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Cultural Excellence Report

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April 2017

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The *ISPE Cultural Excellence Report* shares insights on quality culture improvements across six 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.

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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.

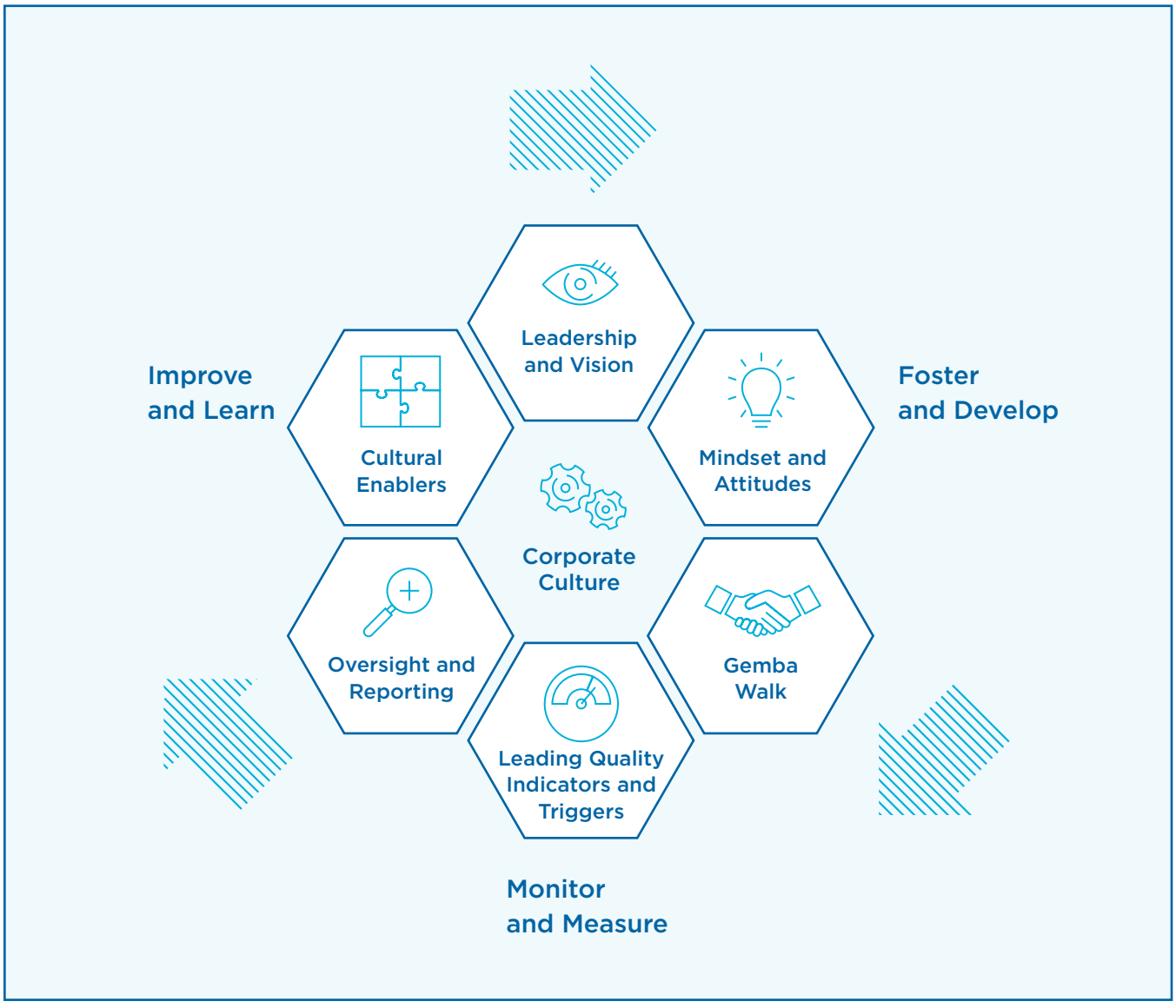
* Speaking at the April 2015 conference, Woodcock also noted that "fear of reporting problems internally within an organization and fear of negative repercussions from reporting them to the agency drives behaviors that are not just nonproductive, but anti-productive."

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

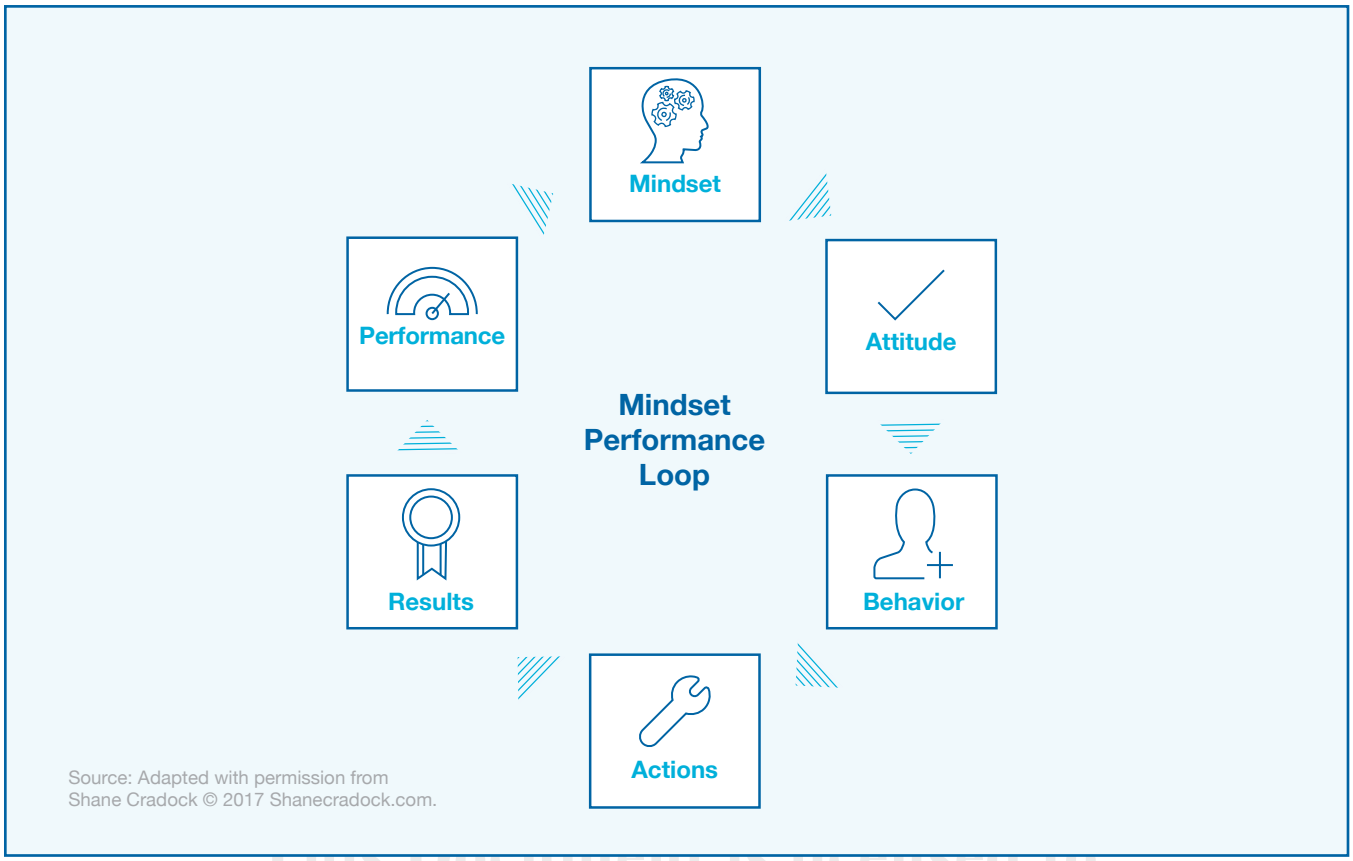
Employees are not afraid to speak up, identify quality issues, or challenge the status quo for improved quality; they believe management will act on their suggestions.

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



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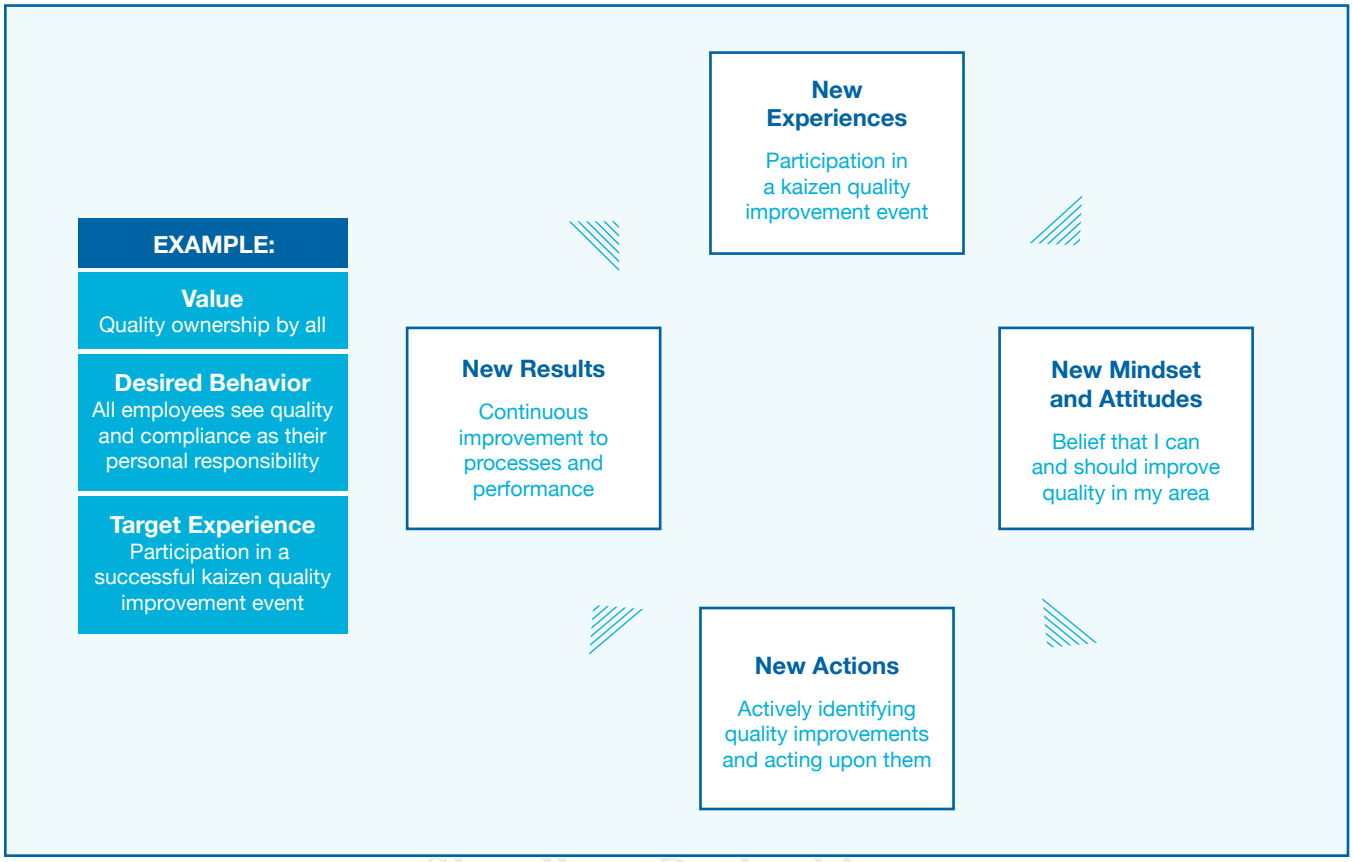
2.4 Experience-Based Approach

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

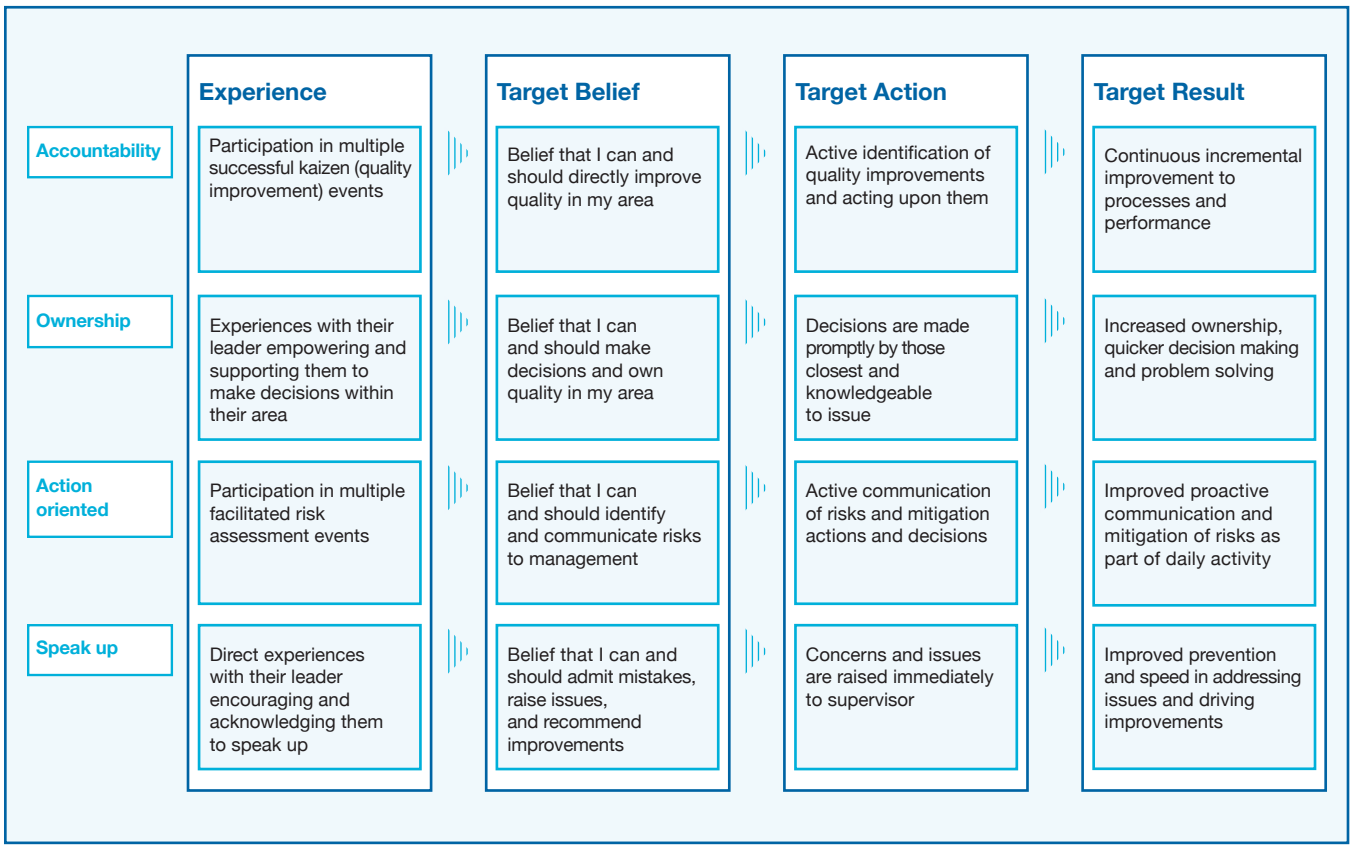


In Lean methodology, companies often use kaizen* events to enable a continuous-improvement culture. A successful kaizen event can positively change the mindset and attitudes of individuals that experience the event directly. These targeted learning experiences have become transformational levers to shift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

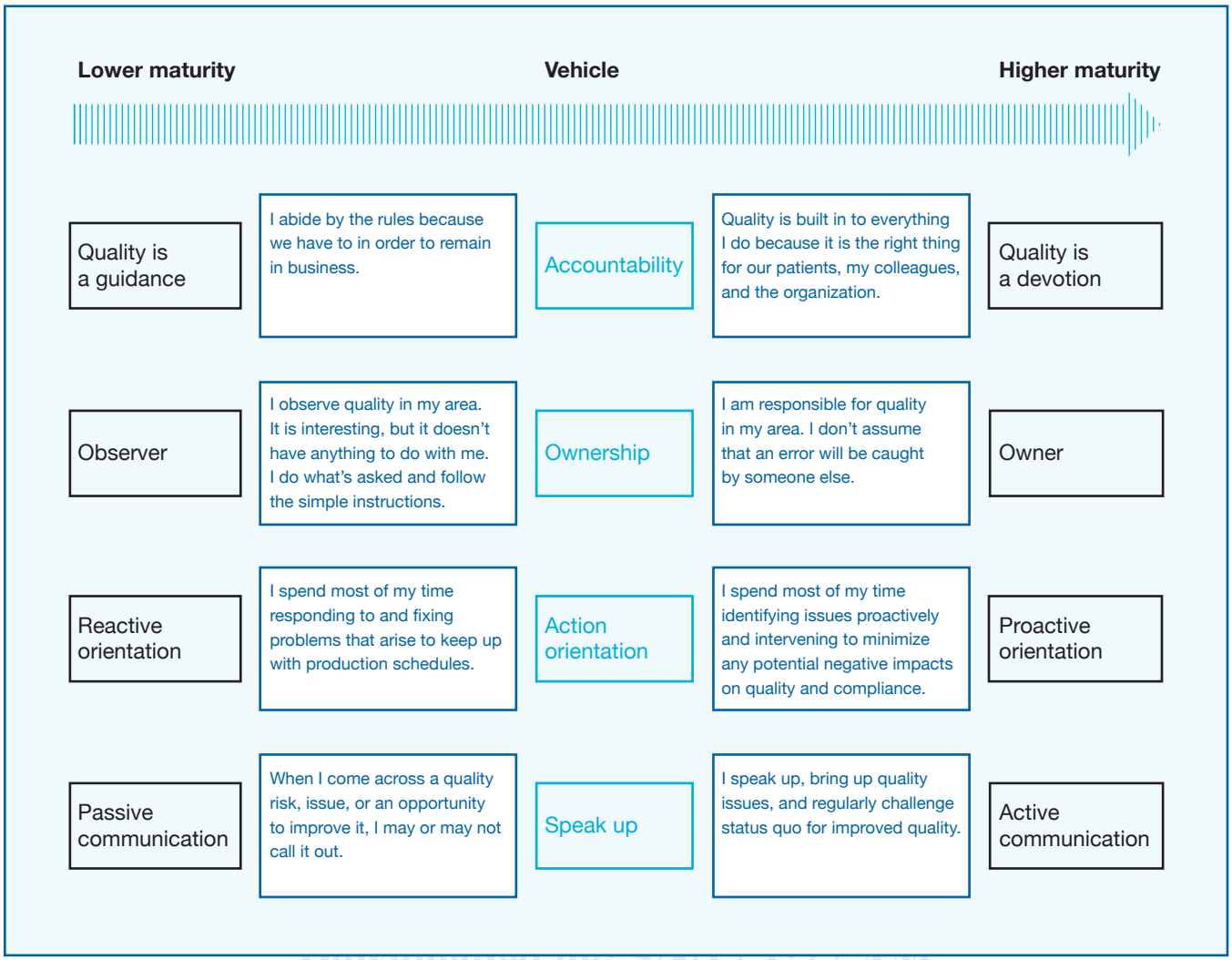


2.5 Mindset Shifts

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.

