization, group, or team that will participate in the assessment.
3. Determine assessment application preference; self-assessment or facilitated assessment.
 - Self-assessment entails the representatives completing the assessment based on their own personal experiences with the target organization, group, or team.
 - Facilitated assessment entails the representatives completing the assessment based on objective observation and interviews with the target organization, group, or team.
4. Determine the appropriate media for executing the assessment (e.g., paper survey, electronic survey, interview) and compiling results.
5. Communicate the purpose of the assessment to the target organization, group, or team.

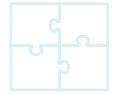
Instructions for executing the Cultural Excellence Assessment Tool are:

1. Using the maturity level scale shown in Table A, put an X in the column that most closely matches the extent to which you disagree/agree with each behavioral criterion.
 - *If you strongly agree with a criterion, for example, put an X in the Level 7 column; if you strongly disagree, put an X in the Level 1 column.*
2. After completing the assessment for each section, identify the behavioral criterion with the lowest level of maturity.
3. Review the “possible improvement actions” for this behavior.
4. Consider other behaviors that indicate improvement opportunities as well.
5. Identify and implement an improvement action to address the behavioral criterion with the lowest level of maturity. Focus on improving these behaviors initially then progress onto the other improvement areas indicated.
6. Monitor progress of cultural excellence improvement with periodic reassessments.

Further resources and tools are presented within each of the individual cultural excellence dimensions throughout this report.

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1 Leadership and Vision

1.1 The Importance of Leadership to Quality Culture

Leadership's thoughts, words, and actions about quality are critical in establishing and maintaining a quality culture; their behaviors are watched and often modeled. Leadership therefore plays a key role in establishing the quality culture within local manufacturing sites and across the company overall.

The ISPE Leadership and Vision (L&V) Subteam conducted a series of "Shaping Excellence" interviews with industry leaders to assess the traits, behaviors, and actions that most positively influence cultural excellence. The team also used the following tools to evaluate leaders' contributions to quality culture and recommend improvements:

- ISPE Cultural Excellence Assessment Tool: Leadership and Vision Section ([Appendix 1](#))
- [Leader 5V Model](#) for holistic leadership
- Assessment tools: [Team Leadership Assessment Tool](#)
- Cultural enablement tools (see [Cultural Enablers](#) chapter)

1.2 ISPE Cultural Excellence Assessment Tool: Leadership and Vision

The ISPE Cultural Excellence Assessment Tool provides self-assessment questions for each of six cultural framework dimensions. The Leadership and Vision section identifies desired states and possible improvement actions—best practices to help reach the desired state target.

Key elements are:

- Create a quality vision
- Share the quality vision throughout the organization
- Model the desired behaviors in support of the quality vision

1.2.1 Communicating the quality vision

We regularly hear from management an emphasis on quality topics and the importance of quality.

A clear vision enables the entire organization to understand the desired state and acknowledge its importance so all can work in alignment with corporate goals and expectations. Leaders should clearly articulate the importance of quality as a business success factor, then share it broadly and frequently within the organization; this can be accomplished both formally and informally. It is essential, however, that leadership return often to the vision's message to maintain agreement and reaffirm its importance.



1.2.2 Modeling leader behavior

When we have quality issues in conflict with business issues, both aspects are always considered by management before taking a decision.

Leaders must make decisions that are congruent with the company quality expectations. Since patient safety is paramount, actions must align with this stated value. When quality issues arise, all aspects must be considered to make the right decisions for patient safety. Because leaders' actions are highly scrutinized in times of challenge and change, it is vitally important that they understand the impact of their words and actions; this will help ensure that the right messages cascade throughout the organization.

Leaders regularly provide sufficient support and coaching to line workers to help them improve quality.

Leader visibility is essential to a positive culture. Leaders who interact effectively with all levels of the organization can influence employee mindset and attitudes about the importance of quality. Leaders who employ both formal and informal communication can gain more exposure and reach different organization levels more effectively.

Leaders always model the desired behavior of "doing the right thing" on issues of quality.

Because their behavior helps shape the thoughts and actions of other employees, leaders must model the principles, values, and vision desired by the company; personalizing the overall message with their own leadership style will increase credibility.

1.3 Shaping Excellence Interviews

The L&V Subteam developed a simple research concept to explore best practice leader-led behavior: Through one-on-one conversational and informal Shaping Excellence interviews, 19 respected industry leaders shared important actions and behaviors by which they shape quality culture ([Appendix 2](#)).

These leaders represented various industry sectors, geographical regions, and executive levels (vice president, global head, senior director). Collectively, they contributed hundreds of years of shared experience. These interviews provided substantial insight into their thoughts and perspectives, producing a data set that includes over 18 hours of audio and more than 125 transcript pages.



1.4 Leader 5V Model

Using the Shaping Excellence interviews, the L&V Subteam developed a model of holistic leadership called the Leader 5V Model (Figure 1-1).

Figure 1-1: Leader 5V model



The five categories are:

Values: Guiding principles, ethical conduct and expectations, humility, empathy, patient focus

Vision: Strategy, unifying goals, game plan, company mantra or credo, desired state

Voice: Passion, credibility, authenticity, clarity, ability to articulate the vision, ability to inspire and motivate others

Visibility: Being present, priorities, responses, and reactions

Vigilance: Accountability, determination, grit, focus, discipline, follow-through



1.4.1 Values

Quality is often described as “doing the right thing when no one is looking.” A leader’s integrity and demonstrated drive to “do good” and “do right” are powerful, positive influences on quality culture.

