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QUALITY CULTURE

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quality INFLUENCE culture

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In this section

Introduction

Nuala Calnan, PhD

In the January/February 2016 edition of *Pharmaceutical Engineering*, the ISPE Quality Culture Team presented its "Six Dimensions of Cultural Excellence" framework in an article entitled "Cultural Excellence: Ensuring that 'Culture of Quality' Is More Than Just a Slogan."[1] During a presentation at ISPE's recent Annual Meeting in Atlanta, Georgia, Team Co-Lead Nuala Calnan, PhD, confirmed ISPE's commitment to publish a comprehensive report on cultural excellence in 2017.

The report will share insights on quality culture improvement across the six dimensions and outline work this team has undertaken to develop a series of approaches, practices, and tools to support industry implementation of this framework, as well as promote behavioral change to benefit the patient. In addition, ISPE will host the 2017 ISPE Conference on Excellence in Quality Culture and Performance: Powerful Tools to Shape Quality Excellence from 25–26 April 2017 in Bethesda, Maryland. Information will be shared via www.ispe.org/events and the iSPEAK blog as it becomes available.

In this Quarterly Report on Quality Culture, three of the six Dimensions of Cultural Excellence subteam leads share some of their work in advance of the final report. This section includes articles from the Leadership & Vision, Gemba Walks, and Leading Quality Indicators subteams.

Finally, quality culture improvement has emerged within the context of the industry discussions arising from the FDA's draft guidance and proposed metrics set. This quarterly report announces an exciting new research program on pharmaceutical manufacturing quality metrics that FDA has embarked upon with the Pharmaceutical Operational Excellence Benchmarking team at St. Gallen University, Switzerland, under the leadership of Professor Thomas Friedli.

ISPE plans to publish a comprehensive report on cultural excellence in 2017

Shaping Excellence

How Leader Actions and Behaviors Influence Quality Culture

Erika Ballman

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

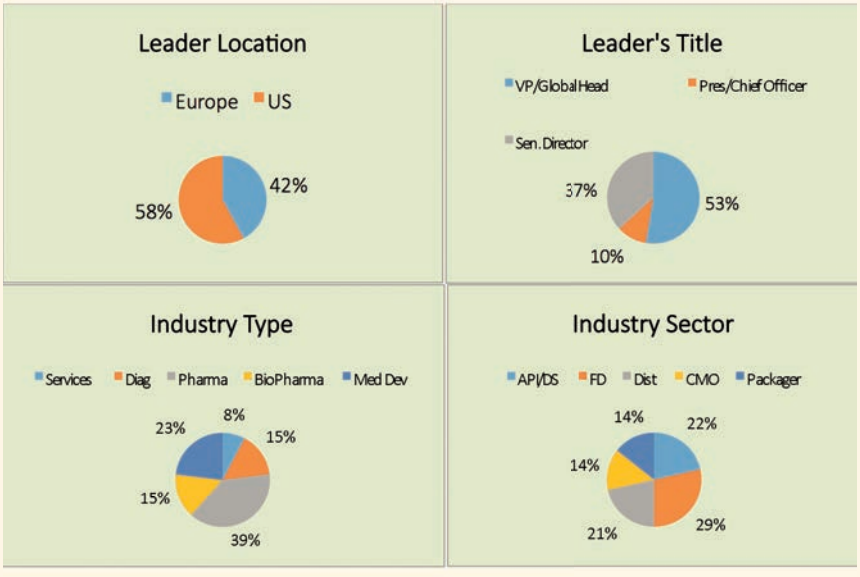
The organization's purpose and the principles govern not only the work we do but how we engage with each other. In terms of a culture of excellence, I look for clarity in principles and purpose, and I look for it to drive the work and shape the experiences that we have.

—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.

Figure 3: 5Vs of leader influence

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

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' companies 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.

The majority of leaders interviewed believe they have a "speak-up" culture where concerns can be raised and employees feel comfortable doing so

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.

