Shaping Excellence

How Leader Actions and Behaviors Influence Quality Culture

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In ISPE's Six Dimensions of Cultural Excellence framework, the first dimension addresses leadership and vision, and explores the leader's role in defining, achieving, and sustaining cultural excellence in pharmaceutical manufacturing.

In this article, Erika Ballman, lead of the Leadership & Vision subteam, describes the process her team used to find shared leadership traits, behaviors, and actions attributable to positive culture. This year the team embarked on a series of groundbreaking "Shaping Excellence" interviews with senior quality leaders from across the pharmaceutical and medical technology industries. A summary of the team's findings was first introduced at the 2016 ISPE/ FDA/PQRI Quality Manufacturing Conference in June 2016. Here, a more comprehensive range of leader insights are shared.

The Importance of Quality Culture

The degree to which quality is embedded in an organization's culture can mean the difference between success and failure.[1]

—François Sallans, Johnson & Johnson

The relationship between corporate quality culture and operational excellence continues to be actively explored. Indeed, ISPE's Quality Metrics Pilot Program Wave 2 findings, presented in June 2016, indicate a statistically significant correlation between the quality culture survey results and the performance metrics of right first time, deviation recurrence rate, and recalls.[2]

It is logical that companies benefit when they emphasize excellence in the way their work is performed, but is a corporate culture of excellence or "quality culture" substantive enough to be communicated or measurable in a way that can be improved? Moreover, how do industry leaders contribute to and help shape quality culture? Are there best practices that can assist and enable a collective mindset to drive toward improving quality?

The ISPE Quality Culture team, co-led by Matt Pearson, Senior Director, Genentech, a member of the Roche Group, and Nuala Calnan, PhD, Dublin Institute of Technology, asks these questions in an ongoing effort to develop practical approaches, practices, and tools the pharmaceutical industry can use to assess and improve cultural excellence. The Quality Culture team's road map is the cultural excellence framework, which consists of six dimensions that are integrated yet studied independently for their impact on quality culture (Figure 1).[3]

Figure 1: The six dimensions of cultural excellence

"Shaping Excellence" Interviews

The role of leadership in fostering and developing a vision of quality forms the starting point of the Six Dimensions framework.[3]
—*Nuala Calnan, Dublin Institute of Technology*

The Leadership & Vision (L&V) subteam focuses on establishing and engendering a vision of quality through leader-led behavior.

Consisting of ISPE members from different pharmaceutical companies and sectors, the L&V subteam developed an ambitious research concept to explore best practice leader-led behavior and ask valued leaders to comment on cultural excellence to find commonalities. Through one-on-one interviews, intended to be conversational and informal, industry-respected leaders shared what they believe are the most important actions and behaviors can leaders take to shape quality culture.

Over several weeks in spring 2016, 19 industry leaders representing various industry sectors and geographical regions were interviewed, guided by questions developed by the L&V subteam. These leaders also represented executive levels (vice president, global head, senior director) of corporate leadership, collectively contributing hundreds of years of shared industry leadership experience. These interviews gave the L&V subteam key insights into shared thoughts and unique perspectives, and produced a research data set that included over 18 hours of audio files with more than 125 transcript pages.

Figure 2 outlines the demographics of the leaders and their organizations.

Defining a Culture of Excellence

Leaders were first asked: "How do you define a culture of excellence? What do you look for? What do you measure?"

There is a bottom-up and a top-down connection. It comes very much from the behaviors, that the behaviors are correct. There is strong support from senior management, but at the same time there is a high level of engagement at the shop floor level.
—*Joseph P. Murphy, Roche Ireland Ltd.*

Employee and employer have a mutually beneficial relationship that allows the individual to feel like he or she is performing and contributing at their best. It is a win-win situation.
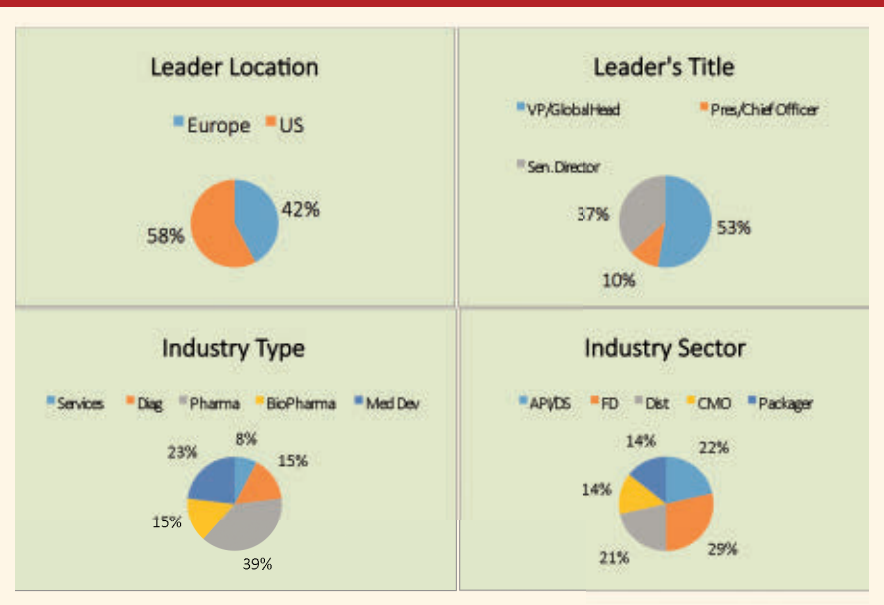—*Allen Napetian, Genentech, a member of the Roche Group*