Soft skills such as humility, empathy, and the ability to listen are connected to higher levels of employee engagement, which is an enabler of positive culture. Leaders must model company-desired behaviors and “walk the talk” as it relates to quality standards.

Courage is an important part of walking the talk, especially when tough decisions need to be made. It takes courage to innovate, push continuous improvement efforts, challenge employees, and break old paradigms.

Leaders can also promote an environment that is open to change, one in which ideas to improve site quality are welcome and employees are not afraid to voice quality concerns. Many leaders’ companies provide anonymous phone lines that allow employees to share confidential concerns of quality, safety, or other topics. In addition, most leaders asserted that their companies have “speak-up” cultures (viewed as ideal for enabling cultural excellence) in which employees feel comfortable sharing their concerns. Some acknowledged, however, there is danger in assuming that a speak-up culture is in place without also verifying it through employee feedback, site metrics, and performance results.

1.4.2 Vision

As mentioned earlier, an organization’s vision, one that includes importance of quality, is an important and powerful tool to developing a strong operational culture.

Best practices identified during the Shaping Excellence interviews related to vision include:

- Keep the vision consistent; frequently shifting messages lead to confusion within the organization.
- Have the determination to ride the cycle of change, even though there will always be those that are resistant or see no reason for it. Celebrate gains and work through the setbacks.
- Seek ways to share the vision often within the organization; the right message cannot be overcommunicated.
- Make the company’s quality vision readily available and ensure that it is communicated by all leaders to all employees.

1.4.3 Voice

When a leader articulates a vision, his/her voice and body language must be viewed as trustworthy. If the leader does not support the stated vision, it can communicate a contradictory message. The leader must speak authentically to influence the desired behavior most effectively.



1.4.4 Visibility

Quality culture scores related to leadership* were discussed in the “ISPE Quality Metrics Initiative: Pilot Program Wave 2 Report.” These scores showed the highest correlation to external quality outcomes and emphasized the importance of leader presence, both on the shop floor and within the organization. [1]

Most companies conduct some level of Gemba activity on the shop floor. The leaders themselves often participate in site walk-throughs, which provide an opportunity to interact with employees, front-line supervisors, and area leaders. Gemba was most commonly viewed as continuous improvement; employee engagement, creating a “listening post” between employees and management, leadership visibility, and evaluating the site’s fit-for-purpose status are additional considerations.

It is common among leaders to hold quality-based discussions. These can be formal (town halls, standing management review meetings, or corporate quality updates) or informal (employee-management round tables, one-on-one meetings with leaders, or plant Gemba walk-throughs). Both types of meetings give leaders an opportunity to talk about quality and allow employees to ask questions. These sessions also allow leaders to listen to quality concerns, issues, and ideas from within the organization.

1.4.5 Vigilance

Vigilance is needed to stay the course, put in the hard work, and endure the ups and downs of a corporate journey of cultural improvement. Remaining consistent to the quality vision is essential.

Leaders must vigilantly monitor and display key performance metrics to hold the organization accountable to continuous improvement goals. If you don’t measure it, you can’t improve it, so understanding the key metrics that drive quality improvement is critical.

Leader best practices include the use of site scorecards, risk assessment heat maps, and regular management overview meetings in which quality metrics are reviewed and discussed, often across various operating sites and multiple functional areas.

LQIs most commonly measured were:

- Measurements of process robustness (process capability)
- Corrective and preventive action (CAPA) effectiveness
- CAPA ratio of proactive to reactive actions
- Preventive maintenance
- Internal audit findings and their risk criticality
- Total cost of quality, as measured as the ratio of prevention vs. remediation cost

* Coaching, daily dialogue, and management presence on the shop floor



Other considerations for LQIs include measures of organizational learning such as the number of green belt and yellow belt certified employees/candidates or other training-related, learning-based metrics. Enabling a learning organization, one in which employees are encouraged to share mistakes and knowledge gained with others, can be a strong enabler of positive quality culture.

Most leaders acknowledged, however, that they are most responsive to lagging quality indicators related to the severity of nonconformances, consumer complaints, recalls, or adverse events. Many indicated a desire to move their organizations toward LQIs for greater review and discussion.

Vigilance also involves monitoring down-line leaders and the entire organization to assess and reassess the state of the culture. A commonly used tool is the employee engagement survey, usually conducted every one to two years. This allows employees to share confidential feedback on the organization and leadership. Leaders suggested that conducting this survey over multiple years to see trends is of most value in “reading” for culture or improvement.

1.5 Leader Self-Assessment Tools

Leaders must consistently monitor the organization and its employees for information that can drive remediation or improvement. And they should invest in their own development as well to evaluate their effectiveness and determine areas in which they can improve as leaders.

Table 1-A shows a concept for assessing leadership teams and improving quality culture within a site or work group. It is intended to inspire future research into tools and methods for assessing leadership team effectiveness, or to aid in the creation of a site-specific tool to focus on unique factors or elements relevant for a particular company.