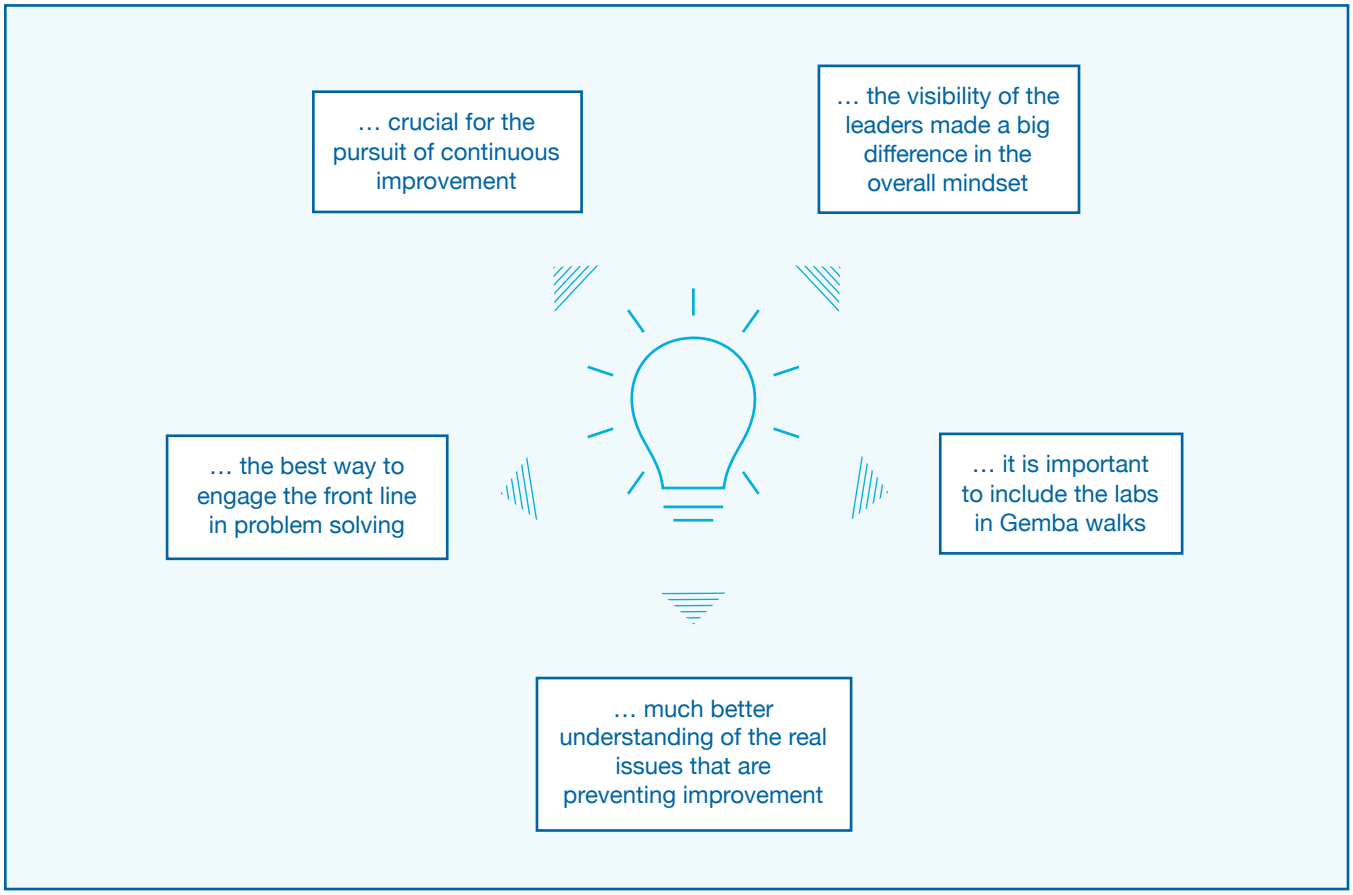
3.1 Gemba Walk Best Practices

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.

It cannot be emphasized enough how crucial it is to create a positive atmosphere during a Gemba walk to make people feel at ease as much as possible. You will still most likely experience some initial shyness from employees in bringing up really sticky points, especially if the culture of the site has previously not rewarded this behavior, but do not let this discourage you from continuing.

- Make the mental shift of asking “Why is this happening?” instead of “Who did it?” to extract valuable existing knowledge from people on the floor.
- Make your Gemba walks about recognition, not auditing, by adopting the simple but important rule of “4 to 1”: Express four recognitions for every action identified.
- It is also critical to create a Gemba walk schedule that covers all area to be visited. Best practice recommends creating an annual schedule so that the walks are a priority on everyone´s itineraries.
- Consider, especially in the beginning, implementing a metric to measure participation and adherence to schedules; once Gemba walks have been ingrained in the site culture, such a metric may be modified to measure the effectiveness of Gemba walks, by measuring the number of completed improvements, for example.

3.1.3 Frequency recommendations

Within the automotive industry, an often-cited benchmark goal for manager time spent on the shop floor is 60%. We recognize that many pharmaceutical manufacturing sites are still a far cry from this target; nevertheless, we have included it within our best practice recommendations for Gemba walk frequencies. These schedule recommendations (Table 3-C) may initially represent a stretch goal, but in our opinion they are manageable in the longer term.

Table 3-C: Recommended frequency for Gemba walks

GEMBA WALKERS	BEST PRACTICE FREQUENCY	MINIMUM RECOMMENDED FREQUENCY
First line supervisors	Each shift, multiple times	Each shift
• Team leaders of individual units in manufacturing/packaging • Quality Culture team leaders in different labs (e.g., raw materials, spectroscopy)	Daily covering different shifts	2 per week
• Head of manufacturing for manufacturing area • Head of packaging for packaging areas • Head of quality control for labs	1 per day	1 per week
Site leadership team	1 per day	1 per month
• Site internal customers • Manufacturing/packaging supervisors • Lab managers • Supply chain team leaders • Manufacturing/packaging and lab managers • Lab supervisors • Manufacturing/packaging team leaders	1 per quarter	1 per year
Site support (e.g., human resources, finance)	2 per year	1 per year

Naturally, the biggest impact for the organization will come from a program of regular Gemba walks by supervisors, team leaders, and site leadership. This level of visibility is absolutely fundamental for success as employees appreciate seeing their supervisors and managers making decisions on the floor.

You may be surprised to learn that we also recommend Gemba walks for internal customers (e.g., purchasing, supply chain planners) and site support functions (e.g., human resources, finance). We believe that both the visited areas and the Gemba walkers benefit significantly from the insights and discussions generated during these walks. Operators and lab analysts gain insight into the bigger picture of the site performance, such as the expectations of external customers that the other functions must address, and internal customers start to understand some of the constraints, real or perceived, that the visited areas may be challenged with.

Indeed, we repeatedly heard that some of the quick wins when implementing Gemba walks were observed from involving internal customers (including planners or raw materials buyers) in Gemba walks at labs or on the shop floor. Gaining an understanding of how current established practices can affect the work downstream often led to a quick removal of the obstacles, resulting in enhanced performance. Communication breakdowns between functions could also be identified and resolved earlier.

We saw again and again how developing a better understanding of current working processes led to a quick resolution of some major pain points. On the positive side, moreover, going to the "real place" provided an excellent opportunity to recognize contributions and achievements of individuals or teams in person.

As a general principle, Gemba walks should be conducted at varying times during the workday and at every shift to get maximum exposure to shop floor and laboratory. Site management showing up during the late shift in the lab or the early morning shift provides an excellent opportunity to show respect to all personnel and at the same time to understand how practices might differ from one shift to another. Other good Gemba walking times are during shift huddles and mid-morning and mid-afternoon, when initial start-up activities are over.

3.1.4 Identifying and following up on improvement actions

As the key purpose of Gemba is to identify continuous improvement opportunities, it is critical to record commitments and agreed actions. One of the easiest ways to do this is to display agreed actions on visual boards in the area. These can either be manual or electronic—whatever works best for the site. The record should reflect the agreed action, the responsible person(s), and due dates. Progress or closure should then be reviewed at following Gemba walks. For longer term actions, the responsible person should provide updates or status reports. An example of how the recording could be organized is provided in Table 3-D.

Remember, however, that compliance-related actions identified during the Gemba walk must be tracked via the site's deviation/corrective action and preventive action (CAPA) system. Similarly, if an agreed action affects good manufacturing practices (GMP) processes or systems, formal site change control must be initiated.

Table 3-D: Example of a Gemba walk action tracker

DATE	ACTION	STAKEHOLDER	OWNER	TARGET DATE	STATUS	COMMENTS

3.2 Gemba Case Study and Lessons Learned

For further illustration of some of the key principles and learnings from real-life implementations of Gemba, the Gemba Walks Subteam has also developed a case study from a global pharmaceutical manufacturing site (Appendix 3) and a summary of the lessons learned from implementing Gemba in labs. We hope that these encourage more manufacturing sites to implement Gemba walks in their quest for a culture of excellence.

3.3 Summary

Gemba is a key concept to enhance the culture of excellence of a site by creating visible management commitment and engaging employees at all levels of the organization. Gemba walks enhance communication of priorities, objectives, and desired behaviors, and foster dialogue and understanding between management and employees. They also provide the opportunity to engage internal customers in the Gemba walks, to allow both sides to better understand the drivers and restrictions in the daily work, and to see the bigger picture in an organization.

Implementing Gemba walks as an isolated tool is certainly not enough to drive cultural change; it does, however, offer the most immediate and direct intervention that a site can implement and hence the boldest move to make a visible cultural change.

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Special thanks go to Jim Powers, Bridge Associates International LLC, for sharing his insights and the lessons learned from many years of implementing Gemba in laboratories of pharmaceutical and consumer health care manufacturing sites.

4 Leading Quality Indicators and Triggers

4.1 Understanding Behavior as a Derivative of Culture

One of the world's leading authorities on organizational culture and leadership, Edgar H. Schein defines culture as "how we perceive, think about, and feel about things." Schein links behavior to culture by indicating that behavior is a *derivative* of the prevailing organizational culture. This link provides a concrete means to understand and interpret the powerful force that culture exerts on day-to-day operations within organizations, and offers a focus for action for those within the pharmaceutical industry seeking to improve their quality culture.

> Culture as a concept is an abstraction, but its behavioral and attitudinal consequences are very concrete indeed.
>
> —Edgar H. Schein [6]

Viewing the relationship between culture and behavior as an abstract-to-concrete continuum is particularly helpful when designing practical improvement strategies. Schein cautions, however, against evaluating cultures in an absolute or superficial way, such as good vs. bad or strong vs. weak. This is sound advice that the pharmaceutical industry should heed if it is to avoid the trap of substituting mere lip service for development of a healthy quality culture. Too often, within the pharmaceutical industry, quality culture manifests as a traditional culture of compliance with an overemphasis on "doing things right" instead of enabling workers to "do the right thing" in the spirit of quality excellence.

This is the foundation for ISPE's Six Dimensions of Cultural Excellence Framework, which supports a transformational journey toward a culture of patient-focused excellence by sharing approaches, practices, and tools. Such a transformation requires the identification and selection of "desired" behaviors to be "hardwired into new habits so that employees become assets to, and champions of, the transformation effort." [5]

The need for a transformation from a compliance-led to an excellence-led culture is further supported by the findings of a 2014 survey of 60 multinational organizations undertaken by CEB (formally known as the Corporate Executive Board) entitled "Creating a Culture of Quality." The survey proposed that organizations must find a new approach to quality, "one that moves beyond the traditional 'total quality management' tools of the past quarter century." [7] The survey also notes that specific actions are needed to shift from a rules-based quality environment to a true culture of quality, and concludes that employees must become passionate about eliminating mistakes by *learning* to apply their skills and make decisions in complex situations while *reflecting* more deeply about the potential risks and consequences of their day-to-day actions.

4.2 The ABCs of Behavioral Science

Moving from the abstract to the concrete, we now examine how this "reflection and learning" can be targeted to pinpoint desired behaviors and inhibit those that are undesirable. In their contribution to the book *Leading Pharmaceutical Operational Excellence*, Morse et al. reference Leslie Wilk Braksick in their change-management model. [5]

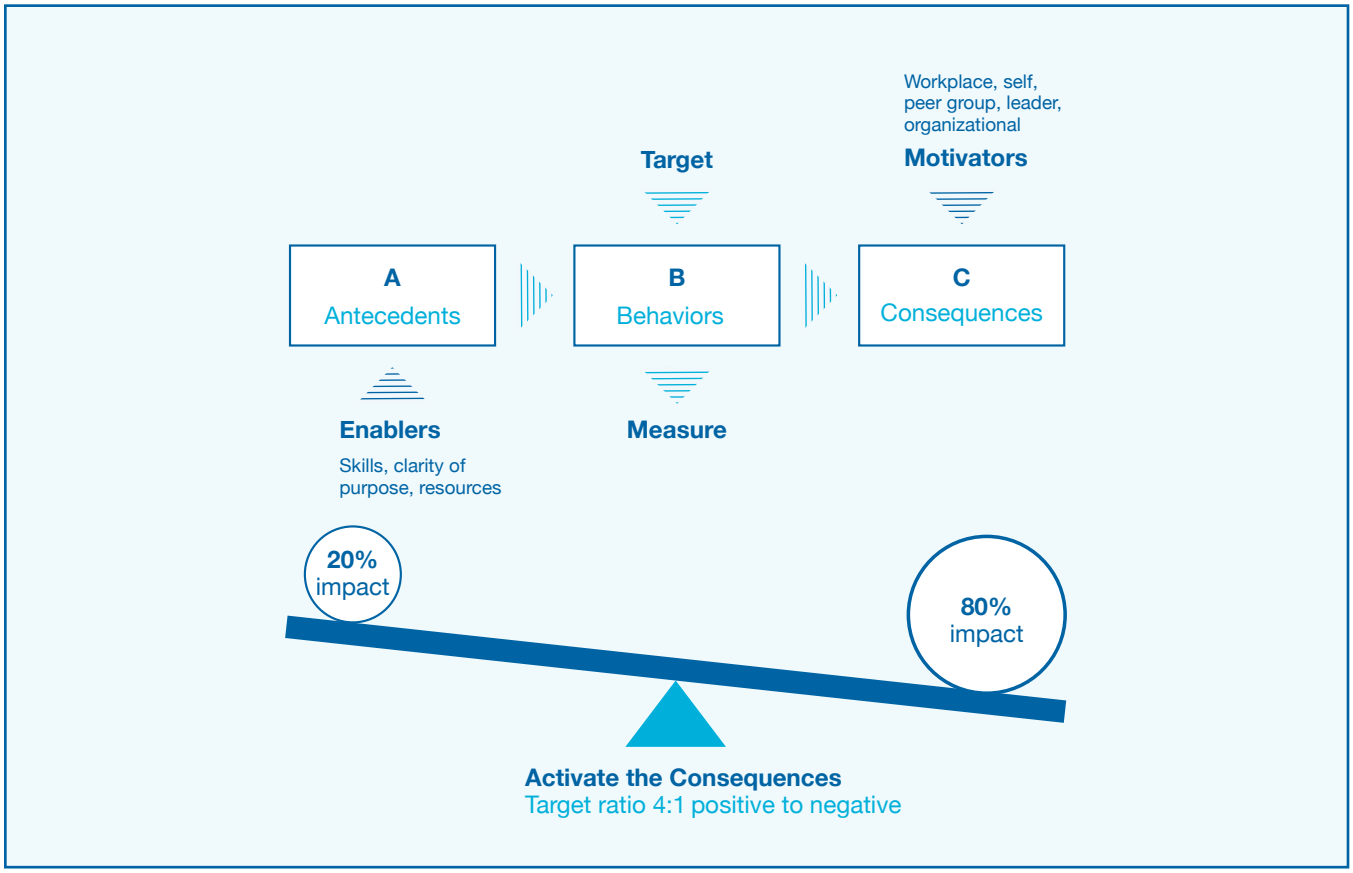
> Great execution depends on—behavior.
>
> —Leslie Wilk Braksick [1]

Braksick's work is founded on the principles of behavioral science and is presented in her book *Unlock Behavior, Unleash Profits: Developing Leadership Behavior that Drives Profitability in Your Organization*. [1] In his foreword to the book, W.R.K. Innes acknowledges the power and complexity of behavioral science when he proposes that behavior is probably "the most powerful, and yet least understood aspect of leadership" and can be "as complex as the human condition itself." Reassuringly, Innes also says that "like any complex system, human behavior is driven by a few simple principles." [1] This chapter provides an opportunity to share these "simple principles" with regard to reinforcing good behavior within your teams.

The "ABC" model of behavioral science outlined by Braksick (Figure 4-1) holds that Antecedents lead to Behaviors, which lead to Consequences. Antecedents are events that precede behaviors; they trigger what people say and do. They enable behaviors; they do not, however, motivate behaviors. In fact, consequences motivate behaviors by either reinforcing or discouraging them (i.e., consequences determine whether desired or unwanted behaviors occur and recur). The sequence, therefore, is as follows:

- Antecedents trigger behaviors
- Behaviors are followed by consequences
- Consequences determine if behaviors will recur

Figure 4-1: The ABCs of behavioral science: reinforcing behaviors



Source: Adapted from Braksick (2007) and N. Morse, et al. (2013)

The significance of this work becomes evident when the actual effects are examined. Braksick holds that antecedents only exert approximately 20% of the influence on what we do or say, whereas consequences exert the remaining 80%. Braksick maintains, however, that leaders, especially those in corporate settings, have an overreliance on antecedents to foster new behaviors, and typically, when they fail to deliver, "they just pile on more antecedents: issue memos, pep talks, training manuals and restate [their] expectations." [1]

Based on their work at Boston Consulting Group, Morse et al. note their experience that managers "persist in spending 80% of their time trying to manage by working on As, leaving Cs largely unmanaged." [5] Braksick advises a combined approach to achieve maximum impact, stating that an antecedent alone will produce small, often temporary changes in behavior, and a consequence alone will produce modest, lasting changes in behavior; antecedents backed up by consequences will produce the greatest effect on changes in behavior. This is important to remember when designing change programs to motivate team and individual behaviors.

4.3 The Rules of Four

The consequences rule defined by Braksick states that consequences have a "4x greater impact on behavior than antecedents." [1] Put simply, this means that consequences are the real motivators (or demotivators). Another rule of four comes from research undertaken by Losada and Heaphy in 2004, which concludes that peak performance is achieved at a 4:1 ratio of positive to negative consequences. [4]

These rules raise two challenges for the pharmaceutical industry that must be considered when targeting desired behaviors within a new learning culture. First, the traditional culture of compliance has relied heavily on rule-based antecedents in an attempt to determine behaviors, such as documenting the requirements in standard operating procedures and focusing on skills and task training. Second, within this environment, consequences tend to be those associated with nonachievement of desired behaviors and are largely negative (e.g., sanctions based on deviations, or retraining for failures attributed to "human error").

Employing the ABC model and the rules of four to drive real change in the elements of daily work that have the biggest impact on patient safety—i.e., the behaviors of all those involved in the supply of high-quality medicines—requires a new way of thinking about the role of compliance and how consequences are designed and used.

Accepting that consequences have four times greater impact than antecedents will require a phase shift in the amount of time spent designing and managing them, from leaving them "largely unmanaged" to investing significant time in designing appropriate, motivating, strategic consequences. Furthermore, for each desired behavior identified, the 4:1 ratio of positive to negative consequences should also be applied for lasting performance outcomes. The behavior tools provided by Braksick's model are simple, but changing mindset and attitudes to emphasize reinforcement instead of enforcement may prove more complex.

4.4 Linking Culture, Attitudes, and Behavior: The LQI Model

Industry-based research coupled with industry engagement through the ISPE Quality Metrics Task Team and Quality Culture Subteam have enabled an inside view of many quality culture and quality metrics programs across a diverse range of companies. The majority of quality metric dashboards in use remain heavily focused on lagging, historical metrics; very few are oriented toward proactive, leading measures of quality performance.

It is useful to look at the differences between leading and lagging indicators; LNS Research by Goodwin provides a simple definition: [2]

- A *leading indicator* can be defined simply as a performance measurement that occurs before a process begins
- A *lagging indicator* is the opposite; it is a measurement that indicates results

Leading indicators often measure behaviors and are predictive; lagging indicators tend to be historical measurements of results that nevertheless offer opportunities for reflection and analysis. Since behaviors are typically precursors of results, Goodwin advises that "it's important for manufacturers to optimize the use of leading indicators where possible to nip potential problems in the bud upstream from the undesired results." [2]

Management reviews of historical, lagging metrics for both the business and the patient are of questionable value, as Gotts states: "Using metrics that measure past events is like driving while looking through the rear window. It's easy not to see an opportunity or threat on the road ahead until you're upon it." [3]

Based on the truism that "what gets measured gets done," the "numbers" selected matter. They convey the choice of organizational culture—the rules-based culture of compliance or a learning-based culture of excellence. They influence and reflect the prevalent mindset and attitudes within the organization—i.e., "how we perceive, think about, and feel about things." Most importantly, they can provide concrete means to employ the ABCs, and to construct meaningful combinations of antecedents and consequences to positively reinforce desired behaviors.