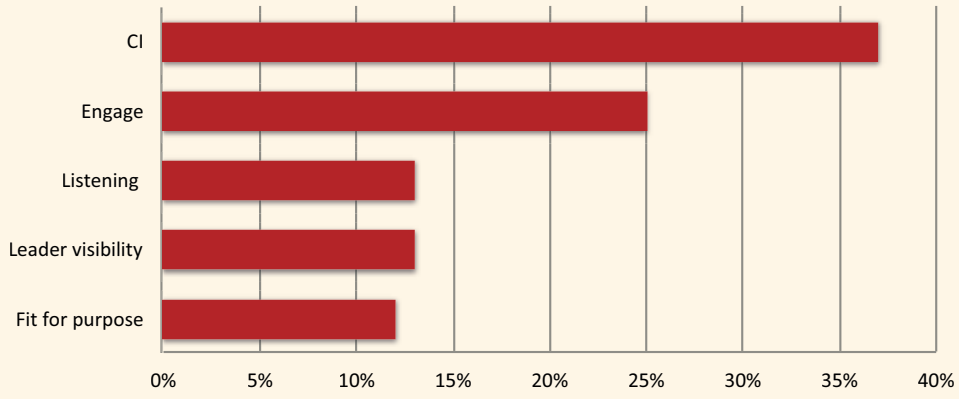
—Steve Steffes, Perrigo

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]

Figure 4: Gemba purpose in leader organizations



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 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.

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

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Gemba Walks in the Pharmaceutical Industry: Best Practices and Recommendations from Real-Life Experiences

Margit Schwalbe-Fehl, PhD

Within ISPE's "Six Dimensions of Cultural Excellence" framework, the third dimension focuses on Gemba and its close links to the leadership dimension as a key engagement and communication tool.

In this article Margit Schwalbe-Fehl, lead of the Gemba Walks subteam, shares insights and best practice recommendations based on real-life Gemba experiences and lessons learned from ISPE member companies.

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 many 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.

Why Do Gemba Walks?

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 improvement are heard.

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.

Sharing Gemba Best Practices

The Gemba Walks subteam reviewed a wide range of practices from other industries and from published examples,[2] as well as experiences 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, and there is no reason why it cannot be used effectively in the pharmaceutical industry.

This confidence was confirmed by listening to the leaders' voices in the interviews the Leadership and Vision subteam performed. These validated our thinking that once Gemba walks are implemented, the organization quickly recognizes their benefits (Figure 1).

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

Understanding 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 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 in the labs. An example of such questions is provided in Table B. It is also useful to provide Gemba walkers with layout plans and to create checklists of what to look for.

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.

Gemba walks demonstrate visible commitment from the leadership to all members of the organization

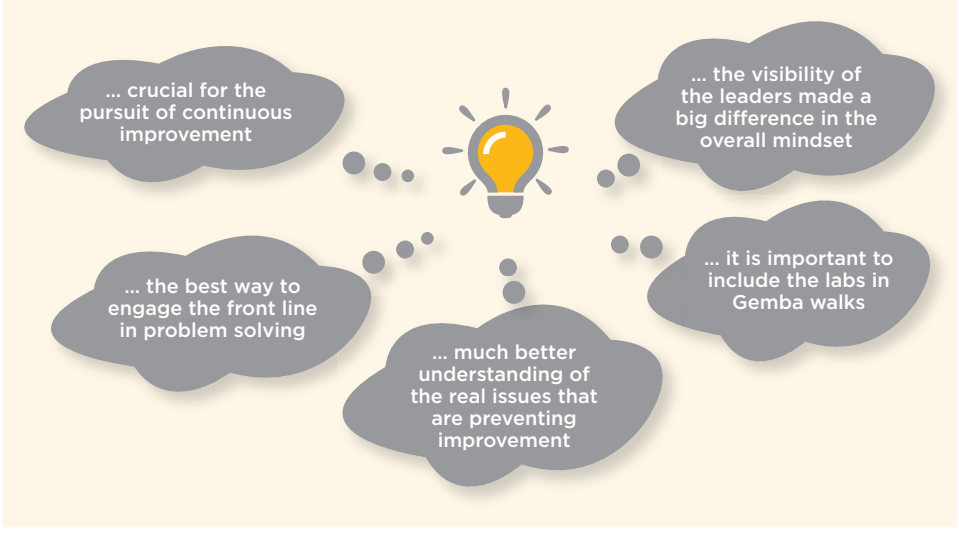
Make your Gemba walks about recognition, not auditing, by adopting the simple but important rule of "4 to 1": Express four recognitions for every action identified.