The organization's purpose and the principles govern not only the work we do but how we engage with each other. In terms of a culture of excellence, I look for clarity in principles and purpose, and I look for it to drive the work and shape the experiences that we have.
—*Mike Vallender, Emergent BioSolutions*

Clear themes emerged in response to these opening questions related to the organizational environment, leaders, and employees:

- The organization has a sense of purpose in which employees are elevated beyond themselves.
- Leaders and employees are engaged and have the right mindset about product quality, service, and patient safety.
- An emphasis on quality drives predictable and improved outcomes, and not solely compliance expectations.
- Leaders articulate clear goals and model their expectations.
- Employees understand the organization's purpose, goals, and expectations and are self-motivated to reach them.

Figure 2. Leader demographics (n = 19)

A clear vision enables those in the organization to see how their roles fit into a bigger picture so they can work in alignment with the overall corporate goals

- The organization promotes continuous improvement and constant learning through words and actions.
- Leaders and employees demonstrate behaviors that enable and drive business success.
- Employees recognize the importance and value of their work product.
- When problems arise, there is a focus on problem-solving, not finger-pointing.

A corporate culture espousing these ideals would prove equally beneficial for companies, regulators, employees, and patients, but how can it be achieved? Furthermore, how can it be sustained? We examined the industry leaders' responses to determine how we might shape this type of culture.

Leader 5Vs

When considering the role of the leader in influencing culture, it is critically important to focus on behavior and actions. Interviewed leaders acknowledged the key role these two elements have in the site and company culture.

There was no mention of external forces—no "silver bullet" solutions—but an implicit and internal attitude, shaped by the leaders' focus and demonstrated commitment to excellence. While leaders must set the tone and vision and provide enabling tools, there was broad agreement that cultural excellence cannot be achieved without an engaged and motivated

workforce. It is not sustained, however, without the support of leadership and an ongoing investment in people, improvements, facilities, new capabilities, and quality and business systems.

It emerged that leading with "head, heart, and hands" requires connections between technical ability, emotional intelligence, and principle-based values. Based on the findings and insights gained, the team created a well-rounded leader model entitled the "Leader 5Vs" (Figure 3) that are associated with positive leader influence on quality culture.

The 5V categories are:

- **Vision:** Strategy, unifying goals, game plan, company mantra or credo, the desired state
- **Values:** Guiding principles, ethical conduct and expectation, humility, empathy, patient focus
- **Voice:** Passion, credibility, authenticity, and clarity, as well as the ability to articulate the vision, and inspire and motivate others
- **Vigilance:** Ability to drive accountability, determination, grit, focus, discipline, and follow-through
- **Visibility:** Leader presence, what he/she gives priority/time to, what he/she reacts and responds to

On vision

To be effective, the vision is to be communicated, understood, and acted upon by every employee and external business partner, including suppliers and contractors.[1]

—*François Sallans*

The Johnson & Johnson credo[4] is a renowned example of vision, as it is the foundation on which all decisions and actions regarding quality are made within the company. Another example of a strong vision is from Emergent BioSolutions: "Protect and enhance 50 million lives by 2025." This communicates the importance the company places on patient safety.

A clear vision enables those in the organization to see how their roles fit into a bigger picture so they can work in alignment with the overall corporate goals. A vision that acknowledges quality also enables everyone in the organization to see its importance.

Every action we take should be aligned with and in support of our vision. If there is misalignment, we have to be willing to have the courage to challenge whether we've strayed from our vision or whether it is no longer relevant. Employees will see right through this, and engagement will suffer.

—*Allen Napetian*

Vision is a critical element of leadership. It is a cornerstone, providing the foundation for the team to build upon. It's important that vision be built in collaboration, allowing all team members to see themselves in it and understand its genesis. It is a critical element in establishing direction from which long-term strategy and planning can be constructed.