4.5 Pinpointing Behaviors, Measuring Results

Having established that the choice of metrics provides an opportunity to positively influence behaviors (and therefore benefit the patient), Braksick's IMPACT model has been adapted for use in the pharmaceutical industry as a quality metrics tool to design behavior-based leading quality indicators, or LQIs, sometimes referred to as leading behavioral indicators (LBIs). The aim is not to prove the superiority of forward-looking metrics over historical ones but to find an appropriate combination of reflection and prediction to help organizations become more proactive than reactive with regard to their quality performance.

At any given time, each individual organization will need to focus on different behaviors to motivate specific areas of performance improvement or, conversely, address recurring quality failures. Therefore, no set of universal metrics is recommended. Rather, the tool is provided to enable the design and redesign of customized LQIs/LBIs as part of the overall journey toward excellence.

The LQI design tool was influenced by a successful collaboration with the Pharmaceutical Operational Excellence (OPEX) Benchmarking team based at University of St. Gallen, Switzerland. The collaboration provided insights into the benefits of designing measurement tools that have a balanced approach to reviewing qualitative progress on a series of enablers as well as measuring quantitative results in the form of metrics.

The tool below describes only the design of the quantitative measures or results. It is based on the Braksick's ABC and IMPACT models and provides a basis for selecting and designing LQIs.

4.6 Designing Measures for IMPACT

The IMPACT model requires the following steps in selecting and designing LQIs/LBIs:

- **I**dentify the desired quality-improvement goal
- Establish the appropriate **M**easure to deliver the goal
- **P**inpoint the "desired" behavior to deliver the goal
- **A**ctivate the **C**onsequences to motivate the delivery of the goal
- **T**ransfer the knowledge across the organization to sustain the performance improvement

Table 4-A shows a pharmaceutical industry example of this tool, focused on promoting right-first-time (RFT) behaviors. For best results and buy-in, these measures should be defined, designed, and agreed upon with the team responsible for delivering the identified goal.

Table 4-A: An example of the IMPACT Tool for designing behavior-based LQIs

I **IDENTIFY GOAL**	Consistent delivery of high-quality medicinal products.
M **SELECT THE MEASURE TOW DELIVER GOAL**	Increase the number of RFT batches to X%.
P **PINPOINT THE BEHAVIORS**	1. Promote and coach for enhanced attention to detail where "quality is everyone's job" through leadership and vision, as well as routine Gemba walks. 2. Encourage a speak-up culture where concerns, issues, or suggestions are shared in a timely manner in a neutral, constructive forum. 3. Begin proactive daily multidisciplinary interim batch issue reviews for early issue detection and resolution.
AC **ACTIVATE THE CONSEQUENCES**	1. Organize team briefings on the consequences of rejected or delayed batch approvals for the business and the patient. 2. Review outcomes from recent rejected or delayed batches or relevant customer complaints with the team. 3. Senior leadership and local management celebrate/acknowledge each RFT batch during Gemba walks. 4. Use local visual management boards for motivation on progress toward goal. 5. Acknowledge and recognize improvement efforts by team members in team/public areas/newsletters. 6. Motivate the team through team awards, e.g., movie tickets, team lunches.
T **TRANSFER KNOWLEDGE AND SKILLS TO SUSTAIN CHANGE**	1. Learning teams use root cause analysis (RCA) tools to proactively identify and document solutions to issues raised. 2. Lessons learned are documented and shared with wider workforce. 3. Lunch-and-learn sessions are arranged to facilitate Q&A between different improvement teams. 4. Create improvement case studies in a shared area on intranet.
LQIs/LBIs	**Leading** 1. Measure and report attendance at the multidisciplinary daily meetings. 2. Number of employee/team RFT improvement suggestions implemented (by period). 3. Number of good catches identified at interim batch reviews (by batch). 4. Number of successful RCA exercises completed (by period). **Trended Lagging** 1. % RFT batch approvals/investigation free lots. 2. % RFT batch records (paperwork completions).

The strength of the tool not only comes from pinpointing the behaviors that matter but from actively designing positive consequences that are meaningful to the team, bearing in mind the optimum 4:1 ratio of positive to negative consequences that are deemed most effective in motivating the behavior in the long term.

Finally, the tool also addresses an often-neglected aspect of change management: sustaining the change. By identifying feedback elements of knowledge transfer (the T in IMPACT) at the beginning, teams can sustain and share the know-how gained in solving the problems under examination. Another key attribute and critical motivating factor in successfully scaling up excellence can be getting the team members involved in what Sutton and Rao call spreading their "splendid deeds from the few to the many." [8]

4.7 "Be Better" Program

One practical way to spread those "splendid deeds from the few to the many" was provided to the ISPE Quality Culture Subteam as a case study during the research for this report. To support the role of leadership in driving culture throughout the organization, one company took an existing site safety program, the "Be Safe" program used to capture safety related continuous improvement ideas, and applied it to the quality arena, entitling it the "Be Better" program.

The goals of the Be Better program were to:

- Give employees a way to capture their ideas to help the site work more effectively and efficiently.
- Give management a way to evaluate these ideas and take appropriate action.

Before rolling out the program, site employees were informed that the Be Better program ***was***:

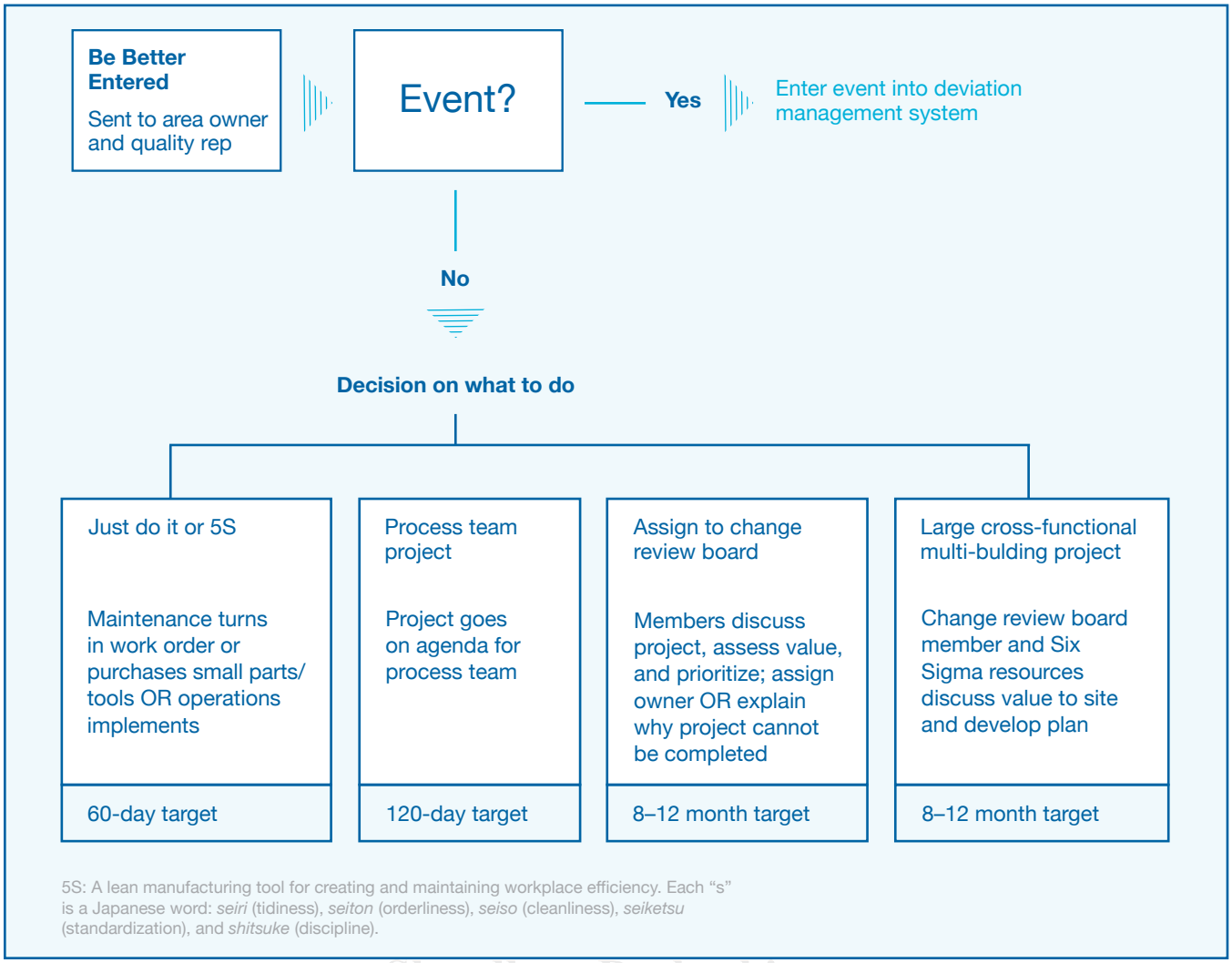
- A program to submit individual continuous improvement suggestions from quality, cost-savings, facility, or error-proofing perspectives, such as:
  - Suggestions for streamlined approaches to meeting quality requirements
  - Batch record instruction set improvements

Site employees were also informed that the Be Better program ***was not***:

- A mechanism to mask issues that belong in the deviation management system

Figure 4-2 shows the Be Better program workflow. Employees initially submit their ideas via an electronic system; the quality representative for that area then reviews the idea to ensure that it truly is an improvement suggestion and not something that should be logged as a deviation. Each suggestion is evaluated to determine if it will be pursued. If the suggestion is deemed actionable, timing and resources are determined and ownership assigned to the appropriate site resources or forums.

Figure 4-2: Be Better decision workflow



5S: A lean manufacturing tool for creating and maintaining workplace efficiency. Each "s" is a Japanese word: *seiri* (tidiness), *seiton* (orderliness), *seiso* (cleanliness), *seiketsu* (standardization), and *shitsuke* (discipline).

Initial program implementation and enrollment did present some challenges, including:

- The site realized that the system also needed a feedback loop to provide status updates and to ensure that employees were engaged on both the front and back ends of the improvement process. This feature took more time and effort to action than was originally anticipated.
- Due to the diversity of ideas submitted, they needed a robust prioritization process to ensure that the program did not create potential distractions from key priorities.

Even with these challenges, the Be Better program was found overall to be positive, with benefits that included:

- Engagement and ideas came from a broader segment of the site's population
- Key Be Better program metrics were used at team meetings as leading indicators for quality and continuous improvement
- Sources of waste, redundancy, and error traps were eliminated

4.8 Monitoring for Quality Triggers

Not all sites are ready to implement LQIs or Be Better–type programs. The premise of this report holds that the key to developing a healthy culture is to enable organizations to define, emphasize, and support desired behaviors and results using practical tools and approaches. This is intended to improve the organization's ability to identify and act upon near-miss shortages, assure transparent problem escalation, and strive for operational excellence.

While "quality culture" refers to both the expressed and implied ways in which an organization operates, determining the health of an organization's culture is not always straightforward. The Cultural Excellence Assessment Tool (Appendix 1) provides a powerful means to assess maturity of key behaviors within an organization and identify improvement areas in which further work would be beneficial.

Given the complexities in the global supply of medicinal products, however, assessing the impact of culture within a dispersed manufacturing network is ever more challenging. This is particularly critical within the context faced by the pharmaceutical industry today, which was characterized by Dr. Janet Woodcock in 2014 as "stressed, complex, and fragmented." [10] Depending on the contractual relationship an organization may have with the manufacturing site under review, it may not be possible to have full access to key performance metrics or to conduct behavior maturity assessments with site staff.

In these instances, a tool that facilitates high-level monitoring for quality triggers across the network may be useful. It can be used as part of an organization's self-inspection program or as part of a supplier qualification program when first assessing culture at a partner site. This Quality Triggers Tool (Appendix 4) poses a range of open questions in a series of semistructured dialogues between an experienced assessor and site leadership, other employees, and quality employees. The assessor can also document his or her observations following a tour of the physical and interactions with site personnel.

Quality triggers include items such as evidence of quality leadership, staff retention/turnover, evidence of employee engagement in quality performance and improvement, employee recognition programs, penetration of continuous improvement efforts, and shop floor awareness of quality policies and procedures. The tool proposes a simple high-, medium-, and low-risk ranking to identify areas of weakness or potential concern, and provides an opportunity to summarize where future, more detailed reviews may be necessary.

The tool emphasizes the role of people and the importance of dialogue in promoting and coaching for cultural excellence. In a *Harvard Business Review* article, Charan proposes that dialogue is the basic unit of work in an organization, calling it the single-most-important factor underlying the productivity and growth of the knowledge worker. He notes that "dialogue shapes people's behaviors and beliefs—that is, the corporate culture—faster and more permanently than any reward system, structural change, or vision statement I've seen." [9] Linking dialogue to the development of cultural excellence illustrates the need to manage the conversations within your organizational network.

4.9 Summary

Designing behavior-based LQIs are one way that organizations can influence the shift from a compliance-led culture to an excellence-led culture of quality. The key to success lies in activating consequences that can motivate desired behaviors that matter to your business and your patients.

Acknowledgments

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5 Management Oversight and Review

As per ICH Q10, “Leadership is essential to establish and maintain a company-wide commitment to quality and for the performance of the pharmaceutical quality system.” [1] Robust oversight and review, engaging both management and employees, reinforces a strong quality culture by demonstrating transparency, fostering trust, and facilitating dialogue. All of this creates learning, brings attention to issues so they can be addressed, and highlights best practices so they can be replicated.

The ISPE Quality Culture Maturity Assessment includes four behaviors/processes associated with management oversight review, along with possible improvement actions that can be considered as best practices to help achieve the desired behavior or process (Appendix 1).

5.1 “What Good Looks Like”

Companies that have a healthy or mature quality culture are usually learning organizations that share knowledge across the organization. Using this characteristic as a guiding principle, the Oversight and Review Subteam focused on identifying and sharing the following industry best practices related to management oversight and review:

- Aligned quality objectives
- Monitoring for continuous improvement
- Leadership involvement
- External party oversight and reporting

The Oversight and Review Subteam also developed a heat map tool to assess and compare an organization’s quality culture at either the enterprise (macro) or site (micro) level.

5.1.1 Aligned quality objectives

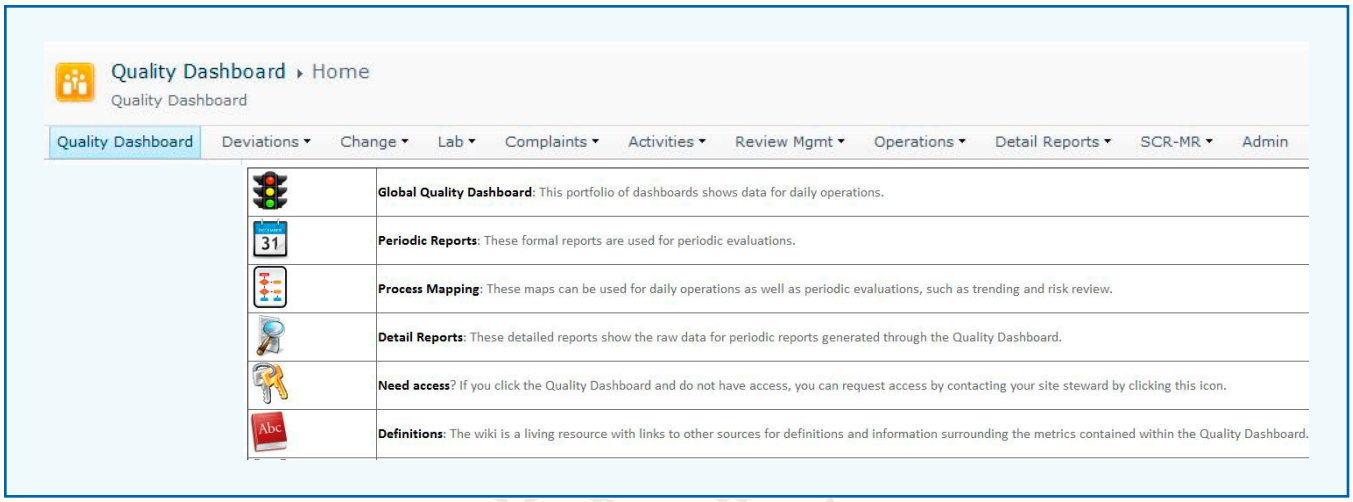
Before developing a global quality dashboard, one company shared how they initially faced several quality metrics challenges in their attempt to align their organization's quality objectives. They had:

- No easy way to review performance across a single site to target root cause(s) of performance issues
- No easy way to track performance for a site-to-site comparison, identify replication opportunities, and/or provide global oversight
- Different reports called for different data views, based on personal preference

To make quality metrics more visible to employees and facilitate standardized report creation, the company developed an intracompany quality dashboard that automatically pulls quality data in real time from various source systems (e.g., TrackWise, SAP). The main global quality dashboard collaboration website (Figure 5-1) displays access links to the following support areas:

- Global quality dashboard
- Periodic reports
- Process mapping
- Detailed reports

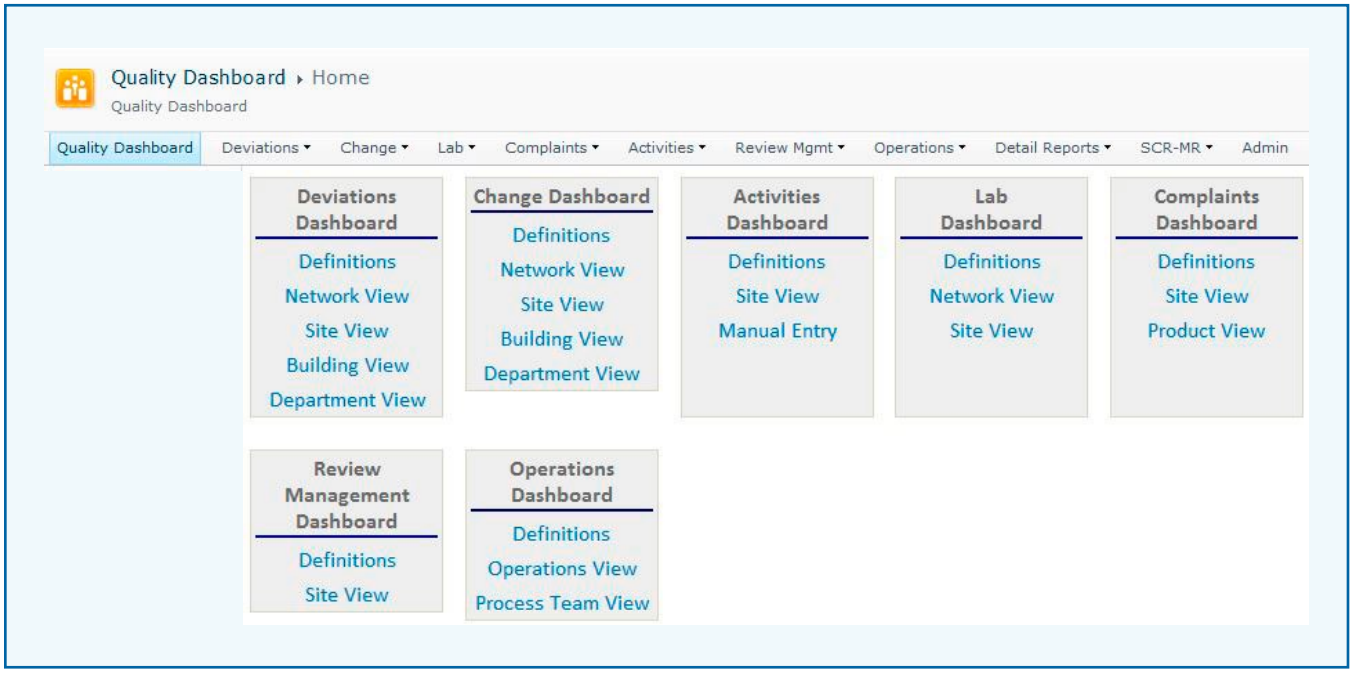
Figure 5-1: Global quality dashboard main site