It is also critical to create a Gemba walk schedule that covers all areas 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.

An often-cited benchmark goal within the automotive industry, regarding the amount of time managers should aim to spend on the shop floor, is 60%. We recognize that many pharmaceutical manufacturing sites are still a far cry from this benchmark; nevertheless, we have included it within our best practice recommendations for Gemba walk frequencies. These schedule recommendations, as described in Table C, may initially represent a stretch target, but in our opinion they are manageable in the longer term.

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 supervisors and managers making decisions on the floor.

Figure 1: Feedback from leaders' interviews



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 Gemba walkers benefit significantly from the insights and discussions generated during these walks. Operators and lab analysts gain insight into the bigger picture of site performance, such as the expectations of external customers that the other functions have to deal with, and internal customers start to understand some of the constraints, real or perceived, that the visited areas may be challenged with.

Table A: Gemba walks

A Gemba walk is:

- An enabler for cultural change in management style and philosophy
- A role-modeling opportunity for leaders
- Empowerment of operators and analysts
- An enabler for continuous improvement through problem solving on the shop floor with the people who experience the problems
- 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; encourages informed decision-making for leaders
- An opportunity for the operators to demonstrate their pride and excellence in their jobs

A Gemba walk is not:

- 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

Gemba is a well-defined element of lean concepts and, as such, an accepted operational excellence tool in many industries that have adopted lean principles

Indeed, it was repeatedly reported to our team 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 obstacles, resulting in enhanced performance. Also, communication breakdowns between functions could 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.

Table B: Example of a 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.

Gaining an understanding of how current established practices can affect the work downstream often led to a quick removal of obstacles, resulting in enhanced performance

Table C: Recommended frequency for Gemba walks by management group

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 ▪ QC 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

Table D: Example of a Gemba walk action tracker

Date	Action description	Stakeholder	Action owner	Target date	Status	Comments

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

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 be either manual or electronic, whatever works best for the site in question. The record should reflect the agreed action, the responsible person(s), and due dates. Progress or closure should then be reviewed at follow-up 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 D. Remember, though, 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 practice (GMP) processes or systems, formal site change control must be initiated.

For further illustration of some 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 and a summary of the lessons learned from implementing Gemba in labs (see pages 62–65). We hope that these encourage more pharmaceutical manufacturing sites to implement Gemba walks in their quest for a culture of excellence.

Conclusions

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.

Gemba walks enhance communication of priorities, objectives, and desired behaviors, and foster dialogue and understanding between management and employees

Implementing Gemba 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 at Bridge Associates International LLC, USA, for sharing his insights and lessons learned from many years of implementing Gemba in the laboratories of pharmaceutical and consumer health care manufacturing sites.

Gemba Case Study

A global pharmaceutical site had been working on initiatives to build an integrated quality culture, one that fosters continuous improvement and in which all employees think with a quality mindset. It recently started two new improvement initiatives: one targeted to improvements to the existing management walk-through process and one to implementation of 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 walks duplicated weekly quality assurance and daily operations walk-throughs, and often created scheduling conflicts. 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 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, the site also decided to implement RTO metrics as an extension of existing site metrics. The site defined a set of base metrics that reflected the manufacturing vision, mission, and principles but were shift-specific and adjustable to the needs of specific areas. They were therefore more directly linked to operational excellence outcomes and directly controlled by the supervisors and operators of each shift.

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. Topics proposed for the management walk-throughs were suggested as a starting point, but the walkers could change the topic to allow open dialogue.

After completing the walk-throughs, leaders who participated in the topic-based walk-through led a discussion at the monthly quality lead team meeting to highlight what they observed and 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 CAPA items.

RTO metrics were reviewed monthly per shift on the shop floor while the scorecard was displayed on the monitor in the control rooms 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 their leadership and discuss hurdles or barriers to obtaining 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 into a formal tracking system, while others were completed and communicated at the next meeting.

The site management team decided to foster a culture of quality by changing the program to provide opportunity for open dialogue and demonstrate management engagement

The review offered an opportunity to share success stories and provide examples of operational excellence

Tangible Results

The site has seen tangible results with the implementation of both initiatives. The new interactive management walk-throughs have identified a number of continuous improvement 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 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.