—*John Pinion, Ultragenyx*

Figure 3: 5Vs of leader influence

Best practices related to vision identified during the leader interviews include:

- Keep the vision consistent: It is detrimental to shift messages too often; it becomes confusing and unclear in the organization.
- Have the determination to ride the cycle of change. Celebrate gains, and work through the setbacks. There will always be those who are resistant to change or see no reason for it.
- Seek ways to share the vision with the organization often; the right message cannot be overcommunicated.
- Ensure that the vision regarding the company's commitment to quality is readily available and can be communicated to all employees by all leaders in the organization.

Leaders must also vigilantly monitor and display key performance metrics to hold the organization accountable to its continuous improvement goals

On values

A common refrain from the interviewed leaders was the central role of integrity. Quality is often described as "doing the right thing when no one is looking"; the personal integrity of both leaders and employees is essential to achieving and maintaining a culture of excellence.

Leader values or "soft skills" such as humility, empathy, and the ability to listen were thought to be highly connected to higher levels of employee engagement, a necessary enabler to a positive culture. Leaders confirmed the importance of modeling desired behaviors and "walking the talk" as it relates to quality systems and standards. This requires that day-to-day decisions be congruent with corporate values.

It's about people. It's how you make them feel. Are you making them feel inspired? Motivated? Full of purpose? Or are you making them feel ignored, small? You've got to define the mission and you've got to have a vision, but it's people who give you your authority as a leader in the first place, so take care of them.

—Chris Bell, Emergent BioSolutions

Courage was also commonly mentioned in leader interviews as an important value. Leaders within organizations must display the courage to make tough calls, innovate, push the envelope, challenge effectively, and break old paradigms. Leaders should also promote an environment that is open to change—where ideas that may help improve site quality are welcomed.

The majority of leaders interviewed believe they have a "speak-up" culture where concerns can be raised and employees feel comfortable doing so. This is viewed as ideal for enabling cultural excellence. Many of the leaders' com-

panies provide anonymous call-in phone lines that allow employees to share concerns confidentially about quality or safety, for example. Some leaders, however, acknowledged that there is danger in assuming the culture is speak-up without verifying this through the employees, metrics, and results.

There's a danger in saying "Of course everyone feels free to speak up." It becomes important for senior leaders to go out, be visible, where the work is being done. If there is a sense of seeing and hearing things for the first time, it's probably an indication that this is not as ingrained in the culture as it should be.

—Conrad Mutschler, Perrigo

On voice

You need messages that are understandable so that everyone can articulate them in his/her own words. This begins with routine and consistent cascades of communication ... a source of information that is understandable and can be interpreted across different leaders and leadership styles.

—Allen Napetian

When a leader articulates a vision, his/her voice and body language must be viewed by the organization as credible and trustworthy. If the leader doesn't believe in the stated vision, however, it can have an unintended opposite effect. The leader must speak authentically to influence the desired behavior most effectively.

On vigilance

Vigilance is necessary to stay the course, put in the hard work, and endure the ups and downs of leading an organization through a journey of cultural improvement. Remaining consistent to the vision is essential.

Leaders must also vigilantly monitor and display key performance metrics to hold the organization accountable to its 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.

Leaders discussed their use of site scorecards, risk-assessment heat maps, and standing management overview meetings, in which quality metrics are periodically reviewed and discussed, often across various operating sites and multiple functional areas.

Leading quality indicators most commonly measured at the leaders' companies are:

- 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, measured as ratio of prevention vs. remediation cost

More unique considerations for leading quality indicators include measurement of organizational learning, such as the number of green belt and yellow belt certified employees or candidates, as well as other training-related and learning-based metrics.

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Most leaders acknowledged, however, that they are most responsive to lagging quality indicators related to the severity of nonconformances and deviations, consumer complaints, and recalls or adverse events. Many indicated a common desire to move their organizations further toward the use of leading quality indicators, like those mentioned, for proactive review and discussion.

Know exactly what it is your organization is doing, what they're experiencing, how they feel about the culture, and what their feedback is and let that drive some of the tactical work that you do to change culture versus taking an "off the shelf" approach ... once you start down the path, continue to get feedback from people. Is this the right thing? Does it resonate with you? That's difficult to do because it requires the leader to be a lot more visible, a lot more engaging than is comfortable to many.
—*Mike Vallender*

You've got to provide timely feedback. To do that, you've got to be a first-class noticer (to paraphrase Warren Bennis). Pay close attention to how words and behaviors are making people feel in the context of the culture you want. Don't let something slide more than once without giving feedback, and encourage others to do the same.
—*Chris Bell*

Every meeting, discussion, or email is a potential opportunity to develop our leaders. If we see a behavior or an action that does not model the leadership we are pursuing, we need to take full advantage by responding.
—*Steve Steffes, Perrigo*

Leader vigilance also involves the periodic monitoring of down-line leaders and the overall organization assessing and reassessing 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 changes and improvements is of most value in "reading" for culture or cultural changes.