The **Global Quality Dashboard** link directs employees to an online application (Figure 5-2) where they can access key performance data for the following activities which can be viewed at a departmental, building, site, or network level:

- Deviations
- Change
- Lab
- Complaints
- Review management
- Operations

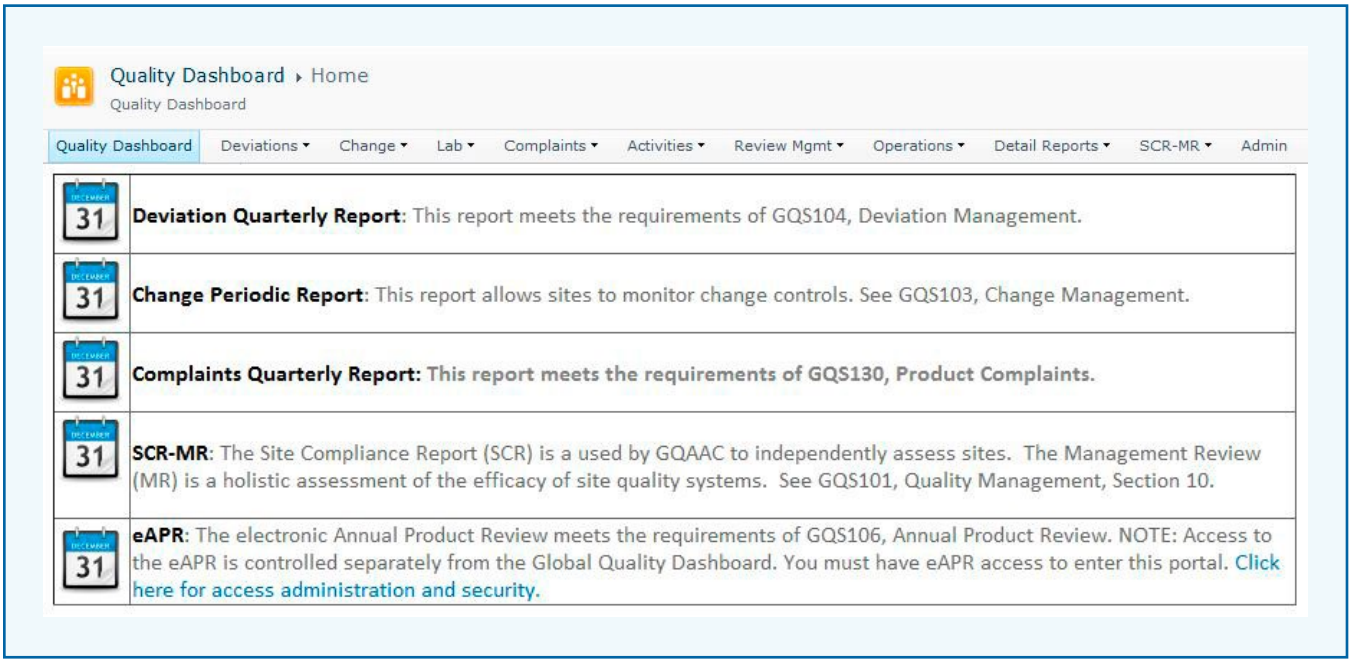
Figure 5-2: Global quality dashboard site



The **Periodic Reports** link directs employees to a page (Figure 5-3) where they can create periodic evaluations with key data populated automatically for:

- Deviation periodic report
- Change periodic report
- Complaints periodic report
- Site compliance report—management review
- Annual product review

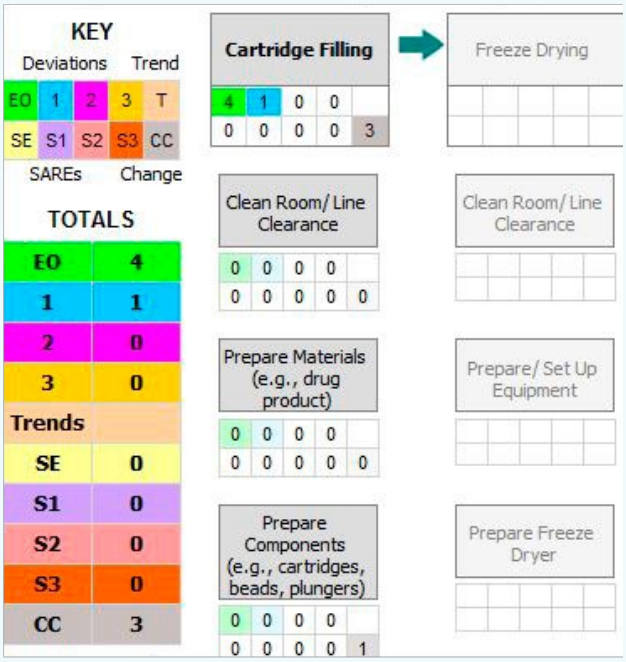
Figure 5-3: Periodic reports site



The **Detailed Reports** link on the main global quality dashboard page allows the authors of these reports to access detailed data associated with the periodic evaluation summary reports.

The **Process Mapping** link directs employees to a page (Figure 5-4) that displays quality metrics related to deviations and change controls for the different operations within a given manufacturing process. These process maps allow groups to target “pain points” and to work with other sites using the same language and process steps.

Figure 5-4: Process map site



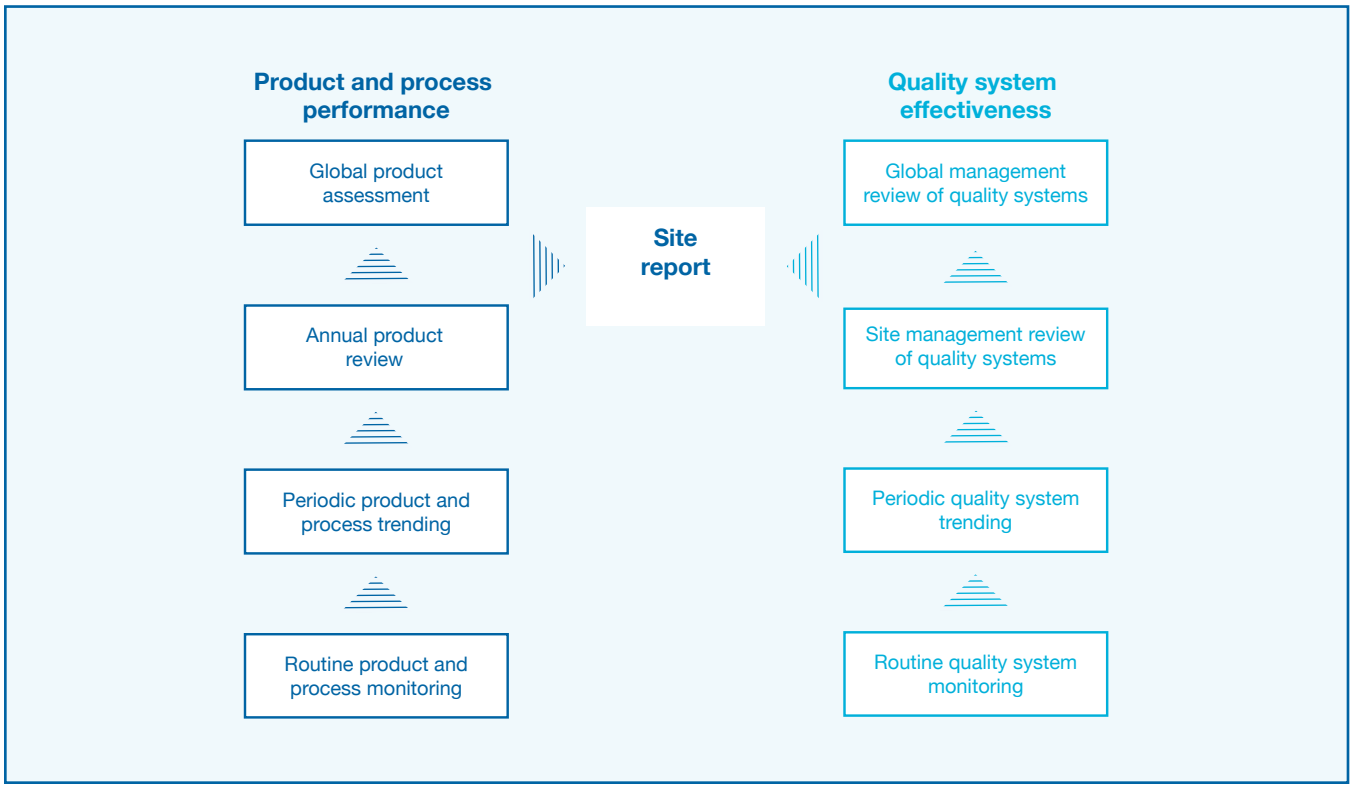
The resulting global quality dashboard has allowed employees at all levels within the organization to focus on evaluating and responding to the data, instead of pulling data from multiple sources to create customized reports. The dashboard has also been instrumental in harmonizing definitions, which makes comparison across manufacturing sites easier and helps replicate improvement faster.

5.1.2 Monitoring for continuous improvement

Monitoring and reviewing product and process performance along with the effectiveness of quality systems are important parts of any quality system. One company who shared their experience conducts this monitoring through a series of reviews, as shown in Figure 5-5.

Product and process performance monitoring is depicted on the left-hand side and quality system effectiveness monitoring on the right. The site compliance report brings relevant information for both together at a site level.

Figure 5-5: Monitoring for continuous improvement



The company's product and process performance monitoring includes the following key activities:

- Routine monitoring of product and process performance indicators is conducted in real time. Process parameters and quality attribute values are reviewed at an appropriate frequency at process team meetings to identify trends.
- Periodic product and process monitoring of product outputs, such as analytical property data and process performance, is conducted at defined intervals (usually quarterly) to identify trends.
- The annual product review (APR) examines process and product performance to ensure a validated state and identify opportunities for continuous improvement. Process assessment, intermediate steps, analytical method performance, stability program, changes, deviations, product complaints, and regulatory changes are all included in the review.
- The global product assessment looks at trends and opportunities for improvement in product and process performance across the whole supply chain for a given product, including active pharmaceutical ingredients, drug product, and packaging operations. The assessment includes a review of all supporting APR summary reports.

The company's quality system effectiveness monitoring includes:

- Routine quality system monitoring to ensure timely and effective execution of core quality management processes (e.g., quality dashboard).
- Periodic quality system trending at defined intervals to evaluate key quality system effectiveness indicators (e.g., deviation quarterly reporting and monthly metrics reviews).
- Management review, an annual self-analysis of the continued suitability, adequacy, and effectiveness of the site's quality system.
- Global management review, which analyzes the global quality system effectiveness and identifies global improvements in system design, execution, and/or monitoring.

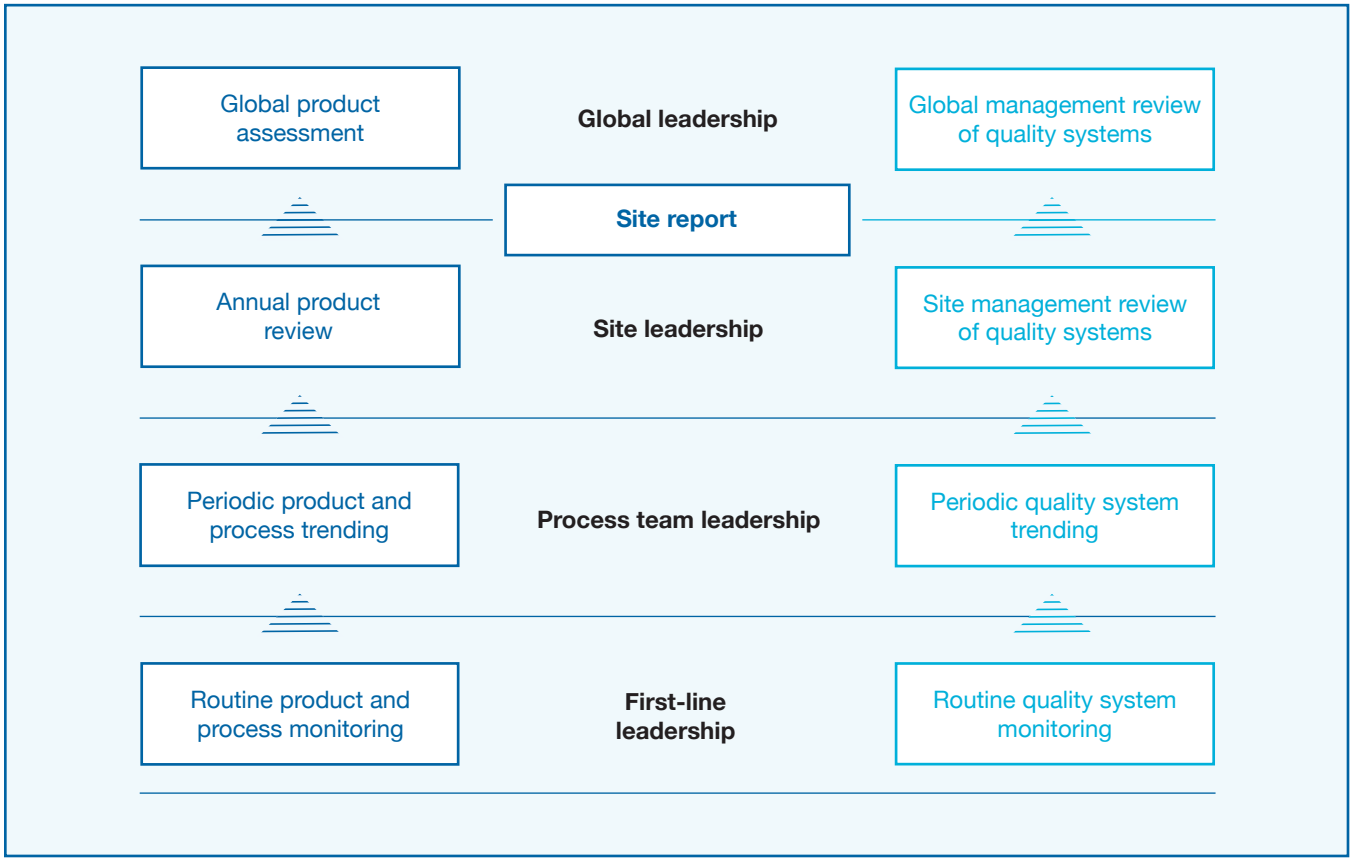
The site report, performed by a corporate quality assurance function, is an independent periodic assessment of the subject site's (company site or contract organization) quality performance, regulatory compliance, and performance risk. It includes a review of good manufacturing practice (GMP) audit findings, regulatory observations, quality metrics, and other data that indicate quality indicator trends and the level of GMP compliance. Site reports are presented to global manufacturing and quality leaders as one mechanism for monitoring quality in execution and to evaluate compliance risk. The site reports are made available to global quality assurance auditors for audit preparation and to qualified persons to assess manufacturing sites.

5.1.3 Leadership involvement

Leadership is involved at every level in the monitoring and review process (Figure 5-6):

- First-line leadership monitors manufacturing and quality processes continuously to support front-line operations and staff.
- Process-team leadership reviews product, process, and equipment trends periodically; quality system trends are also reviewed to ensure that established quality systems are being executed consistently.
- Site leadership reviews the site as a whole, monitoring the product quality and assuring appropriate design and execution of site quality systems.
- Global leadership oversees company products and global quality systems through global product assessment reviews, global management review of quality systems, and site reports.

Figure 5-6: Leadership involvement



5.1.4 External party oversight and reporting

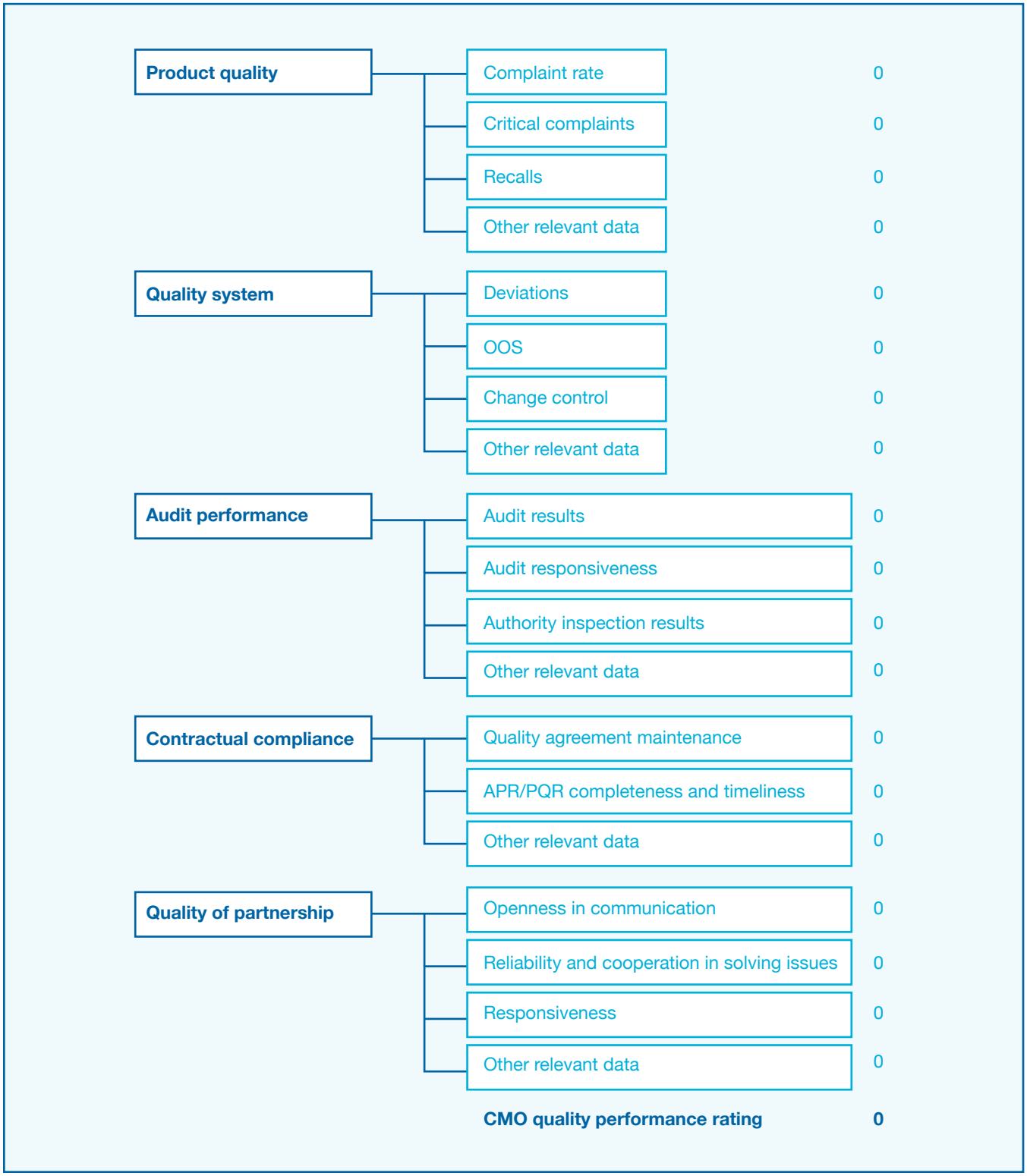
As part of quality oversight for contract manufacturing organizations (CMOs), one company shared how they assess the quality performance of each CMO according to a predefined set of evaluation criteria and ratings.

The evaluation has five dimensions:

1. Product quality
2. Quality system
3. Audit performance
4. Contractual compliance
5. Quality of partnership

For each dimension, various criteria must be assessed. Each criterion is rated on a scale from 1 to 4, then an overall CMO quality performance rating is calculated (Figure 5-7).

Figure 5-7: CMO quality performance evaluation



The quality performance rating defines the "surveillance class" assigned to the CMO as either "control," "coach," or "monitor." These classes reflect the level of confidence and satisfaction with the CMO's quality performance and define the level of effort and scrutiny required to manage the CMO. This may include increasing level of information through additional and more detailed documentation, greater documentation review and approval, more frequent audits and technical visits, and/or more analytical tests performed by contract giver.