Table 1-A: Team Leadership Assessment Tool

SAMPLE ASSESSMENT AREAS	DEVELOPING Potential for coaching or mitigation	EXPERIENCED Continue to learn and improve	MATURE Leaders can teach and mentor others
Experience level, majority of team	0 to 1.5 years in same or similar level of responsibility	1.5 to 5 years in same or similar level of responsibility	> 5 years in same or similar level of responsibility
Employee turnover	High department turnover (> 60% in last 5 years); lost key personnel or intellectual property	Moderate department turnover (< 60%) in last 5 years	Longstanding staff; employees lost only to promotion or new internal opportunity
Environment for change	Rapidly changing environment; changes are addressed reactively	Changes are addressed reactively and proactively	Stable environment; few changes occur or are anticipated; future changes are anticipated and responses are planned
External regulatory forces	High regulatory risk; significant or escalated regulatory actions	Moderate regulatory risk; escalated deviations or complaints	Low regulatory risk; standing trend of good regulatory inspections, lack of escalated regulatory actions
Recurring deviations/ quality issues	High recurrence rate (> 60% repeat issues); true root cause not found or addressed	Moderate recurrence rate (20%–60%); issues may or may not be addressed and true root cause may or may not be found	Low recurrence rate (< 20%); root cause is found and addressed
Speak-up culture	Employees do not speak up in meetings or provide significant input into improvements or problems	Employees occasionally provide input into improvements or problems	Issue solutions come from the floor; feedback mechanisms exist and are used by employees
Learning organization	Problems and solutions are not shared with staff or discussed for learning; coaching and training are weak	Training programs are mature but day-to-day learning or process knowledge could be shared more broadly	Technical information is well understood by most who have access to process-relevant information (e.g., critical process parameters); problems are shared broadly as opportunities to learn, improve, and prevent recurrence



1.6 Summary

Individual leader actions and behaviors clearly contribute to site and company culture. There are commonalities among industry leaders related to behavior, actions, and traits that facilitate employee engagement, attainment of site goals, and a corporate culture of excellence.

Leaders can:

- Share a vision about the importance of quality frequently and broadly within the organization
- Demonstrate decision-making and behaviors that align with the company's stated quality vision
- Value excellence above focus on regulatory compliance alone
- Shape employee experiences and mindset through formal and informal quality discussions where site metrics are reviewed and quality issues can be raised
- Establish Gemba walks as a best practice activity for the shop floor, laboratories, and other functional areas; consider Gemba guidelines or checklists to aid the walk-through
- Develop key site metrics, implement leading quality metrics, and monitor proactive measurements to drive continuous improvement
- Provide organization-wide structural enablers to support improvement and inspire an environment of continual learning
- Challenge the organization to drive for excellence and create a culture in which patients and employees benefit

The [Cultural Enablers](#) chapter discusses leader tools that can further shape employee attitudes about quality and executional excellence:

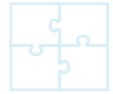
- Situational leadership
- Coaching and mentoring for culture
- Strategic deployment
- Top-down goal alignment
- Hiring and onboarding
- Enabling a learning organization

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2 Mindset and Attitudes

2.1 Introduction

Mindset and attitudes play an important role in driving cultural performance, although they can be difficult to define, observe, and measure. The purpose of this section is to raise awareness of the need to assess, monitor, and shape mindset and attitudes within the organization to improve and sustain cultural performance. The Mindset and Attitudes Subteam has researched this topic and assessed feedback from industry colleagues to provide the following insights on shaping cultural excellence.

The following definitions will be used within this report:

- **Culture:** A way of thinking, behaving, or working that exists in a place or organization
- **Mindset:** An established set of attitudes
- **Attitude:** A settled way of thinking or feeling about something
- **Behavior:** The way in which something or someone functions

2.2 Behavioral Criteria and Improvement Actions

The following behavioral criteria from the ISPE Cultural Excellence Assessment Tool ([Appendix 1](#)) are recommended to assess, monitor, and shape cultural excellence mindset and attitudes. Possible improvement actions are also provided.

2.2.1 Accountability

Employees consistently see quality and compliance as their personal responsibilities.

Establishing clear individual accountability for quality and compliance is a foundational step in helping shape quality mindset and cultural excellence. Accountability should be communicated consistently through job descriptions, onboarding, current good manufacturing practice (cGMP) training, and performance goals, and be supported by coaching, capability development programs, rewards, and recognition. Leaders should hold themselves and others accountable for performing to quality and compliance standards.



2.2.2 Ownership

Employees have sufficient authority to make decisions and feel trusted to do their jobs well.

Individual ownership of quality and compliance is a primary driver for shaping quality mindset. When individuals are fully engaged, empowered, and taking action to improve product quality, organizations typically benefit from continuous improvement and faster decision-making.

2.2.3 Action orientation

Employees regularly identify issues and intervene to minimize potential negative effects on quality and compliance.

Establishing the expectation that individuals demonstrate action orientation helps shape quality mindset and foster cultural excellence. Leaders should promote and leverage proactive efforts (e.g., risk assessments, Gemba walks, employee suggestions) to reinforce support for the desired behavior. Additionally, it is important that rewards and recognition be aligned to support proactive efforts, rather than reactive fire-fighting efforts.

2.2.4 Speak up

Employees are not afraid to speak up, identify quality issues, or challenge the status quo for improved quality; they believe management will act on their suggestions.