On visibility

Quality culture scores related to leadership (coaching, daily dialogue, and management presence on the shop floor) were also demonstrated in the "ISPE Quality Metrics Initiative: Pilot Program Wave 2 Report" as those with the highest correlation to external quality outcomes, emphasizing the importance of leader presence.[2]
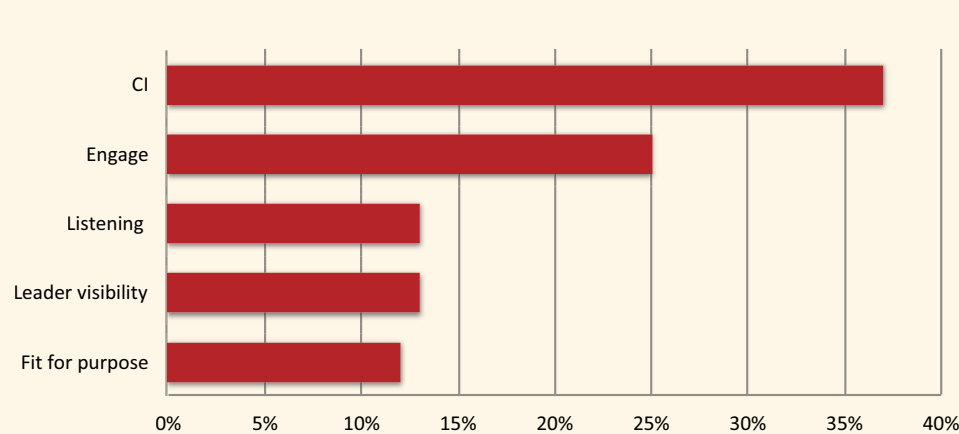
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Figure 4: Gemba purpose in leader organizations

leaders to listen to the quality concerns, issues, and ideas raised by employees at all levels of the organization.

Conclusion

The individual leader's actions and behaviors clearly contribute to site and company culture. Our research has shown that there are commonalities among industry leaders related to behavior, actions, and traits that can aid in employee engagement and the attainment of goals, as well as facilitate a corporate culture of excellence.

All interviewed leaders indicated that their companies conduct some level of Gemba activity on the shop floor. The leaders themselves often participate in site walk-throughs, providing an opportunity to interact with employees, front-line supervisors, and area leaders. Gemba was most commonly viewed as a continuous improvement (CI) tool or philosophy (Figure 4).

According to the ISPE Quality Metrics Pilot Program Wave 2 data, the highest range in quality-culture scores were from the "leadership categories" in the areas of Dialog and Gemba, as defined below:[2]

Dialog: We have daily quality metrics reviews and quality issue discussions on the shop floor.

Gemba: Management is on the floor several times a day both for planned meetings and also to observe and contribute to the daily activities.
                    —ISPE Survey Questions: Leadership Section [2]

This highlights an opportunity for industry leaders to positively affect these areas with greater leader presence and by holding other leaders accountable for reaching higher levels of visibility.

Everywhere you go, you set up listening posts like town hall meetings or roundtable meetings. You have the ability to get to know and relate to the people of the organization.
                    —Louis Yu, Valeant Pharmaceuticals International

It became clear that employee attitudes and mindsets can be shaped by leader storytelling and quality testimonials. The leaders interviewed indicated that they hold formal and informal quality-based discussions. These are achieved formally with town hall meetings, standing management review meetings, and corporate quality updates; informal methods include employee-management roundtables, one-on-one meetings with leaders, and plant Gemba walk-throughs. These sessions provide leaders with an opportunity to talk about quality and allow employees at all levels to ask questions. Another critical element of these sessions is that they allow

For those leading and driving cultural transformation programs, key points to consider include:

- Share a vision that includes the importance of quality frequently and broadly within the organization.
- Demonstrate decision-making and behaviors that align with the stated quality vision and value excellence above sole focus on regulatory compliance.
- Shape employee experiences and mindsets through formal and informal quality discussions where site metrics are reviewed and quality issues can be raised.
- Use Gemba as a best practice activity for the shop floor, laboratories, or other functional areas. Consider Gemba guidelines or checklists to aid the walk-through.
- Develop key site metrics and implement leading quality metrics and proactive measurements to drive continuous improvement.
- Provide structural enablers to support organizational improvement and inspire an environment of continual learning.

Crucially, leaders can challenge their organizations to drive for excellence and create a culture where all benefit. ■

Acknowledgments