To drive continuous improvement and dialogue, the outcome of the CMO quality performance evaluation is shared with the CMO at least annually (e.g., in business review meetings). This dialogue is key to creating an inclusive process that addresses challenges and identifies new approaches. It provides clarity on expectations and perceptions.

5.2 Cultural Excellence Heat Map

The ISPE Cultural Excellence Assessment Tool (Appendix 1) is an effective way to gauge an organization's maturity in each of the six cultural excellence dimensions. To further strengthen the utility of this tool across a manufacturing network, the Oversight and Review Subteam have developed a companion tool called the Oversight and Review Heat Map (Figure 5-8). This displays the Cultural Excellence Assessment Tool output in a manner that helps identify best practices and areas of opportunity across a range of manufacturing sites assessed as part of a peer-to-peer network overview.

Figure 5-8: Oversight and review heat map

	Leadership & Vision				Mindsets & Attitudes				Gemba & Shop Floor Engagement	
	1	2	3	4	5	6	7	8	9	10
	We regularly hear from management an emphasis on quality topics and the importance of quality.	When we have quality issues in conflict with business issues, both aspects are always considered by management before taking a decision.	Leaders regular provide sufficient support and coaching to line workers to help them improve quality.	Leaders always model the desired behavior of "doing the right thing" on issues of quality.	All employees consistently see quality and compliance as their personal responsibility.	Employees have sufficient authority to make decisions and feel trusted to do their jobs well.	Employees regularly identify issues and proactively intervene to minimize any potential negative impact on quality and compliance.	Employees are not afraid to speak up, bring quality issues, challenge status quo for improved quality and believe management will act on employee suggestions.	There are both formal and informal processes in place to ensure management routinely visits the shop floor to observe, assess, listen and coach the employees, such as Gemba Walks.	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.
Site A	R	R	R	R	R	Y	R	Y	R	Y
Site B	Y	Y	R	Y	G	G	G	G	G	G
Site C	G	G	G	G	Y	G	G	G	G	G
Site D	Y	Y	R	Y	Y	G	Y	G	G	G
Site E	G	G	R	G	G	G	G	G	G	G
Site F	R	R	R	R	Y	G	Y	G	Y	Y
Site G	R	R	R	R	Y	G	Y	G	Y	Y
Site H	G	G	G	G	G	G	G	G	G	G
Site I	G	G	Y	G	G	G	G	G	G	G
Site J	Y	Y	R	Y	Y	G	Y	G	Y	Y
Site K	G	G	R	G	Y	G	G	G	G	G
Site L	G	G	R	G	Y	G	Y	G	Y	G
Site M	R	R	R	R	Y	G	R	G	R	R

	LQIs & Triggers			Management Oversight & Review				Cultural Enablers			
	11	12	13	14	15	16	17	18	19	20	21
	Quality metrics and goals are consistently designed and selected to promote / motivate desired quality behaviors.	Up-to-date quality metrics (e.g. right first time figures, excellence targets on defects, rejects) are regularly posted and easily visible near each production / work area.	All workers can routinely explain what quality information is tracked and why and outline their role in the achievement of quality goals.	Quality goals and objectives are routinely established, linked and aligned with organizational goals.	Management is consistently involved in reviewing and assessing product, process and quality system performance.	The company's oversight and reporting capabilities are systematically applied to effectively manage external manufacturing performance within the supply chain.	Management regularly involves line workers in problem identification, problem solving, troubleshooting and investigations.	Improvement opportunities and problems are acknowledged quickly, mistakes are formally reviewed and company looks to share and learn from them.	Management enables employees at all levels within the organization to identify and communicate risks well across the organization.	We routinely recognize and celebrate both individual and group improvement achievements in performance quality.	Employees regularly receive training that effectively helps them ensure quality in their work fostering a learning organization.
Site A	R	G	Y	R	Y	G	Y	R	Y	G	Y
Site B	Y	R	G	Y	Y	G	Y	Y	Y	G	Y
Site C	G	G	G	G	G	G	G	G	G	G	G
Site D	Y	Y	Y	Y	Y	G	Y	Y	Y	G	Y
Site E	Y	G	G	G	G	G	G	G	G	G	G
Site F	Y	Y	R	Y	Y	G	Y	Y	Y	G	Y
Site G	Y	R	R	R	R	Y	R	R	R	Y	R
Site H	G	G	G	G	G	G	G	G	G	G	G
Site I	Y	G	G	G	G	G	G	G	G	G	G
Site J	Y	Y	Y	Y	Y	G	Y	Y	Y	G	Y
Site K	Y	G	G	G	G	Y	G	G	G	Y	G
Site L	Y	G	G	Y	Y	G	Y	Y	Y	G	Y
Site M	Y	R	R	R	R	G	R	R	R	G	R

Red	Maturity Level: Strongly Disagree, Disagree
Yellow	Maturity Level: Slightly Disagree, Neutral, Slightly Agree
Green	Maturity Level: Agree, Strongly Agree

1. Each column on the heat map includes the behavior or processes associated with a specific cultural excellence dimension.
2. Each row on the heat map represents an individual site or functional area.

The tool can be used at either a macro or global level by assessing and comparing individual manufacturing sites or it can also be used at a micro or site level by assessing and comparing individual departments or functional areas. Each maturity assessment level is then given a color rating: red = strongly disagree/disagree, yellow = slightly disagree/neutral/slightly agree, and green = agree/strongly agree.

The horizontal view indicates an individual site/area's performance; the vertical view indicates cultural excellence performance at a program level. This provides oversight of an organization's areas for improvement as well as its strengths, and shows the activities supporting each cultural behavior that should be continued or replicated to other sites/areas in the network.

5.3 Conclusion

Robust management of oversight and review are an important part of an organization's quality culture. Done well, they demonstrate transparency, which fosters trust; facilitate dialogue, which creates learning; bring attention to issues so they can be addressed; and highlight best practices so they can be replicated.

Acknowledgments

The author wishes to acknowledge the assistance and support of Bart Shrode, Perrigo, in the development of the ISPE Oversight and Review materials.

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6 Cultural Enablers

6.1 Cultural Excellence Value Proposition

The value proposition for enabling cultural excellence in an organization is multifaceted: Engaged employees build strong processes and systems that are continuously improved; these provide sustainable growth, reduce costs, increase profitability, and create a happy, collaborative team.

This chapter demonstrates examples of potential cultural enablers to enhance any of the six cultural dimensions included in the framework. It provides a system improvement and behavioral accountability process and a template that ties process improvements to key performance indicators and key behavioral indicators. It also provides a sample road map that may be used for each key role in the system to standardize your plan for process improvement, role-based behaviors, training, and sustainability/control.

6.2 Cultural Enablement Guide

Enablement requires key behavioral indicators at all levels within an organization. “Cultural excellence” is, after all, the culmination of all six cultural dimensions at peak maturity: leadership and vision, mindset and attitudes, Gemba walks, LQIs and triggers, oversight and review, and cultural enablers.

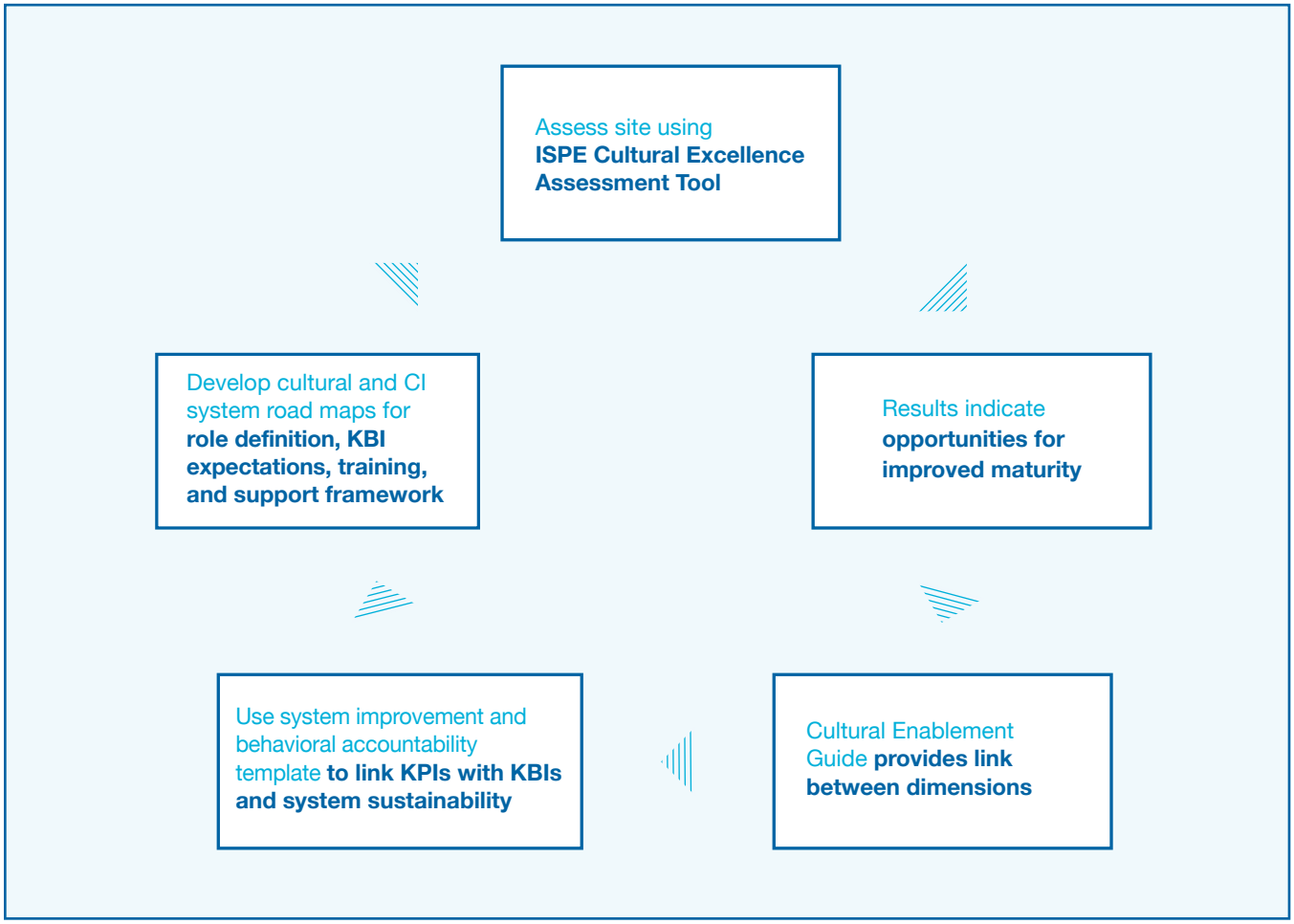
It is important users start their cultural excellence journey by assessing the current state of their system and the maturity of their organization (Figure 6-1). This will identify opportunities for improvement. Tools and templates for each of the six dimensions have been detailed in previous segments of this report.

The first step is the Cultural Enablement Guide, which describes each cultural dimension and how it relates to six core enablement categories: learning organization, model behaviors, people recognition systems, identify and recognize change, true root cause and corrective/preventive action, and continuous problem solving.

The system accountability and behavioral accountability matrix may then be used to improve processes and programs within the organization. This tool demonstrates how to attain key performance indicators (KPIs) while linking key behavioral indicators (KBIs) for each level in the organization.

Last, the cultural and continuous improvement (CI) road map example documents how to manage each role within the system, including what you are working to attain and how you go about doing this. It includes examples of plan-do-check-act (PDCA) cycles for improvement, training, behavior indicators, and risk assessment.

Figure 6-1: Cultural Enablement Tool



6.2.1 Overview

The Cultural Enablement dimension transcends all other cultural excellence areas. The guide presented demonstrates enablement tool examples for each cultural excellence dimension; these may be used to improve the six core categories of cultural enablement (Table 6-A).

Table 6-A: Cultural enablement core categories

	CULTURAL ENABLEMENT GUIDE	ENABLEMENT TOOL EXAMPLES	LEADERSHIP AND VISION	MINDSET AND ATTITUDES	GEMBA WALKS	LQIS AND TRIGGERS	OVERSIGHT AND REVIEW
Cultural enablers	Learning organization	Situational leadership	•	•	•		•
		Coaching/mentoring	•	•	•	•	•
		Strategy deployment	•			•	•
		Goal alignment (top down)	•	•	•	•	•
		Hiring/onboarding	•	•			
	Model behaviors leader/ manager/associate	System A3	•	•	•	•	•
		Learning aligned to strategic goals	•	•		•	
		L/M/A KBI examples	•	•	•	•	•
		Leader standard work	•	•	•	•	
	People recognition system	Standard approach in meeting or communication	•	•	•	•	•
		Recognize KBIs	•	•	•	•	•
		Tie reward to recognition	•	•	•	•	•
	Identify and recognize change	Balanced scorecard	•	•	•	•	•
		Control charts			•	•	•
		Statistical/capability analysis			•	•	•
		Engagement and enablement		•	•	•	•
		Poka-yoke		•	•	•	
	True root cause analysis with preventive and corrective action	Kepner Tregoe		•	•	•	
		Process mapping		•	•	•	
		Cause-and-effect diagram		•	•	•	
		Causal circle (UDEs)		•	•	•	
		Radar chart		•	•	•	
		Risk assessment		•	•	•	
		5 Whys		•	•	•	
	Continuous problem solving	PDCA		•	•	•	•
		DMAIC		•	•	•	•
		Future state mapping		•	•	•	•
		Control systems		•	•	•	•

6.2.2 Glossary

The following is a partial glossary of Cultural Enablement Guide tools that are prevalent in industry. It does not describe each tool in detail as there are multiple resources that provide this information (see the Reference for use of tools section).

Learning organization

Situational leadership: A leadership model that describes adapting leadership to a style appropriate for the development level of managers/associates that the leader is trying to influence; a framework for employee development.

Strategy deployment: A process for setting direction within an organization and steering toward it; any form of organizational improvement in which solutions emerge from people closest to the problem or plan. The name comes from the Japanese term *hoshin kanri*, which means "direction management."

Model behaviors

Key behavioral indicators (KBIs): Actions tied to beliefs; consistency of behaviors tied to goals or KPIs that provide results. KBIs should be understood at leader, manager, and associate levels for each process or system.

Leader standard work: A management work system that involves leaders demonstrating key behaviors by walking the Gemba (going to where the work is), observing exceptions or abnormalities, asking questions, and enabling/supporting the people in the process/system.

System A3: A template for a logical and critical-thinking process that can be applied to any discipline; a systematic, problem-solving template or pattern that may be used in an investigation, improvement, or activity.

People recognition system

Recognize KBIs: Reward the leaders, managers, and associates that demonstrate actions tied to beliefs. These behaviors are aligned to goals and KPIs, providing improved results.

Identify and recognize change

Poka-yoke: Error-proofing a system or process; from the Japanese *yokeru* (avoid) *poka* (mistakes).

True root cause and CAPA

5 Whys: An iterative interrogative technique used to explore cause-and-effect relationships for a particular problem; it involves asking "Why?" at least five times to drill down from multiple causes to potential root causes.

Balanced scorecard: A strategic performance management tool to identify and improve internal functions and their resulting metrics. A balanced scorecard enables a view of cross-functional metrics across the value stream for governance.

Cause-and-effect diagram: Also called an Ishikawa or fishbone diagram, this shows the causes of a specific event or problem; causes are often assigned categories called the 6Ms: manpower, machine, method, material, measurement, and Mother Nature

Causal circle: Also known as causal loop, a diagram that depicts how different system variables are interrelated using directional arrows to connect identified causes or UDEs; helps distinguish causes from effects.

Kepner Tregoe: A four-step methodology for gathering information, prioritizing and evaluating it, and making unbiased, risk-assessed decisions; best alternatives scrutinized against potential problems and consequences to minimize risk.

Radar chart: Also known as a spider chart, a two-dimensional chart that displays three or more quantitative variables starting from the same point.

Undesirable effects (UDEs): A list of problems that may be mapped in a cause-and-effect diagram or a causal circle.

Continuous problem solving

Control systems: A control plan to sustain a system improvement that includes a culture change.

Define, measure, analyze, improve, and control cycle (DMAIC): A data-driven improvement cycle for improving, optimizing, and stabilizing business processes and designs; the core tool used to drive Lean Six Sigma projects.

Future state mapping: A map that bridges the gap between current state and ideal state processes.

Plan-do-check-act (or adjust) cycle (PDCA): A repetitive four-stage model for continuous improvement in business process management; also known as the Deming or Shewhart cycle.

6.2.3 Reference for use of tools

There are many references that may further understanding of these tools; a few are listed below:

- American Society for Quality
- Gemba Academy
- *Juran's Quality Handbook*
- Ken Blanchard Companies: Situational Leadership
- Kepner Tregoe
- Lean Enterprise Institute
- Villanova University's online Lean Six Sigma certification program

6.3 System Improvement and Behavior Accountability

Cultural excellence through enablement requires more than setting goals and KPIs; actions and behaviors must be aligned across the organization. To that end, we have included a powerful tool that uses a systems approach to identify possible improvements and the associated necessary behaviors. Provided below are a template and a companion guide with recommendations for completion of the template.

6.3.1 Overview/template

The System Improvement and Behavior Accountability Template (Table 6-B) is a tool that helps users truly understand their systems and processes prior to commencing an improvement initiative. It starts by asking you to identify the system or process to be managed or improved, as well as the owner of that process. You then state the purpose or business case behind your need to manage or improve this system. This aligns all areas on the purpose of change and builds accountability at all levels.

You then identify the expected KPIs or results necessary to manage the system. It is important to think through this thoroughly as this key element will drive behaviors in your system. Once KPIs have been identified, it is essential to describe expected or model behaviors necessary to improve or manage the system—how you "walk the talk." Remember: A behavior is an action or something that you can take a picture of someone doing. Be sure to develop behaviors for each role and all levels.

Next, identify key behaviors at the strategy level for leaders. These are key goals and tenets that they will demonstrate through action, such as a leader Gemba or attendance at a KPI report session. Leaders set the goals, the budget, and enable the workforce to develop and manage systems.

Once that's done, identify system manager or subject matter expert (SME) behaviors. These individuals generally manage and maintain systems or processes. They develop the scorecards that tell whether you are winning or losing, they Gemba more frequently, and they generally manage the system resources—both human and electronic.

Finally, establish the behaviors necessary for associates. These individuals use the tools each day to execute the system or process. They are generally front-line employees that need visual management systems and triggers to administer the tools in the system. Enabling them is critical to the success of the system; these results drive behaviors that control the system or process.

You will then list:

- Tools used within the system
- Process and schedule or scorecard
- Visuals or signals that indicate whether you are winning or losing at any point
- Measurements used to monitor the system at different points

It is important to improve systems, engage employees at all levels, and demonstrate successful results. It is just as important to sustain the gains that you have achieved. This is why you must create a control strategy or plan for your system. A system cannot be only person-driven or leader-enabled. It must be set with measures to adjust appropriately over time while assuring key systems are sustainable. In many cases, this means documented procedures and hard-coded scorecards with KPIs and KBIs that are transparent across the organization. A control or sustainability system is the last step in successful system development.

Table 6-B: System improvement and behavior accountability template

<table>
<tr><td colspan="2">SYSTEM/IMPROVEMENT: Name</td><td colspan="2">BUSINESS PROCESS OWNER: Owner</td></tr>
<tr><td colspan="4">PURPOSE: Business case/planned improvement reason</td></tr>
<tr><td rowspan="2">KPIs OR OUTCOME/RESULTS EXPECTED</td><td colspan="3">BEHAVIOR EXPECTED</td></tr>
<tr><td>Leadership</td><td>Managers or SMEs</td><td>Front line</td></tr>
<tr><td>[List]</td><td>[Roles]</td><td>[Roles]</td><td>[Roles]</td></tr>
<tr><td>Tools</td><td>Structure/schedule</td><td>Signals</td><td>Measurements</td></tr>
<tr><td>[List]</td><td>Process map, schedule, etc.</td><td>What signals good or bad?</td><td>Performance metrics
• List including target and current condition

Behavioral metrics
• List including target and current condition</td></tr>
<tr><td colspan="4">Control system</td></tr>
<tr><td colspan="4">[List or description]</td></tr>
</table>

6.3.2 Template elements, descriptions, and tools

Below is a companion guide to the System Improvement and Behavior Accountability template, which includes descriptions and tool examples that may be used when developing and maintaining your system (Table 6-C).