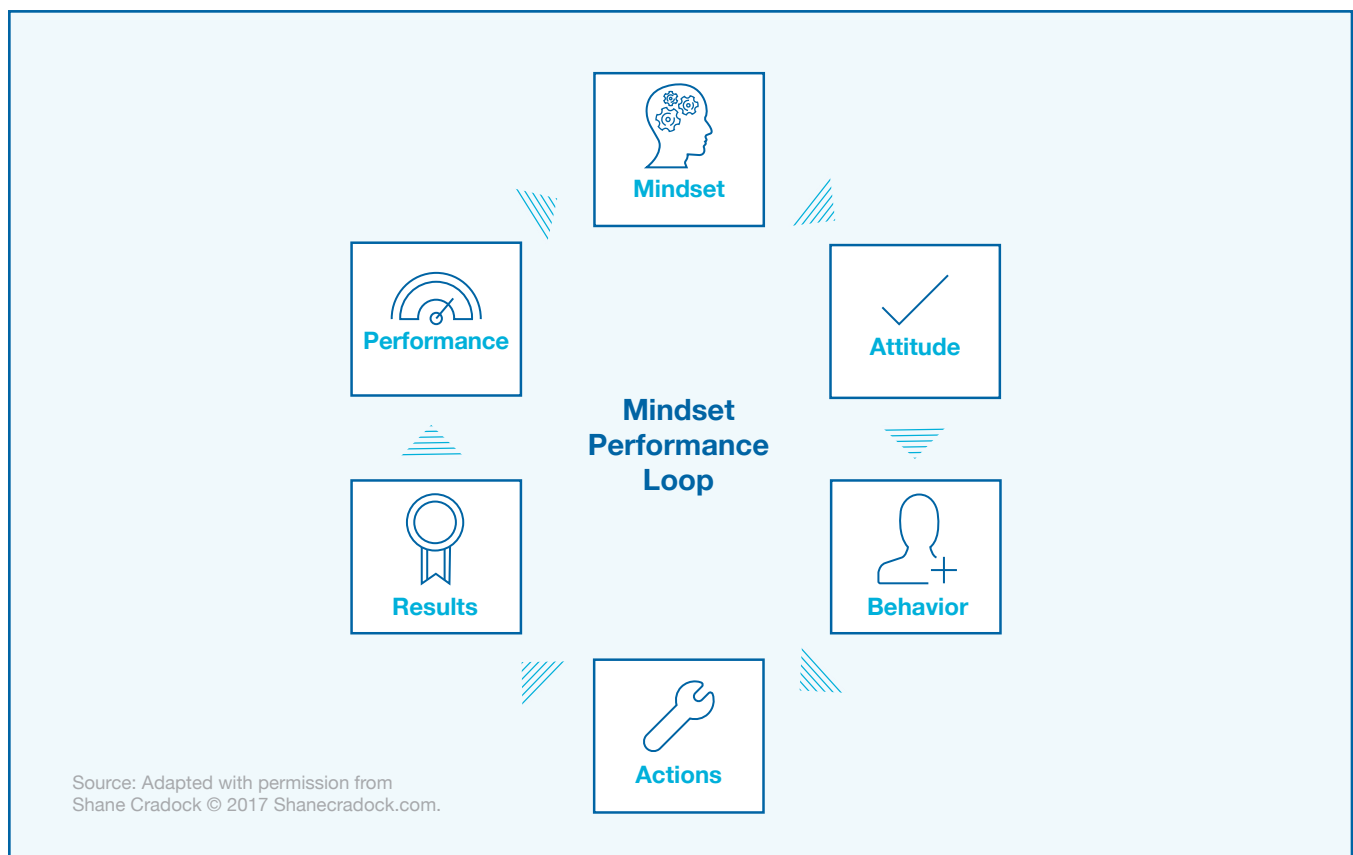
Empowering individuals to speak up and raise quality issues helps foster quality mindset. Leaders should support this by modeling the desired behavior, building trust, and creating an environment in which individuals feel comfortable raising quality issues, engaging front-line personnel in problem solving, and involving employees in continuous-improvement activities.



2.3 Mindset Performance Loop

A company's ability to monitor and shape mindset and attitudes can greatly increase results and performance. Figure 2-1 shows the process in which mindset influences attitudes, which influence behaviors, which influence actions, which influence results, which influence performance. This becomes a continuous-improvement loop as new results and performance further inform mindset.