Table 6-C: Template elements, descriptions, and tools

ELEMENT	PROMPTING QUESTIONS	TOOLS
Purpose	• What problem does this solve? • What is the business need? • Why do you need to create a system to solve this?	• Charter • Gemba • Voice of the customer • Quality event rate • Process map
Outcome/Results	• Where are we now? Where do we need to go? • What is the goal we need to attain? • Are the goals aligned across the organization? • What do we need to achieve to be successful?	• KPIs; goals cascaded • Radar chart • Cause-and-effect diagram • Reward and recognition
Behaviors (leader, manager, or subject matter expert, front line)	• What is the model behavior necessary per role? • Is this behavior specific and required of this role? • Can you take a picture of this person demonstrating this behavior?	• Behavior matrix • Development plan • Skills matrix • Gemba or meeting attendance
Tools	• Is the tool to measure behavior necessary? • Will is show behavior is working or not? • What is the purpose of the behavior? • How does this tool show the behavior is working?	• Gemba • SWOT analysis • Behavior matrix results
Structure/Schedule	• What is the process telling you? • What are the steps in your process and how can you measure them? • How do you communicate through the value chain?	• Gemba • Process map • Value stream map
Signals	• What is the trigger to show if something is good or bad? • How to know if you are moving the needle in the right direction?	• Visual management • Gemba
Measures	• Do these measures show if you are winning or losing? • Can you identify the resulting performance/behavior from this measure? • Can each role impact these measures?	• KPIs • Balanced scorecards • Gemba, shared report-outs
Control System	• How do you assure sustainability? • Who manages the system? • How do you adjust to stay on track?	• Visual management • Standard work • Procedures

6.4 Culture and Continuous Improvement Capability Road Map Development

Cultural enablement and excellence is a journey. It takes time and commitment to implement. That is why we have looked into several models that provide a road map for implementation. The culture and continuous improvement capability road map combines several key factors road map to ensure that the appropriate plans, systems, training, tools, and enablers are provided.

6.4.1 Example: Front-line employee

Table 6-D shows an example of a road map for a front-line employee that is very general. This type of road map, which can be used for each role in a system, includes role definitions, behavior expectations, training requirements (technical, soft skill, continuous improvement specific, or advanced such as risk assessment), and supporting framework. The supporting framework is key to meeting the needs of each role. Supporting structures include procedures (references, job aids, or tools), consultation, practice, coaching, line sharing or best practices, and reinforcement. The specific elements within a road map may vary by role as well as process or improvement project. Organizations can use this enablement tool and template to build a plan, agree and cascade goals and expectations, manage and monitor processes and systems, and assure transparency and accountability throughout.

Table 6-D: Culture and continuous improvement capability road map

DEFINITION OF A FRONT-LINE PERSON
An individual involved in all phases of operations (e.g., planning, manufacturing, supply chain, quality)

DESIRED PERFORMANCE
- Perform informal continuous improvement within their work area
- Provide technical expertise to support continuous improvement and cultural excellence
- Provide information for activities, including updates to existing culture and continuous improvement management documents and/or identification/implementation of new controls

CULTURE AND CONTINUOUS IMPROVEMENT MANAGEMENT PROCESS					
OVERALL PROCESS	**PLAN**	**DO/ASSESS**	**CHECK/ACT**	**MONITOR**	**COMMUNICATE**
		Identify and analyze	**Decide and formulate**	**Review/Control**	
Identify and discuss concerns, issues, risks, and improvement opportunities with supervisor/manager Provide input and/or propose improvement opportunities solutions as experts in the areas they are responsible for Engage in improvement opportunities Be aware of your actions' effects and potential consequences on output quality	Work with line management to align goals and develop a plan for your specific area	Identify risk, issue, or opportunity Access root cause, impact, and potential solutions	Decide whether to act or escalate the identified risk, issue or opportunity using improvement methodologies Propose or participate in the solution	Provide feedback to supervisors on whether the solution worked KPIs KBIs Controls	Know when to communicate to your supervisor and peers Know what information to document for the record or future reference: knowledge management/ lessons learned Document event and solutions, decisions and rationale appropriately

LEARNING ROADMAP					
BEHAVIORAL REQUIREMENTS	TRAINING				
	Technical skills	Soft skills	CI program specific (as needed)	Advanced (optional)	Support
System accountability matrix	Continuous improvement essentials		1. PDCA 2. DMAIC and others, as appropriate	1. Local training material for CI processes 2. Root cause analysis and RM 3. Decision-making	1. Readily available job aids and tools – Templates/checklists /examples – Case studies 2. Consultation provided by leaders, managers, and subject matter experts on specific identified opportunities/improvements 3. Opportunities to practice – Real-time quality event identification and communication – Regularly-scheduled Gemba walks 4. Coaching – Quality event identification and communication – Practical application of continuous improvement 5. Knowledge sharing – Best practices – Lessons learned – Documentation and communication 6. Reinforcement and recognition – Expectations for proactive improvement are in place and managed as part of performance management – Proactive improvement discussions integrated into activities (e.g., daily, weekly, quarterly)

DEVELOPMENT ROAD MAPS FOR EACH ROLE	ROAD MAPS INCLUDE
Frontline	Role definitions
Area expert	Behavioral expectations
Area manager	Training requirements
Leadership	• Technical skills
Subject matter expert	• Soft skills
	• Program-specific CI
	• Advanced
	Supporting framework
	• References /job aids/tools
	• Consultation
	• Practice
	• Coaching
	• Line sharing
	• Reinforcement

6.4.2 Elements and tools

In the above examples, a road map should be built for a value chain or for a department to align goals and priorities across the organization. It is also important to build a road map for leaders, managers/SMEs, and front-line employees/associates. Each role has unique requirements within each process or system, as well as specific expectations for KPIs and KBIs. Training may also vary by role. Table 6-D describes the road map elements and shows some examples of tools or job aids. There are many ways to build a road map that meet the needs of an organization. This enablement example ties a PDCA and Communicate methodology with training, metrics, tools, and behaviors for each role in a process or system. A user can implement all elements of a road map or specific sections as appropriate for their needs.

6.4.3 Importance for all roles

Creating road maps enables the culture of the organization and provides transparency and accountability in the process. Road maps can be created at site level, which is where most organizations apply them. In this model, we suggest that users incorporate specific road maps for each role: leader, manager, front line, or SME.

6.5 Sustaining Cultural Enablement

As noted above, sustainability is a key element for any change, especially when it affects culture. It is important to build in controls such as procedures, standard work, visual controls, and Gemba to build and sustain a system. Culture doesn't change overnight. It takes time, commitment, and reinforced behaviors.

Acknowledgments

The author wishes to acknowledge the ISPE Cultural Enablers Team members: Claudia Sigg, Boehringer Ingelheim; Kristi Castro, Proctor & Gamble; and Kevin Robertson, ABC Laboratories.

7 Conclusions and Next Steps

ISPE believes the approaches, practices and tools shared in this report provide key insights as well as a practical framework for companies embarking on a journey toward building healthy quality cultures.

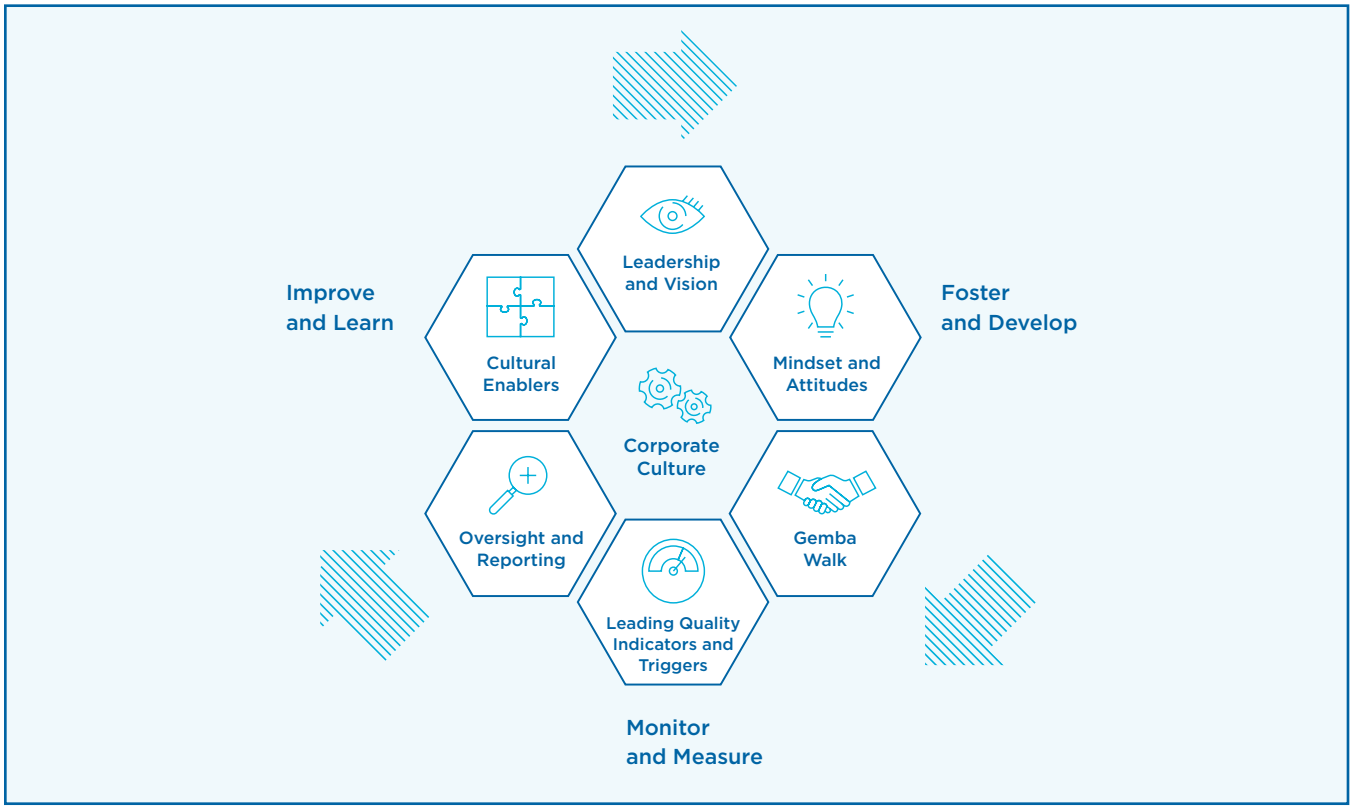
Cultural excellence recognizes quality not as an operational burden or compliance requirement, but as a necessity that allows companies to make decisions that best benefit the patient. This report seeks to define, emphasize, and support the demonstration of desired behaviors as a means to deliver enhanced quality outcomes.

The ISPE Six Dimensions of Cultural Excellence framework, in conjunction with, the ISPE Cultural Excellence Assessment Tool (Appendix 1) facilitate a holistic assessment of those elements required to foster, develop, monitor, measure, learn, and ultimately improve an organization's quality culture.

We hope that the practices shared and practical tools presented are just the beginning of a broader initiative that continues to reflect, learn, and share experiences that will ultimately shift the pharmaceutical industry beyond compliance toward excellence.

The ISPE Quality Culture Subteam wish to express their gratitude to all who have helped to shape this Cultural Excellence Report.

Figure 7-1: Six dimensions of cultural excellence



Appendix 1

Cultural Excellence Assessment Tool

Instructions

This tool shows desired states for 21 key cultural excellence behavioral criteria, grouped by dimension.

- Using the maturity level scale below, 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.*
- After completing the assessment for each section, identify the behavioral criterion with the lowest level of agreement.
- Review the "possible improvement actions" for this behavior (and consider other possible improvement actions).
- Identify and implement an improvement action to address the behavioral criterion with the lowest level of agreement.
- Monitor progress of cultural excellence improvement with periodic assessments.

Note: This is the original document as presented to study participants; content has not been modified.

Maturity Level 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

	DESIRED STATE	LEVEL 1 Strongly disagree	LEVEL 2 Disagree	LEVEL 3 Slightly disagree	LEVEL 4 Neutral	LEVEL 5 Slightly agree	LEVEL 6 Agree	LEVEL 7 Strongly agree	POSSIBLE IMPROVEMENT ACTIONS	CULTURAL ENABLERS
1	Leadership and vision									
1.1	We regularly hear from management an emphasis on quality topics and the importance of quality.								1. Ensure a corporate policy that articulates the organization's expectation for quality excellence is communicated across the organization. The vision, regarding the organization's commitment to quality is regularly available and communicated by Leadership to all in the organization. 2. Have leaders hold employee town halls, round tables and regular employee meetings to convey the Quality Vision throughout the organization. 3. Ensure leaders in all areas include quality goals into yearly business performance objectives for themselves and their employees. 4. Have leaders regularly discuss quality expectations and benefits and examples of strong quality, including personal quality stories, to promote proactive quality-minded behaviors.	• Quality town halls, round tables • Standing employee 1:1 or skip-level meetings • Goal alignment (top down)
1.2	When we have quality issues in conflict with business issues, both aspects are always considered by management before taking a decision.								1. Ensure quality is explicit as a leadership priority in the corporate policy and vision. 2. Have leaders model and encourage an environment of openness and respect for different viewpoints that values teamwork and new ideas. 3. Ensure there are decision making models, learning examples, training and coaching in place to support the expectation that both business and quality issues are considered. 4. Have leaders explain and share examples where decisions have been made considering both quality and business issues. Patient risk (including that of limited drug supply) is considered foremost in quality decisions.	• KBIs • Model behavior: leader, manager, associates
1.3	Leaders regularly provide sufficient support and coaching to line workers to help them improve quality.								1. Have leaders of the organization take purposeful steps to systematically demonstrate their commitment to quality by modeling quality focus and providing support. 2. Have leaders show shop-floor presence during routine Gemba and walk-throughs. Leaders stay aware through regular employee 1:1's and standing meetings about production issues and challenges. 3. Ensure leaders are trained and capable in building trust and an environment in which employees feel safe to admit mistakes they've made and their share quality improvement ideas. 4. Align rewards and recognition program to support leadership engagement in providing employees with regular support and coaching on quality improvements.	• Gemba • Coaching/mentoring • Situational leadership
1.4	Leaders always model the desired behavior of "doing the right thing" on issues of quality.								1. Ensure leaders "walk the talk" by personally demonstrating a commitment to quality outcomes that support patient safety and consider drug supply. 2. Ensure leaders demonstrate holding themselves and others accountable for quality behaviors that are aligned with the corporate policy and vision. 3. Have leaders in all areas include quality goals into yearly business performance objectives for themselves and their employees. 4. Have leaders explain and share examples where decisions have been made considering both quality and business issues. Patient risk (including that of limited drug supply) is considered foremost in quality decisions.	• KBIs • Model behavior: leader, manager, associates • People recognition systems

	DESIRED STATE	LEVEL 1 Strongly disagree	LEVEL 2 Disagree	LEVEL 3 Slightly disagree	LEVEL 4 Neutral	LEVEL 5 Slightly agree	LEVEL 6 Agree	LEVEL 7 Strongly agree	POSSIBLE IMPROVEMENT ACTIONS	CULTURAL ENABLERS
2	Mindset and attitudes									
2.1	All employees consistently see quality and compliance as a personal responsibility.								1. Ensure employee job descriptions reflect the importance of quality work, upholding cGMPs and continual improvement. 2. Have quality culture behavior and performance goals built into yearly objectives for business and employees. 3. Ensure reward and recognition program is aligned to support employee ownership of quality and quality culture behavior demonstration. 4. Deploy and enable common continuous improvement methodology training and experiences within the organization (e.g., Lean/Six Sigma, quality risk management, knowledge management) to engage employees in quality improvement work and provide positive quality improvement experiences where they have the opportunity to directly improve quality.	• Job descriptions, • Performance management process • People recognition systems • Training and coaching
2.2	Employees have sufficient authority to make decisions and feel trusted to do their jobs well.								1. Ensure there are decision making guidelines, training and coaching in place to support the expectation that both business and quality issues are considered. 2. Deploy and enable common continuous improvement methodology training and experiences within the organization (e.g., Lean/Six Sigma, quality risk management, knowledge management) to engage employees in quality improvement work and provide positive quality improvement experiences where they have the opportunity to directly improve quality. 3. Ensure process is in place to capture ideas to improve current processes and encourages employees to submit improvement suggestions (with a feedback loop is in place to provide an update on whether improvement actions will be implemented and the status of implementation to the employees). 4. Ensure employees have job function training that is competency based as well as training in good manufacturing practices. Employees need to have the technical knowledge to understand how their roles and responsibilities impact quality.	• Training and coaching • Communications • Decision-making guidelines • Improvement suggestion process
2.3	Employees regularly identify issues and proactively intervene to minimize any potential negative impact on quality and compliance.								1. Ensure employees have and can use processes to communicate quality violations via a whistleblower policy or an ombudsman's office. 2. Deploy and enable common continuous improvement methodology training and experiences within the organization (e.g., Lean/Six Sigma, quality risk management, knowledge management) to engage employees in quality improvement work and provide positive quality improvement experiences where they have the opportunity to directly improve quality. 3. Ensure reward and recognition program recognizes employees providing suggestions to proactively mitigate potential risks to product quality. 4. Ensure process is in place to capture ideas to improve current processes and encourages employees to submit improvement suggestions (with a feedback loop is in place to provide an update on whether improvement actions will be implemented and the status of implementation to the employees).	• Ombudsman's office • Training and coaching • People recognition systems • Quality risk management • Knowledge management

	DESIRED STATE	LEVEL 1 Strongly disagree	LEVEL 2 Disagree	LEVEL 3 Slightly disagree	LEVEL 4 Neutral	LEVEL 5 Slightly agree	LEVEL 6 Agree	LEVEL 7 Strongly agree	POSSIBLE IMPROVEMENT ACTIONS	CULTURAL ENABLERS
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.								1. Implement a formal process to develop leadership capability in being able to observe and assess employees' mindset and attitudes related to the importance of quality and employee ownership (e.g., training, surveys). 2. Ensure leaders are trained and capable in building trust and an environment which employees feel safe to admit mistakes they made. 3. Involve employees in common continuous improvement methodology training and application within the organization (e.g., Lean/Six Sigma, quality risk management, knowledge management). 4. Leaders to regularly discuss quality culture expectations and examples with groups as well as with individuals to promote proactive quality behaviors.	• Cultural assessment tools • Training and coaching • Quality risk management • Knowledge management
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.								1. Develop and implement a formal Gemba process with defined schedule, frequency and participation. 2. Develop Gemba guides to help participants develop good dialogue. 3. Increase visibility and status tracking of identified continuous improvement opportunities (on a whiteboard in the area or other easily accessible place). 4. Provide coaching to leaders how to do an effective Gemba walk.	• Training and coaching • People recognition systems • Knowledge management • Gemba tools/templates
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.								1. Ensure leaders are encouraging and supporting open communication and reporting of quality issues and concerns. 2. Have leaders bring customer quality stories back to the shop floor to ensure links are made between work and outcomes. 3. Ensure process is in place to capture ideas to improve current processes and encourages employees to submit improvement suggestions (with a feedback loop is in place to provide an update on whether improvement actions will be implemented and the status of implementation to the employees). 4. Utilize time during Gemba walks to recognize desired behaviors in individuals and teams and continuous improvement contributions.	• Behavior-based quality training • Gemba • Coaching/mentoring • KPIs • Reward/recognition based on model behaviors