Figure 2-1: The Mindset Performance Loop



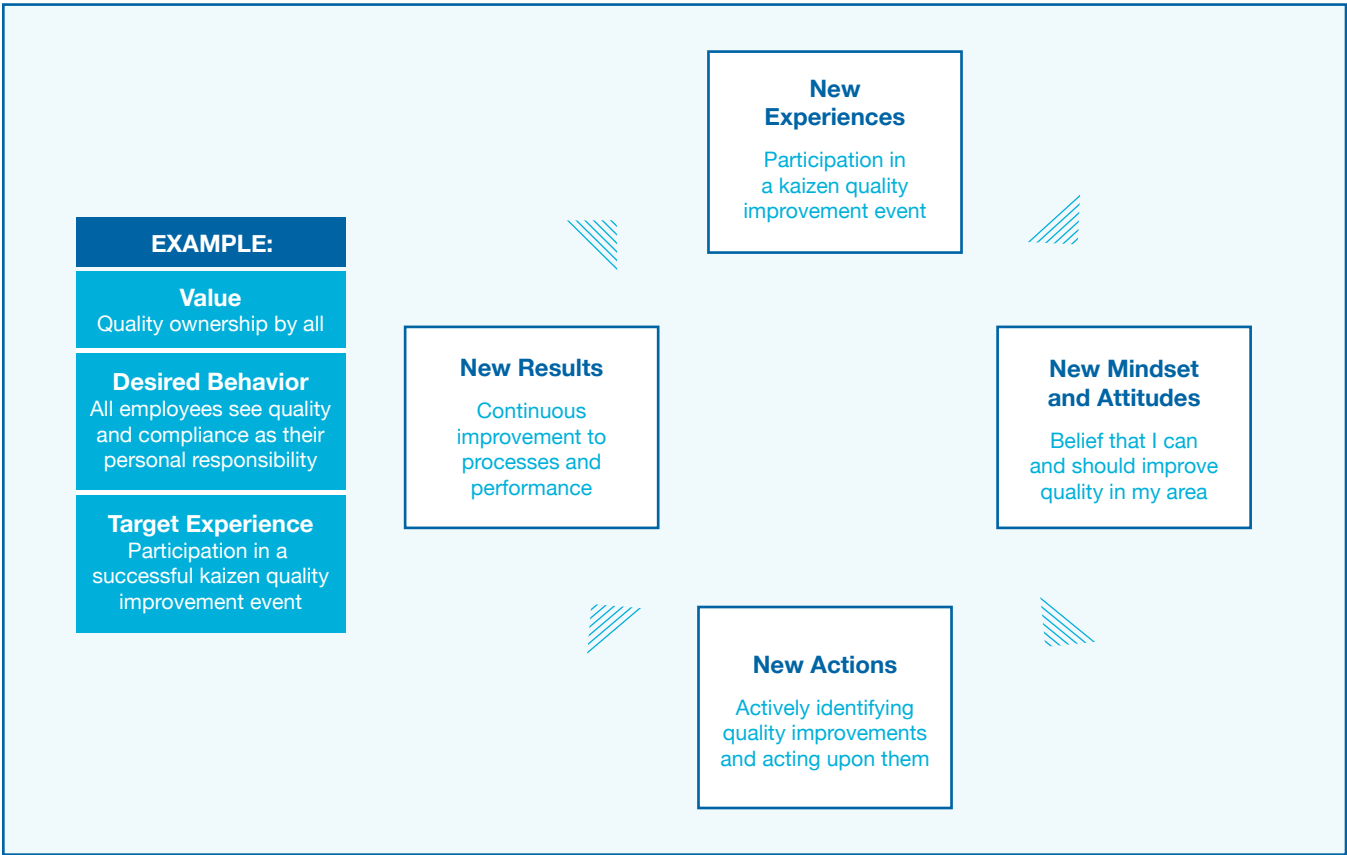


2.4 Experience-Based Approach

The ISPE Mindset and Attitudes Subteam determined that by understanding how mindset and attitudes can affect performance, managers can help shape them through targeted learning experiences. Much adult learning is based on experience and practical application. Managers can use this approach to give members of their organizations new learning experiences that can positively shift mindset and attitudes.

Figure 2-2 demonstrates how quality mindset can be shaped using experience-based learning. New positive learning experiences generate new positive mindset and attitudes, which generate new actions, which generate new results, which generate new learning experiences, and so on.

Figure 2-2: Shaping quality mindset: Experience-based approach



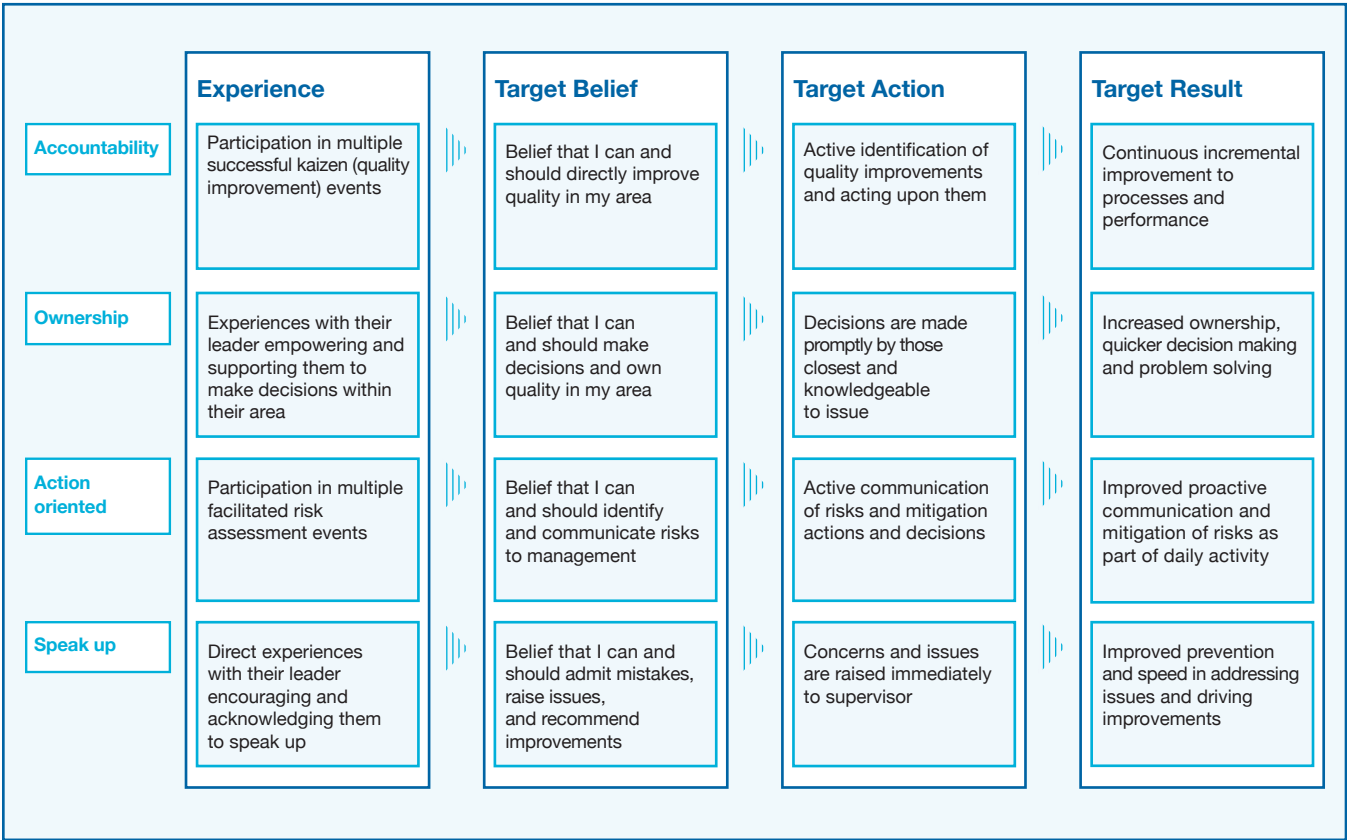
In Lean methodology, companies often use kaizen* events to enable a continuous-improvement culture. A successful kaizen event can positively change the mindset and attitudes of individuals that experience the event directly. These targeted learning experiences have become transformational levers to shift mindset and attitudes from non-quality thinking to a culture of quality continuous improvement.