	DESIRED STATE	LEVEL 1 Strongly disagree	LEVEL 2 Disagree	LEVEL 3 Slightly disagree	LEVEL 4 Neutral	LEVEL 5 Slightly agree	LEVEL 6 Agree	LEVEL 7 Strongly agree	POSSIBLE IMPROVEMENT ACTIONS	CULTURAL ENABLERS
4	Monitoring and measurement									
4.1	Quality metrics and goals are consistently designed and selected to promote/motivate desired quality behaviors.								1. Undertake a review of current key performance indicators (KPIs) to ensure those selected are relevant to the employees responsible for delivering them and are clearly linked to the desired behaviors. 2. Implement a formal process to develop leadership capability in being able to observe and assess employees' mindset and attitudes related to the importance of quality and employee ownership (e.g., training, surveys). 3. Perform a metric and behavior assessment to validate the desired behaviors are being encouraged via the quality metrics and key performance indicators (KPIs). 4. Involve line workers in development of quality metrics and key performance indicators (KPIs).	• Smart KBI metric design training (designing metrics that matter) • Behavior-based quality training • Gemba • Coaching/mentoring • Situational leadership
4.2	Up-to-date quality metrics (e.g., right first time figures, excellence targets on defects, rejects) are regularly posted and easily visible near each production/work area.								1. Utilize visual management system with key performance indicators (KPIs)/key behavioral indicators (KBIs) accessible at each production line. 2. Make employee and group recognition systems are also visible and accessible at each production line. 3. Conduct routine team reviews of quality metric performance and recognition as planned activity in the work schedule. 4. Post and review tracked quality information with line workers. Supervisors to use quality measure performance as point of discussion and focus for improvements.	• Recognition and reward systems training • Learning teams development training • Coaching and mentoring • Gemba • "Who is our patient?" education sessions
4.3	All workers can routinely explain what quality information is tracked and why and outline their role in the achievement of quality goals.								1. Have workers lead the line reviews of targets and progress on a rotating basis. 2. Review quality metrics and highlight team based improvement initiatives periodically during Gemba. 3. Involve line workers in development of quality metrics and key performance indicators (KPIs). Train workers on the definition of the Key Behavioral Indicator (KBIs), and what that means for product quality. 4. Post and review tracked quality information with line workers. Supervisors to use quality measure performance as point of discussion and focus for improvements.	• Smart KBI metric design training (designing metrics that matter) • Behavior-based quality training • Gemba • Learning teams development

	DESIRED STATE	LEVEL 1 Strongly disagree	LEVEL 2 Disagree	LEVEL 3 Slightly disagree	LEVEL 4 Neutral	LEVEL 5 Slightly agree	LEVEL 6 Agree	LEVEL 7 Strongly agree	POSSIBLE IMPROVEMENT ACTIONS	CULTURAL ENABLERS
5	Management oversight and reporting									
5.1	Quality goals and objectives are routinely established, linked, and aligned with organizational goals.								1. Establish company-wide quality targets with initiatives in place to reach those targets. 2. Establish standard and regular quality metric review process and expectations across the organization. 3. Create an intra-company website accessible to all employees were quality metrics are automatically posted in real time from source systems (e.g., TrackWise, SAP). 4. Create manage for daily improvement (MDI) visual factory boards to provide transparency to status of key quality initiatives and targets.	• Smart KBI metric design training (designing metrics that matter) • Behavior-based quality training • Gemba • Coaching/mentoring • Goals aligned vertically and horizontally throughout the organization
5.2	Management is regularly involved in reviewing and assessing product, process and quality system performance.								1. Have first line leadership hold daily quality metric reviews and quality issues discussions on the shop floor. 2. Hold cross-functional (e.g., operations, quality, engineering, technical services) leadership reviews of end to end processes, metrics and quality issues to ensure integrated understanding and management of quality performance. 3. Have site leaders take turns in presenting the site quality system management reviews and product quality management reviews. 4. Ensure global leadership regularly participates in the global quality system management reviews and product quality management reviews by tracking attendance and engagement.	
5.3	The company's oversight and reporting capabilities are systematically applied to effectively manage external manufacturing performance within the supply chain.								1. Establish quality targets and objectives through a joint process team comprised of company and contract manufacturer management. 2. Joint process team leadership facilitates intercompany (e.g., company and contract manufacturer) participation in review of quality metrics and discussion of quality issues (including CAPA). 3. Utilize person-in-the-plant observations to assess the effectiveness of oversight activities. 4. Quality agreements include company-specific practices and expectations (i.e. not just external regulatory requirements).	
5.4	Management regularly involves line workers in problem identification, problem solving, troubleshooting and investigations.								1. Foster employee engagement and empowerment by establishing a mechanism for employees to submit continuous improvement ideas (e.g., "idea garden") to assist in reaching quality goals. Include in the process a feedback loop to provide an update on whether improvement will be implemented. Engage the employees in the implementation. 2. Train leaders and employees in structured problem solving and process thinking (e.g., root cause analysis, error proofing, process improvement) to create common terminology and ground to discuss improvements. 3. Implement quality continuous improvement (i.e., kaizen) to engage and empower line workers to improve quality in their processes. 4. Create a compliance hotline where any employee can anonymously report a suspect compliance or integrity issue.	• Tools for formal notification to management process • Continuous improvement tools/process • Training and mentoring • RCA training

	DESIRED STATE	LEVEL 1 Strongly disagree	LEVEL 2 Disagree	LEVEL 3 Slightly disagree	LEVEL 4 Neutral	LEVEL 5 Slightly agree	LEVEL 6 Agree	LEVEL 7 Strongly agree	POSSIBLE IMPROVEMENT ACTIONS	CULTURAL ENABLERS
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.								1. There are formal processes for capturing improvement suggestions, reporting near misses and actively seeking insights and shared learning. 2. Ensure there is a standard lessons-learned process deployed to capture lessons learned and actively share findings to employees and areas that are applicable. 3. Enable communities of practice to connect subject matter experts for knowledge sharing and collective problem solving. 4. Implement a rapid response team, which quickly reacts upon problems and goes to the shop floor for assessing and supporting.	• Learning organization model • Training • Alignment tool • Team building
6.2	Management enables employees at all levels within the organization to identify and communicate risks well across the organization.								1. Ensure a risk management program is in place to effectively identify and communicate risks across the organization to improve quality. 2. Enable communities of practice to connect subject matter experts for knowledge sharing and collective problem solving. 3. Ensure shift changes include the communication of identified risks and quality issues from the previous shift to the next. 4. Align rewards and recognition program to incent knowledge sharing (vs. knowledge hoarding), demonstration of model behaviors, and open sharing of risk/lessons learned including those resulting from mistakes.	• Organizational development training • Performance management process • People and process recognition systems • Training and coaching • Knowledge-transfer tools
6.3	We routinely recognize and celebrate both individual and group improvement achievements in performance quality.								1. Implement and communicate formal incentive program for quality goal performance, including consequences for poor quality. 2. Implement process to recognize and celebrate top quality improvements (e.g., quality cultural excellence award) across the organization. 3. Implement reward and recognition program for desired quality behavior (peer-to-peer; leader to employee). 4. Enable informal recognition practices and methods to be utilized for real time in the moment reinforcement of desired quality culture behaviors.	• Recognition and reward systems training • KBIs based upon achievements in quality
6.4	Employees regularly receive training that effectively helps them ensure quality in their work fostering a learning organization.								1. Ensure employees have job function training that is competency based as well as training in good manufacturing practices. 2. Implement or enhance formal organizational development processes to build the capabilities necessary to foster a learning organization: decision making, proactive problem solving, transparency, accelerated team- based learning, enabling change and continual improvement. 3. Implement training for leaders and their key role in fostering a culture of quality. 4. Ensure training includes the "why" (Why we are doing the things we do?) and not only the "how" (How we are doing the things we do?). Ensure employees understand the rational, e.g., the rationale behind the processes and not only the process steps.	• Learning organization model • Training • Alignment tool • Team building

Appendix 2

"Shaping Excellence" Interview Template

Questions for Site Leaders

SECTION 1: PARTICIPANT INFORMATION				
Interview date and time:			Recorded ◯ Y ◯ N	
Name:			Title:	
Company:			Functional area:	
Home site location:			Employees at home site:	
Years in industry	◯ > 25	◯ 20–25	◯ 15–20	◯ 10–15
	◯ 5–10	◯ < 5		
Industry	◯ Pharmaceuticals	◯ Biopharmaceuticals	◯ Medical devices	◯ Diagnostics
	◯ Services	◯ Other		
Activity	◯ API/DS	◯ Secondary/DS	◯ Packaging	◯ Contract
	◯ Distribution	◯ Other		
Global employees	◯ < 500	◯ < 1,000	◯ < 2,500	◯ > 5,000
	◯ > 10,000	◯ Other		
Interview method	◯ Face to face	◯ Web-based telecon	◯ Email return	◯ Telephone
	◯ Other:			
Management level	◯ Executive	◯ Founder/President	◯ Vice president	◯ Senior director
	◯ Director/Associate director		◯ Manager/Senior manager	

2

SECTION 2: LEADER 5VS—VISION, VALUES, VOICE, VISIBILITY, VIGILANCE		
L1	How do you define a culture of excellence?	
	What do you look for?	
	What do you measure?	
L2	What leadership traits are most important for cultural transformation?	
L3	How do you describe your leadership style?	
L4	Do you have a clear stated vision within your organization?	
L5	How was (and is) the vision communicated?	
L6	How do you ensure leaders deliver consistent messages congruent with the company vision?	
L7	What have you learned about leadership over time?	
	Has your approach or style changed?	
	How?	
L8	What are the most important actions a leader can take to foster positive culture?	
L9	What are the most dangerous inactions of a leader?	
L10	Do (did) you have a mentor?	
	Do you mentor or coach other leaders?	
	Formally or informally?	

SECTION 3: LEADER INFLUENCE ON MINDSET AND BEHAVIOR		
B1	Do you assess employee engagement, either formally or informally?	
	How?	
	How frequently?	
	Can you share any metrics?	
B2	Do you have a speak-up culture?	
	Do employees raise concerns and provide feedback?	
B3	Are there formal or informal feedback loops to encourage employee input?	
	Does the company act on suggestions it receives?	
	How?	
B4	What are the most important behaviors leaders can model to motivate others in quality excellence?	
B5	As the industry faces increasing demand (speed to supply vs. quality) how do you engage your team to sustain a positive culture?	
B6	Are any of your company's performance metrics based on behavior?	
	What are they?	
	How are they measured?	

SECTION 4: GEMBA PROCESS		
G1	Do your manufacturing sites conduct routine Gemba walks?	
G2	What is their frequency and purpose?	
G3	Do you personally participate in Gemba walks?	
	If so, what is your role?	
	If you don't participate personally, what is the highest level of site leadership involved?	
G4	Do you use the Gemba process to encourage positive behavior or provide recognition?	
	To drive engagement?	
	To provide communication?	
	How?	
G5	Does Gemba confirm that desired behaviors (identified in the vision) occur consistently on the shop floor?	

SECTION 5: LEADING QUALITY INDICATORS AND MONITORING		
M1	What LQIs do you measure?	
M2	Do LQIs have specific performance targets?	
M3	Do you use these measurements to reflect and improve quality culture?	
M4	Do you use visual indicators to show current progress against KPI targets, such as visual management boards?	

SECTION 6: LEADER OVERSIGHT AND REPORTING (VISIBILITY/VIGILANCE)		
O1	Are there formal processes for action-oriented responses against metrics-based triggers?	
O2	What do you personally monitor? (Describe both this site and the global organization.)	
O3	To which metrics are you most responsive?	
O4	How do you identify areas of vulnerability or weakness that require focused effort?	
O5	What do you do when you observe positive cultural change from your team?	

SECTION 7: CULTURAL ENABLERS		
E1	How do you pass along the cultural quality message?	
	How do you validate that its intention is being sustained?	
E2	Do you consider your organization a “learning organization”?	
	Why?	
E3	How do you invest in employee education and development?	
E4	How are improvement learnings shared?	
	Do you discuss misses or near misses?	
E5	What tools or strategies are used to motivate positive behaviors that support a healthy culture?	

Appendix 3

Gemba Case Study

A global pharmaceutical site had been working on initiatives to build an integrated quality culture, one that fosters continuous improvement (CI) and in which all employees think with a quality mindset. It recently started two initiatives, one targeted to improvements in the existing management walk-through process and one designed to implement right-to-operate (RTO) metrics. Both were built on the principles of the Gemba walk.

Monthly management walk-throughs were already a part of the site's self-inspection program, but there was room for improvement in the way they were conducted. The walks focused on housekeeping and facility maintenance improvements and were performed by a large group. This could be intimidating for employees who worked in the visited area, and could prevent productive interactions. Site management also felt that the walk-throughs duplicated weekly quality assurance and daily operations walk-throughs and often created scheduling conflicts. Finally, while observations from the walk-throughs were categorized, trended, and reported, it was difficult to identify true quality indicators.

The site management team decided to foster a culture of quality by changing the program to provide an opportunity for open dialogue and demonstrate management engagement. At the same time, the focus of the walk-throughs became more interactive and topic based.

In addition to these improvements, site leadership also decided to implement RTO metrics as an extension of existing site metrics. They defined a set of base metrics that reflected the manufacturing vision, mission, and principles but were shift-specific and adjustable to the needs of each area. They were therefore more directly linked to operational excellence outcomes and controlled directly by the shift supervisors and operators.

Implementation

The site designed the process to be less formal, to encourage open conversation, and move away from a checklist approach. A topic was proposed each month, along with potential questions to generate conversation. Suggested topics came from the quality lead team and could be derived from different sources, like the site self-inspection program, quality management reviews, or industry hot topics. The walk-throughs were no longer scheduled at specific times; instead, management was encouraged to go any time during their assigned month. Suggested topics were proposed for management walk-throughs as a starting point, but the walkers could change the topic to allow open dialogue.

After completing the walk-throughs, leaders who participated led a discussion at the monthly quality lead team meeting to highlight what they observed and report any concerns expressed on the floor. Meeting minutes captured the discussion. Follow-up items were tracked via the meeting action tracker or, if warranted, as corrective and preventive action (CAPA) items.

RTO metrics for each shift were reviewed monthly on the shop floor while the scorecard was displayed on the monitor in the control room of the area in which the review occurred. The review was facilitated by the shift supervisors, who explained the metrics results. All shift operators, operations managers, the operations director, and site head participated.

The RTO metrics review became a forum in which employees could interact with leadership to discuss hurdles or barriers to achieving operational excellence. At the same time, the review also offered an opportunity to share success stories and provide examples of operational excellence. It also provided a space for conversations around the pulse of the organization, concerns or questions on the floor, or areas where leadership could help reduce or eliminate barriers. The scorecards were made available on a collaboration site so that shifts could see their performance (and that of other shifts) at any time. The meetings were scheduled for 20 minutes per shift, and all follow-ups were tracked by the operations director. Some were entered in a formal tracking system, while others were completed and communicated at the next meeting.

Results

The site has seen tangible results with the implementation of both initiatives. The new interactive management walk-throughs have identified a number of CI opportunities as well as safety enhancements. With the implementation of RTO metrics, the site has seen an increase in engagement; “be-safe” and “safe start” stories are shared more frequently, while human error deviations such as entry errors have gone down.

One tangible outcome occurred in API production: A leader was observing manual addition in an area that had recently undergone improvements. The operator voiced a concern that while he had two manual additions, they were being performed differently; they should be treated the same way. As the leader asked more questions to better understand the process, he discovered improvements for storing secondary containers for the addition. With the two-way communication, two improvement opportunities were identified that would have been missed in the previous walk-through style.

One of the RTO metrics that indicated the need for improvement was related to training. Following a discussion at an RTO metric reviews, a training representative was added as a participant. The resulting discussion uncovered and corrected a barrier that was causing this metric to be missed. The training metric is now consistently on target to meet the expectation for operational excellence.

Both initiatives have been very well received by all involved parties. Leadership finds the walk-throughs informative, and operations personnel like having the opportunity to share their concerns. It took time to get past viewing the RTO metrics as a “scoring” exercise instead of an opportunity for improvement and greater interaction. In the meantime, the approach is well accepted and valued as a way to share success and remove barriers to CI.

The site intentionally kept the programs simple, allowing them to be adjusted to the needs of individual areas and providing some flexibility in implementation. Based on the learnings from these two initiatives, the site believes that the better the programs are tailored to the site’s working style, the easier they are to implement and the more successful their outcomes.

3

Gemba Walks in Laboratories: Lessons Learned

Implementation

Sites can implement Gemba in their laboratories successfully whether they have prior experience or not. It is possible to implement Gemba in the labs only (using the labs as pilots for Gemba implementation, for example), although the site will benefit more when Gemba becomes part of the site culture and the approach is implemented throughout all operational areas (such as manufacturing, packaging, and warehouse).

Up-front training and communicating the why and how of Gemba will make the implementation much more effective. The most important factors are:

- Teach Gemba walkers the dos and don'ts of Gemba, including best practices
- Plan detailed implementation steps
- Do a first practical exercise in Gemba walking
- Train ice-breakers
- For the visited areas, create awareness of who is coming, and how often; detail objectives and opportunities

It is often debated how formal a Gemba program should be. When implementing Gemba walks, a formal program helps emphasize the cultural change of getting people out of their offices and demonstrates management commitment to a published schedule. This perpetuates the desired behavior by allowing people to observe management making decisions right on the shop floor. If the desired culture change has been achieved, Gemba will be part of the site's DNA and the questions will surface more readily.

In the labs, Gemba walks can be performed either along the path of a product sample from receipt through release of results, or in a particular area, such as the raw materials lab. A mixture of approaches usually works best to ensure that the walkers understand all facets of lab work.

Surprises

Even the first training Gemba walks often created an "aha" moment, especially for organizations that did not do Gembas before. For many customers—even for some site management—the Gemba walk was their first time in the lab. They were often not aware of the knowledge and competencies of front-line workers. In these situations, Gemba walks provided much-needed understanding of an analyst's complex and difficult job, and the many steps involved in a single analysis, such as the time needed to prepare samples and instruments, requirements for data assessment, and level of rigor around the data. Gemba walks also addressed the lack of familiarity with basic processes for chemistry and microbiology analysis.

One of the most frequent quick wins after implementing Gemba walks was removal of artificial complications in planning and prioritization (and repeated reprioritization). These issues could often be resolved relatively easily through some basic communication between the supply chain and the labs. Many sites found examples in which testing was supposed to have stopped years prior but was still being performed due to a lack of communication.

The overall learning was that once people talk and understand the drivers behind their customers' actions, it is relatively easy to improve the overall outcome for the site.

Challenges

The hardest part of Gemba is tracking commitments agreed upon during the walk, especially when they are owned by more than one part of the organization. Best results occur when sites capture commitments on visual boards, lab leaders own communication about the progress, analysts are empowered to address such issues that have previously been discussed and actions are agreed upon. This requires understanding that making the change is a collective responsibility.

Culture shifts and tangible results

The successful implementation of Gemba walks in labs has helped build trust. Leadership has also been able to see that analysts are interested in their work and understand their contributions as part of the overall site performance, which leads to robust engagement of untapped hearts and minds. By enhancing the understanding of how supply chain and operations practices affect work done in the lab, tangible improvements in meeting schedules and output quality were achieved. The visible interest in how lab results are used has led to a significantly better quality of work and reduction in stress.

The most consistent tangible results were:

- Enhanced planning between supply chain and labs for raw material orders/testing and finished goods testing
- Adjusting key performance indicators (KPIs) to drive overall results instead of departmental objectives: e.g., replacing the lab cycle time KPI by adhering to a lab schedule produced better operations planning accuracy, fewer schedule changes, and less wasted time
- Artificial barriers affecting workflow, inventory, and timing were removed
- A better quality of work, with fewer deviations and out-of-spec results
- Lower rate of absence among lab personnel

Cautions

Expect that people in visited areas will be shy at first, especially if they have never experienced direct interactions with site management. This should not be interpreted as a sign that Gemba walks are not working. Be patient and willing to create an atmosphere that is positive and makes people feel at ease.

Gemba walks are meant to replace conference room meetings, so make sure to stop routine meetings that would replicate meetings in the labs. Don't add Gemba on top of old practices. Don't convert Gemba walks into audits. It may be tempting to "save" time by trying to do both at the same time, but that is the surest way to kill the benefit of Gemba walks. Gembas are meant to be short; don't overcomplicate the process or extend them to become hour-long meeting substitutes.