* Kaizen (change for better): the practice of continuous improvement; industrial or business techniques for implementing continuous improvement; “kaizen events” are short-duration projects with a specific aim for improvement.



Because negative experiences can hinder efforts to improve cultural performance, we recommend that you provide positive and generative experiences when conducting this type of targeted mindset-and-attitudes-shift work. Figure 2-3 lists experience-based examples that can help shape mindset and attitudes, emphasizing targeted, positive experiences.

Figure 2-3: Shaping quality mindset: Experience-based examples



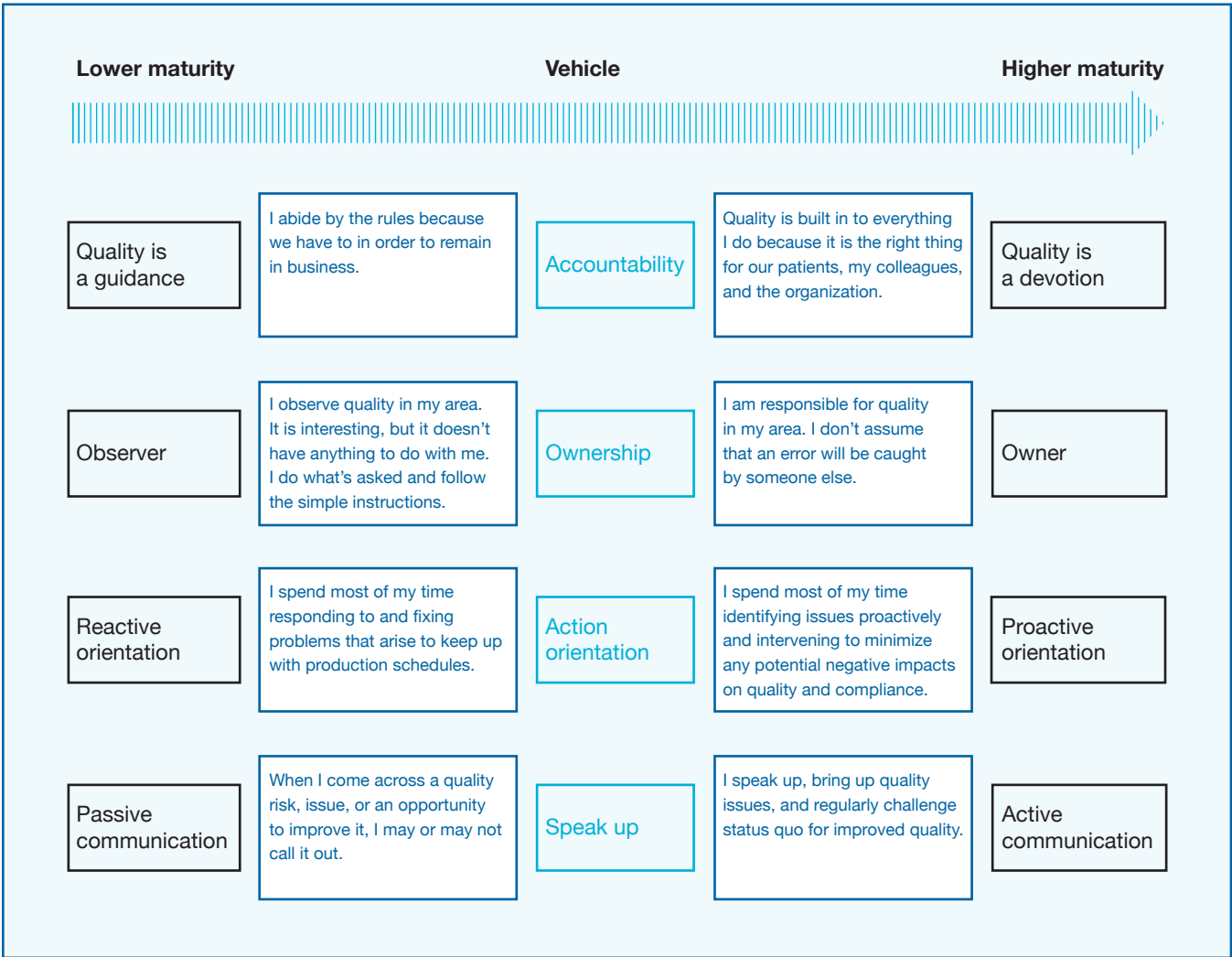


2.5 Mindset Shifts

Management awareness of mindset and attitudes combined with an understanding of their effect on behavior, results, and performance can increase an organization’s capability to improve cultural performance.

Figure 2-4 shows examples of poor (lower maturity) and good (higher maturity) behavioral performance, and indicates vehicles that can shift mindset and attitudes. These examples can be used to facilitate dialogue on and evaluation of desired mindset and attitudes. The higher maturity example provides a desired behavioral target, which can help speed the shift of mindset and attitudes within an organization.