Leaders might be uncomfortable in the laboratory at first; some may not have a laboratory background, and may not understand the operation and its complexities. In these cases, the solution is to ask a lot of questions during the first walks and let analysts explain what they do and why they do it. Being interested in their work is the best door opener.

3

Continuous improvement

We recommend the following best practices, based on years of experience with Gemba walks in labs:

- Always ask yourself if the Gemba walks add value. If not, why? Find opportunities for adjustments.
- Measure Gemba performance with simple metrics, such as adherence to schedule and the number of CI opportunities implemented as a result.
- Measure tangible results from CI opportunities.

Appendix 4

Quality Triggers Tool

DATE	
SITE	
LOCATION	
PRODUCTS	
ESCORTS	
ASSESSORS	
OBJECTIVES	
SCOPE	

PART I: LEADERSHIP DIALOGUE—ASSESSOR, SITE LEADERSHIP, MANAGEMENT		
1. Organization and management		
1.1 Company/site organization	Comments, documentation, evidence	Risk rating: Low, medium, high
Experience/track record What is the site/organizational track record with respect to the services/products provided?		
Organizational structure • How is the quality department organized? • How is independence ensured? • How many layers of management are in the organization? • What is the span of control of each level? • What is the ratio of quality to total personnel? – Is this considered low/high? • What is the pharmaceutical experience of the leadership team and key personnel including quality and manufacturing management related to requirements of the organizational responsibilities? • What is the history and stability of the organization (e.g., ownership, significant or frequent organization changes.)? • What's the turnover rate during the past three years? – Is the rate considered high? – If so, what are the underlying reasons? – Have any actions taken to reduce the turn over?		
Temporary employees and consultants • Are temporary employees used? • Where are temporary employees utilized? • Why are temporary employees utilized (seasonality or variations in manufacturing volumes)? • What's the policy for "permanent" temporary employees (i.e., employees that have been utilized for an excessive period with no permanent status)? • What level of training is provided to temporary employees during on-boarding? • Does the site use consultants? – If so, how are they utilized (common routine activities or special projects)?		
Evidence of decision-making • Where are quality decisions made—centrally (above site, i.e., HQ) or locally (within site)? • At what level are decisions made? – Do employees have the authority to make appropriate decisions on their own (i.e., on the shop floor and at the supervisory levels)? – Are issues raised to the appropriate level at the appropriate time? • How are risk management and risk management tools employed in decision making. – How are these documented and approved?		

PART I: LEADERSHIP DIALOGUE—ASSESSOR, SITE LEADERSHIP, MANAGEMENT		
1.2 Management involvement in creating and maintaining quality awareness	Comments, documentation, evidence	Risk rating: Low, medium, high
Environment of quality awareness • How are management functions involved in creating and maintaining awareness of quality? • How is quality awareness communicated (upward, downward, and lateral)? • How are those communications structured and in what frequency? • How is communication about quality issues managed? • How is transparency ensured?		
Quality policy, strategy, goals, objectives, and performance • How is management involved in the development of quality strategies, policies, and goals? • How are quality goals developed? – Do employees have input into quality goals? • How are the quality goals communicated within the organization? • What processes and tools are in place for the development and monitoring of goals and assessment of results? • What are the quality metrics defined? • How are they communicated? • How are they monitored? • Are there visual reminders of quality values and metrics where they can be seen by employees?		
Customer/patient focus • How is customer satisfaction determined?		

PART I: LEADERSHIP DIALOGUE—ASSESSOR, SITE LEADERSHIP, MANAGEMENT		
1.3 Management commitment to quality	Comments, documentation, evidence	Risk rating: Low, medium, high
Management commitment to quality • What is the firm/site's quality mission? • How is management commitment defined/demonstrated? • To what extent does the management provide time/resources and support for quality improvement?		
Is there a policy on fraud and/or falsification of documentation or data?		
What type of support for the quality mission is provided (external resources, training programs etc.)?		
Continuous improvement for quality • What investments have been made in quality improvement during the past three years? • Are there formal processes for capturing and evaluating quality improvements/employees' suggestions?		
How does management resolve chronic quality problems (repeated audit observations, common root causes affecting quality issues, recurring deviations, etc.)?		
• Does management disseminate quality information and metrics to all personnel? • Are there visual reminders of quality values and metrics where they can be seen by employees? • How often is feedback provided to employees on quality? • How does management information on quality to employees—informal discussion, postings on bulletin boards, meetings, other?		
• How are regulatory inspection and audit observations communicated throughout the organization? • How does management assure that quality commitments are executed?		
Continuous/quality improvement • Is there an established environment of proactive continuous improvement related to quality? • Are there examples of continuous improvement or operational/facility enhancement/excellence projects? – If so, were these implemented as a result of a prior quality failure or proactively identified and implemented? – What resources are provided for continuous and/or quality improvement initiatives? • Are employees trained on improvement tools (e.g., SPC, Six Sigma, Lean)? • Are there benchmarking examples to provide a basis for continuous improvement and identification of best practices? • Is continuous improvement linked to quality elements and metrics? • Is there evidence of continuous improvement successes?		
Does functional or operational management serve on quality council or teams, participate in strategic planning for quality, provide resources for quality, and perform other tasks to plan and deploy quality goals?		

PART I: LEADERSHIP DIALOGUE—ASSESSOR, SITE LEADERSHIP, MANAGEMENT		
1.4 Personnel management: Employee engagement, empowerment, training and development	**Comments, documentation, evidence**	**Risk rating: Low, medium, high**
Do all employees have job descriptions?		
• Who is responsible for employees' development? – How is employee development is managed? – Do they have development plans?		
What resources are provided for training?		
Are employees given opportunities for participation in improving quality? • If so, give examples of how (e.g., serving on a quality council, taking part in a product or process design review, making presentations on quality). • Do employees have opportunities for providing input on quality issues? • Do employees know the quality goals for their department or area of intervention? • Do they know what is the quality impact of their job?		
Are there examples of personnel development and empowerment?		
Is there a system for the anonymous reporting of quality issues in the event an employee is not comfortable using the routine system? • If so, has information on the system been communicated to all employees? • Is the system being used by employees? • What do employees think of the system?		
Is there a policy prohibiting reprisal against employees for the reporting of quality issues? • If so, has the policy been communicated to all employees? • What is the opinion of employees regarding the company's compliance with the policy?		
Recognition Is there a system to engage and recognize employees? • If so, describe the system. • Is there recognition for achieving quality goals?		

PART II: EMPLOYEE DIALOGUE—ASSESSOR/EMPLOYEES FROM OPERATIONS		
2. Organization and management		
2.1 Company/site organization	**Comments, documentation, evidence**	**Risk rating: Low, medium, high**
What is your opinion of how quality decisions made— centrally (above site, i.e., HQ function) or locally (within site)? • Do employees feel they have the authority to make appropriate decisions on their own (i.e., on the shop floor and at the supervisory levels)? • In your opinion are issues raised to the appropriate level at the appropriate time?		
2.2 Management involvement in creating and maintaining quality awareness	**Comments, documentation, evidence**	**Risk rating: Low, medium, high**
Quality policy, strategy, goals, objectives, and performance • Do employees feel they have input into quality goals? • How are the quality goals communicated to you? • How are quality metrics communicated to you? • Are you aware and involved in how quality metrics and performance are monitored?		
2.3 Management commitment to quality	**Comments, documentation, evidence**	**Risk rating: Low, medium, high**
How is commitment to quality defined and demonstrated by the management? • Are you aware of the firm's/site's quality mission? • In your opinion, to what extent does the management provide time/resources and support for quality improvement?		
Are you aware of the policy on fraud and/or falsification of documentation or data?		
Are you ever involved with your management in resolving chronic quality problems (repeated audit observations, common root causes affecting quality issues, recurring deviations, etc.)?		
Do you believe that management disseminate quality information and metrics effectively to all personnel? • Are there visual reminders of quality values and metrics where they can be seen by you and your colleagues? • How often is feedback provided to you on the quality performance of the site/function/area? • How does management provide this information on quality to you—informal discussion, postings on bulletin boards, meetings, other?		
Continuous/quality improvement Are you involved in or aware of examples of continuous improvement or operational/facility enhancement/excellence projects? • What resources are provided to you for continuous and/or quality improvement initiatives? • Are you and your colleagues trained on improvement tools (e.g., SPC, Six Sigma, Lean)?		
Are you aware of how functional or operational management serve on a quality council or teams, participate in strategic planning for quality, provide resources for quality, and perform other tasks to plan and deploy quality goals?		

PART II: EMPLOYEE DIALOGUE—ASSESSOR/EMPLOYEES FROM OPERATIONS		
2.4 Personnel management: Employee engagement, empowerment, training, and development	**Comments, documentation, evidence**	**Risk Rating: Low, medium, high**
Do all employees have job descriptions?		
Who is responsible for you and your colleagues' development? • How is employee development managed? • Do employees have development plans?		
What resources are provided for training?		
Are employees given opportunities for participation in improving quality? • If so, give examples of how (e.g., serving on a quality council, taking part in a product or process design review, making presentations on quality, etc.).		
Is there a system for the anonymous reporting of quality issues in the event an employee is not comfortable using the routine system? • If so, has information on the system been communicated to all employees? • Is the system being used by employees? • What do employees think of the system?		
Is there a policy prohibiting reprisal against employees for the reporting of quality issues? • If so, has the policy been communicated to all employees? • What is the opinion of employees regarding the company's compliance with the policy?		
Recognition Are you aware of the system to recognize employees? • Is there recognition for achieving quality goals?		

PART III: QUALITY EMPLOYEE DIALOGUE—ASSESSOR/EMPLOYEES FROM QUALITY		
3. Key quality systems		
3.1 Notification to management	**Comments, documentation, evidence**	**Risk rating: Low, medium, high**
How are quality and compliance issues raised to management? • Is there a system for anonymous reporting of quality issues in the event an employee is not comfortable in using the routine system?		
Who determines customer and regulatory notification of issues? • Are these centrally decided (above site, i.e., HQ function) or locally (within site)?		
3.2 Deviation management	**Comments, documentation, evidence**	**Risk rating: Low, medium, high**
Is the deviation rate consistent with the technology, manufacturing volume, and mix of products? *(Note: this may indicate that manufacturing or laboratory deviations are not being appropriately raised and investigated).*		
Deviations • How are deviations raised? – Who raises them? – Do employees have the authority to raise or report a deviation and do they know who to raise a deviation to? (Review deviation reports to verify who is raising manufacturing deviations—is it quality, manufacturing or both?) – Are deviations raised in a timely manner after the occurrence of the event? • Who investigates deviations? – How are deviations determined? – What level of management is involved in the investigation? – How and when is an investigation is considered as completed?		
What is the quality of deviation handling, including investigations and CAPA? – Is root cause analysis documented in the investigations? – Is there an appropriate evaluation of impact to other batches, products? – Is appropriate CAPA documented or only retraining? – Is CAPA closed effectively and in a timely manner? – How is CAPA effectiveness measured?		
3.3 Training and effectiveness	**Comments, documentation, evidence**	**Risk rating: Low, medium, high**
Training How are training needs of employees determined with respect to quality? • How is training performed? – Is it a mix of that includes on-the-job-training, or standard operating procedure (SOP) review only? – Is there evidence that employees are trained on too many SOPs at one time? • How is training effectiveness evaluated? Are verbal or written tests provided for SOP training?		
Does the training program adequately cover temporary employees? • Is there a qualification program for new employees based on training accomplishments?		

PART III: QUALITY EMPLOYEE DIALOGUE—ASSESSOR/EMPLOYEES FROM QUALITY		
3.4 Supplier management and supply chain transparency	**Comments, documentation, evidence**	**Risk rating: Low, medium, high**
How are suppliers selected (cost, value)? • Is it via procurement function or cross-functional teams, including quality? • Is there an acceptable supplier quality management program (selection, oversight, etc.) for raw material suppliers, APIs, contactors, testing laboratories, warehousing, logistics, and transportation? – Is this program audited?		
Is there a supply chain security program? • Is there awareness/sensitivity around the importance of supply chain security? • What procedures and processes do they have in place to prevent supply chain related adulteration, diversion, and counterfeiting? • Do they have processes to respond to supply chain security failures?		
3.5 Annual product review	**Comments, documentation, evidence**	**Risk rating: Low, medium, high**
Does the APR report trends and appropriate metrics for critical quality attributes? • Is there a comprehensive and holistic view of the robustness of the product/process? – Does this include critical process parameters and process capability?		
3.6 Batch disposition	**Comments, documentation, evidence**	**Risk rating: Low, medium, high**
Who has the authority to reject batches? • How is this documented? • Who can overturn a decision to reject a batch?		
3.7 Self-inspection	**Comments, documentation, evidence**	**Risk rating: Low, medium, high**
Is there evidence that the self-inspection program is robust? • Are observations generally minor? • Are observations generally limited to the same findings? • Are CAPAs adequate and effective? • Who participates in self-inspections? • Is there cross functional representation among the inspectors? • Who has the authority to determine the final content of a self-inspection report?		
3.8 Fraud	**Comments, documentation, evidence**	**Risk rating: Low, medium, high**
Is there a policy on fraud and does the policy provide examples such as data integrity? • Is there a system to determine necessary actions following the discovery of fraud? • Has information on the policy been widely communicated? • Are there examples that policy has been followed? – Are employees aware of this? • Is there any evidence the policy is not being followed?		

PART IV: SITE TOUR OPERATIONAL ASSESSMENT—ASSESSOR		
4. Operations		
4.1 Procedures and processes	**Comments, documentation, evidence**	**Risk rating: Low, medium, high**
Are quality and manufacturing processes and procedures well defined and documented? • Are procedures written in the native language for operators to understand? • Are the quality and manufacturing processes and procedures well defined and documented? For example, do operators describe their operation and responsibilities in a way that indicates they have mastered these elements? • Can operational personnel retrieve appropriate procedures? • Is there evidence of an adequate number of employees to perform required work?		
4.2 Documentation and data integrity shop floor observations	**Comments, documentation, evidence**	**Risk rating: Low, medium, high**
Are documents completed in real time and does the information correspond to the process step being performed? • Are there any indications of increased risk of data integrity issues, especially handwritten entries in logbooks and lab notebooks? • Does data “look too good” and appear to lack natural variability? • Given the amount of information documented is there evidence of a lack normal/expected paperwork corrections? • Do numerical entries in tables drift indicating they may not have been entered real time?		
4.3 Knowledge	**Comments, documentation, evidence**	**Risk rating: Low, medium, high**
Do operational personnel demonstrate an appropriate understanding of the tasks they are executing and how it fits in to the overall production system? • For example, do operators describe their operation and responsibilities in a way that indicates they have mastered these elements?		

PART V: OVERALL ASSESSMENT INTERACTION—ASSESSOR			
5. Overall	Yes	No	Comments
Was information organized, readily available, and delivered quickly when requested?	◯	◯	
Was the attitude towards audits, regulatory inspections, regulatory queries etc. during conversations about past inspection results acceptable?	◯	◯	
Was the response to constructive criticism acceptable?	◯	◯	
Were the responses to inquiries met with openness? • Does the responder seem to know it all and always be right? • Does the responder blame the inspector, workforce, facilities, etc.?	◯	◯	
During the interviews with leadership and employees, was there a sense of trust in the responses provided and in the discussions held? • Did nonverbal signals and communication reinforce this perception of trust?	◯	◯	
Is the respondent open to other points of view or suggestions to change?	◯	◯	
Does management or supervision permit operators or other appropriate personnel to respond to questions or do they respond to all questions raised?	◯	◯	
Does the respondent appear to have excuses and blame the inspector, workforce, facilities, etc. for shortcomings or failures?	◯	◯	
Is there too much “agreement”? • Does the respondent agree to every request without confirmation of ability to deliver results or without understanding or evaluating impact to operations?	◯	◯	
What is the attitude of employees towards their responsibilities, management, and company? • In discussions with employees, do they demonstrate a positive attitude towards their responsibilities, management, and company?	◯	◯	

CONCLUSION	
Category risk rating: Check one rating for each section	
Part I	◯ Low ◯ Medium ◯ High
Part II	◯ Low ◯ Medium ◯ High
Part III	◯ Low ◯ Medium ◯ High
Part IV	◯ Low ◯ Medium ◯ High
Part V	◯ Low ◯ Medium ◯ High
Overall Risk	◯ Low ◯ Medium ◯ High

Additional comments:

About the Authors

Erika Ballman is the Quality and Regulatory Site Manager for Albemarle Corporation in South Haven, Michigan. She currently heads quality operations for the Charlotte, North Carolina-based company's API manufacturing site. During her nearly 20 years in the pharmaceutical industry she has held technical and quality leadership roles with Baxter BioScience and Perrigo Company. She earned a BS in chemistry from Michigan State University, East Lansing, Michigan, in 1998. An ISPE member since 2003, Ballman has been a contributor to the ISPE Quality Metrics Team and member of the ISPE Quality Culture Core Team since its formation in 2013. Erika currently leads the ISPE Leadership & Vision Subteam of the Quality Culture Core Team.

Nuala Calnan, PhD, is an adjunct Research Fellow with the Pharmaceutical Regulatory Science Team at the Dublin Institute of Technology, Ireland. With over 20 years' experience in the pharmaceutical industry, Dr. Calnan's research and industry consultancy focuses on the integration of knowledge excellence, operational excellence, and cultural excellence in delivering enhanced quality outcomes for the patient. She is currently a member of the St. Gallen University–led team who were awarded a one-year FDA research grant to examine the role of quality metrics in determining risk-based inspection planning. An ISPE Member since 1997, Nuala also co-leads the Quality Culture Team and the ISPE/PQLI Task Team on Knowledge Management.

Kira Ford received her BSc in biochemistry from Virginia Tech, Blacksburg, Virginia, and has over 28 years of experience with Eli Lilly and Company. As Director, Global Quality, she is responsible for the quality standards, practices, business processes and implementation tools for both the Lilly quality system supporting the pharmaceutical enterprise and the global quality system supporting manufacturing and product supply. As a Site Quality Leader for over a decade, Kira gained first-hand experience and insight into the important role that a strong quality culture and focus on quality metrics plays in improving site performance as well as employee satisfaction and engagement. In her current role, she continues to work on culture and metrics as key elements of a robust and effective quality management system. She has been an ISPE member since 2014.

Tami Frederick is Global Director, Corporate Quality Systems for Perrigo Company. A chemical engineer by education with 23 years in the pharmaceutical industry, Tami has held positions in quality assurance and control, research and development, regulatory affairs, and technical engineering. She is a certified Lean Six-Sigma black belt and a Certified Quality Engineer. Tami has led multicultural quality teams in the implementation of global quality systems such as global change control, EDMS, SQM, quality investigation and CAPA, global quality programs, global technology councils, new business integration, and auditing to support compliance. She is a strategic, global continuous improvement leader and change agent advancing the culture of sustainable quality throughout all levels in the organization. She has been an ISPE member since 2015.

Matt Pearson is a Senior Director at Genentech, Inc., a Member of the Roche Group. As Head of Global Quality Continuous Improvement, he oversees operational excellence, quality risk management, knowledge management and learning for Roche Pharma Technical Operations Quality. Prior to joining Genentech in 2006, Matt enjoyed a successful 12-year career with General Electric, serving in various leadership roles, including time as VP of Servicing Operations and Lean Six Sigma Black Belt. He holds a BS in business administration from the University of Missouri as well as an MBA. Matt is a member of the ISPE Quality Metric Team and the Co-Lead for the ISPE Quality Culture Subteam. He has been an ISPE member since 2007.

Margit Schwalbe-Fehl, PhD, is a Managing Partner of Bridge Associates International LLC, a consulting firm specializing in quality and manufacturing excellence. She works with clients in Europe and the US to implement robust and effective quality management systems, developing quality strategies and supporting organizational development activities. Prior to her career in consulting, during her more than 25 years in the pharmaceutical industry, Dr. Schwalbe-Fehl held positions with increasing levels of responsibility in the field of quality at major global pharmaceutical companies. An ISPE member since 2007, she holds a diploma in chemistry and a PhD in analytical chemistry from Johannes Gutenberg University in Mainz, Germany.