Figure 2-4: Shaping cultural excellence: Mindset shift examples





2.6 Summary

Mindset and attitudes affect performance and culture. Although not easily observed, they can be better understood by monitoring behaviors and actions. Cultural excellence is not a project, but an ongoing commitment by leaders and individuals to model desired behaviors and hold others accountable to behavioral standards.

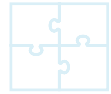
Making behavioral changes within an organization takes time and commitment. Effective change management practices can help improve the velocity of change adoption. Leaders should establish a vision and a well-laid-out plan that helps employees understand where they are going and why, coupled with measuring progress or feedback against the plan.

Leaders can influence mindset and attitudes by:

- Clarifying behavioral expectations for employees
- Monitoring behavioral performance
- Providing positive cultural learning experiences to reinforce desired behavioral expectations
- Assessing cultural performance to address gaps

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3 Gemba

The Japanese term *Gemba* means “actual place.” Jim Womack, author of *Gemba Walks*, expands this definition to call Gemba the place in an organization “where humans create value.” [1] Gemba is a well-defined element of Lean concepts and, as such, an accepted operational excellence tool in industries that have adopted Lean principles. The well-known Toyota production system has used Gemba walks for decades. Within the pharmaceutical industry, however, the concept of Gemba has not yet been widely implemented.

The concept is strikingly simple. Womack, the guru of Gemba walks, describes it as: “I just take walks, comment on what I see and give courage to people to try.” [1] In the pharmaceutical industry, however, you may hear complaints that supervisors, let alone management, rarely have time to go out on the shop floor or into the laboratories where they could interact with employees and observe what is really going on.

Gemba walks demonstrate visible commitment from the leadership to all members of the organization. They allow site leadership to spread clear messages using open and honest dialogue and get a real indication of the progress of behavioral change at all levels. They empower employees because their contributions to site results are recognized and their ideas for continuous improvements heard.

3.1 Gemba Walk Best Practices

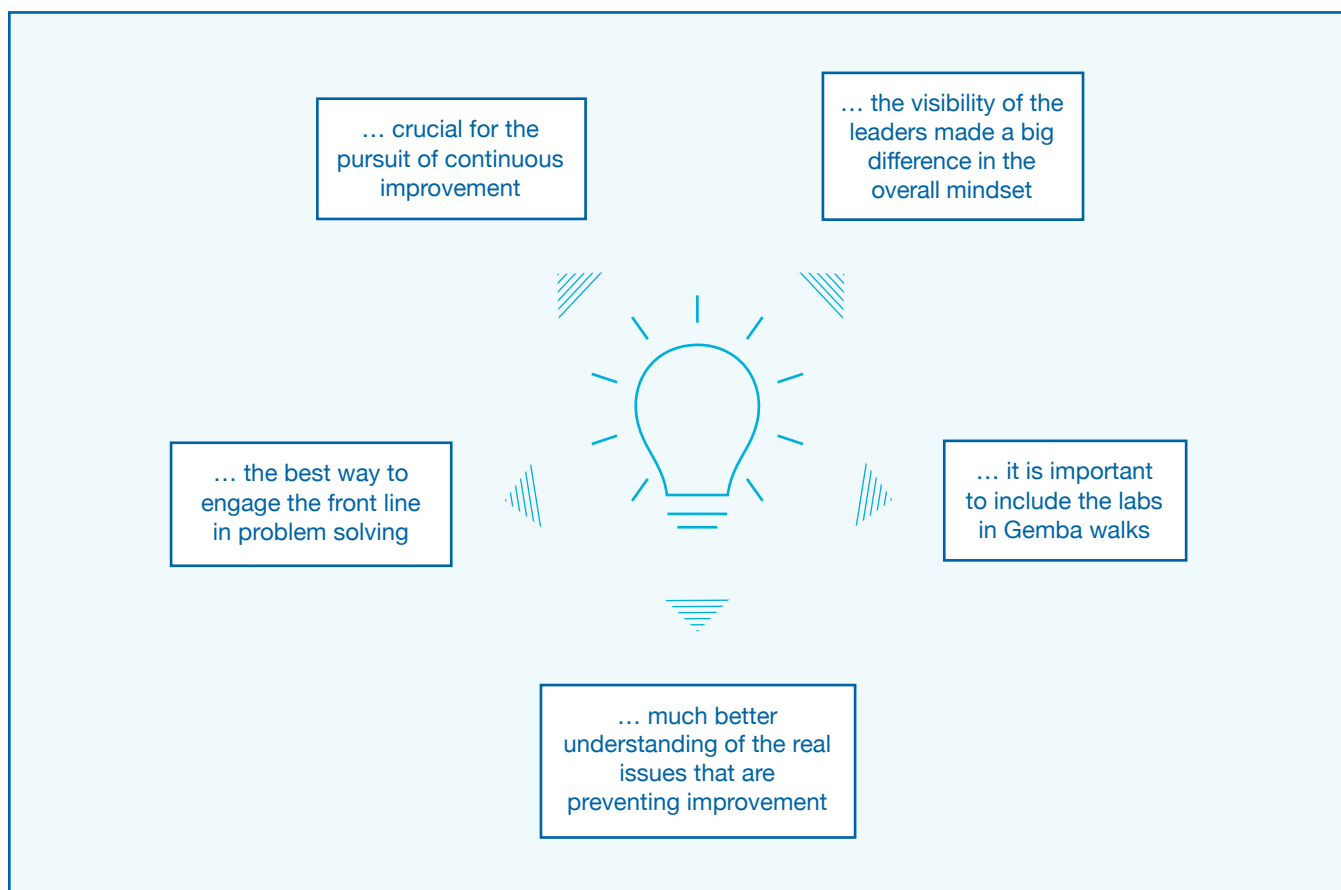
Following an extensive review of practices in this area, it is the view of the Gemba Walks Subteam that Gemba walks should replace, or at least substantially reduce, traditional conference-style meetings and hence minimize the production of the many charts and reports created, just for such meetings, to communicate progress related to shop floor activities. Because Gemba walks facilitate stand-up style meetings on the shop floor or in the lab, they tend to be much shorter and more efficient than the typical conference-room presentations. Furthermore, decisions are often made more quickly because all participants have all the necessary information right in front of them.

The Gemba Walks Subteam reviewed a wide range of practices from other industries and from published examples [2] as well as experience from ISPE members. The subteam has been ambitious in defining “best” practices, confident, based on the evidence, that the approach has worked well in all manufacturing industries; there is no reason it cannot be used in the pharmaceutical industry.



The confidence was confirmed by listening also to leaders' voices from the L&V Subteam's "Shaping Excellence" interviews. These validated our thinking that once Gemba walks are implemented, the organization quickly recognizes their benefits (Figure 3-1).

Figure 3-1: Feedback from "Shaping Excellence" interviews





3.1.1 What a Gemba walk is and what it is not

Our starting point in outlining these Gemba best practices is to define what a Gemba walk is and what it is not, within the context of the pharmaceutical industry (Table 3-A). Understanding these distinctions is a key success factor for your Gemba program.

The most significant difference is to make the mental shift from asking “Who did it?” to “Why is this happening?” to really extract valuable existing knowledge from people on the floor. This will only happen in an atmosphere where employees feel safe to speak up and share their observations and proposals freely.

Table 3-A: Gemba walks

A GEMBA WALK IS ...	A GEMBA WALK IS NOT ...
• An enabler for cultural change in management style and philosophy • A role-modelling opportunity for leaders • A way to empower operators and analysts • An enabler for continuous improvement through problem solving on the shop floor with the people who experience them • An opportunity to find the root cause of issues, spot waste and quality risks, and for leaders to remove obstacles • A coaching/mentoring opportunity to build and/or enhance capabilities and behaviors and recognize and reinforce desired behaviors • An enabler for communication of site priorities/challenges and how the unit’s performance contributes to the overall success of the site • An opportunity to learn from the shop floor, foster; encourages informed decision making for leaders • An opportunity for the operators to show their pride and excellence in their jobs	• An audit (neither quality/compliance nor environmental health and safety) • A general complaint/venting session • A debate to defend individual viewpoints without facts • A troubleshooting exercise in which participants focus exclusively on areas with (technical) issues

3.1.2 How to implement and execute Gemba walks

Our examination of successful programs showed that before implementing Gemba walks it pays to communicate both the purpose and overall approach to all levels of the organization by explaining the why, the who, and the when.

Training of the Gemba walkers by practicing a few Gemba walks should be considered in the implementation phase to ensure that Gemba walks are effective and provide value to the organization from the beginning. This training can be supported by tools such as a set of prompts or questions that help start the dialogue on the shop floor, in the warehouse, or the labs. An example of such questions is provided in Table 3-B. It is also useful to provide Gemba walkers with layout plans and to create checklists of what to look for.



Table 3-B: Example of Gemba walk pocket guide

GEMBA GUIDE (A) LEADER SELF-ASK QUESTIONS	GEMBA GUIDE (B) LEADER COACHING QUESTIONS
1. What is the process? Look for: Steps that add value, flow between steps, standardization of tasks	1. What is the standard? Hopefully it will be clear at a visual glance. Helps check understanding of the standard.
2. What is normal/abnormal? Look for: Standard work, expected state, variation to the expected state	2. How do we develop a standard? Used where a standard is ambiguous or lacking.
3. What is working well? Look for: Standards being followed, ideas being generated, lessons shared	3. How clear is the standard to those doing the work? Reveal the depth to which standards have been put to use.
4. What is not being followed? Look for: Checklists not populated, equipment in poor condition, poor housekeeping, variation to standard work	4. How clear is the standard to those not doing the work? Leaders should require that they can understand the status of safety, quality, and on-time output in less than five seconds each.
5. What is broken? Look for: Equipment requiring repair, safety hazards, status of line clearance controls	5. How well are we performing against the standard? The variation in responses can reveal a lot about how well people understand their standards.
6. What is not understood? Look for: Variation to standard, poorly constructed procedures, understanding of team priorities	6. Why are we not performing to the standard? This is a golden opportunity for a leader to practice the five why questioning. Fight the urge to give the answer!
7. What is creating waste? Look for: Any forms of waste—transport, inventory, motion, waiting, overproduction, overprocessing, defects	7. What can we do to improve the current condition? This question can be used as a catch-all in any situation, any condition, any Gemba.
8. What is creating strain? Look for: Poor workstation design, inadequate environmental and/or ergonomic design factors, overburdening of activities	8. How can we make the abnormal condition more immediately visual? Often the reason problems persist is because they go undetected.
9. What is creating unevenness? Look for: Uneven production schedules, variation in staffing levels, process interruptions	9. Why do you think I asked you these questions? The true learning happens when people practice for themselves how to look at and assess their process through a different lens.
10. What is not visible enough? Look for: Signals to problems, performance indicators, management presence, communication of team priorities, standards	10. What other questions would you have liked me to have asked? The main use of this question is for the leader's learning.