A continuous improvement from the RTO metrics relates to training—one of the predefined scorecard metrics. Following a discussion at an RTO metrics review, 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 were 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 means to share success and remove barriers to continuous improvement.

The site intentionally kept the programs simple and adjustable to the needs of individual areas and allowed some flexibility in implementation. Based on the learnings from these two initiatives, the site believes that the better the programs are tailored to the working style of the site, the easier they are to implement and the more successful the outcome. ■

Implementing 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. In the beginning, implementing Gemba walks through a formal program helps emphasize the cultural change of getting people out of their offices and demonstrating 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 questions will surface more readily.

Up-front training and communicating the "why" and "how" of Gemba will make the implementation much more effective

In the labs, Gemba walks can be performed either along the path of a product sample from receipt through release of results, or in one particular area, such as a raw materials lab. A mixture of approaches normally 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 labs. They were often not aware of the knowledge and competencies in their labs. 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 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 the removal of artificial complications in planning and prioritization (and repeated reprioritization). They could often be resolved relatively easily through some basic enhancements in communication between the supply chain and the labs. Many sites found examples where testing was supposed to have been stopped years prior but was still being performed due to a lack of communication.

Expect that people in the visited area will be shy at first, especially if they have never experienced direct interaction with site management

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 resulted in building trust and seeing the excitement in the eyes of the analysts that people are interested in their work. The analysts appreciate 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 practices in supply chain and operations have an effect on work done in the lab, tangible improvements in meeting schedules and improving the lab 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:

1. Enhanced planning between supply chain and labs for raw material orders/testing and finished goods testing
2. Adjustments in key performance indicators to drive overall results instead of departmental objectives: Replacing the key performance indicator of lab cycle time, for example, by adhering to a lab schedule, resulted in better planning accuracy for operations, fewer schedule changes, and less wasted time
3. Artificial barriers affecting workflow, inventory, and timing were removed
4. A better quality of work, with fewer deviations and out-of-spec results
5. Lower lab personnel absentee rates

Cautions

Expect that people in the visited area will be shy at first, especially if they have never experienced direct interaction 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 also 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.

Continuous Improvement

Sites should undertake 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 continuous improvement opportunities implemented as a result.
- Measure tangible results from continuous improvement opportunities. ■

One of the most frequent quick wins after implementing Gemba walks was the removal of artificial complications in planning and prioritization

Leading Indicators of Quality: Pinpointing Behaviors and Measuring Results

Nuala Calnan, PhD

The fourth dimension of ISPE's "Six Dimensions of Cultural Excellence" framework focuses on those elements related to the monitoring and surveillance of key "triggers" and the design and development of leading quality indicators (LQIs).

In this article Nuala Calnan, PhD, head of the LQI subteam, shares key insights on the inherent links between culture and behavior, and outlines the role of leading measures of quality in driving desired patient-focused behaviors. This article shows how Leslie Braksick's IMPACT tool can be adapted for use in pharmaceutical manufacturing for the design of meaningful measures that pinpoint specific desired behaviors to promote a culture that enshrines prevention rather than cure.

Understanding Behavior as a Derivative of Culture

Culture as a concept is thus an abstraction, but its behavioral and attitudinal consequences are very concrete indeed.[7]

—Edgar H. Schein

An article published in *Pharmaceutical Engineering* earlier this year[2] introduced the work of Edgar H. Schein, one of the world's leading authorities on organizational culture and leadership. The article included his definition of culture: "how we perceive, think about, and feel about things."[7]

Schein formally 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.

Viewing the relationship between behavior and culture as an abstract-to-concrete continuum is particularly helpful when designing practical improvement strategies. Schein cautions against evaluating cultures in an absolute or superficial way, however, 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 strong quality culture. Too often this manifests as a traditional culture of compliance with an overemphasis on "doing things right" instead of enabling the workforce to do the right thing.

This is the foundation for ISPE's Six Dimensions of Cultural Excellence Framework (Figure 1), 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."[6]

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*, which 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."[8] The CEB survey 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 on the potential risks and consequences of their day-today actions.

Figure 1: The six dimensions of cultural excellence

Moving from the abstract to the concrete, we now examine how this "learning" can be targeted to pinpoint the 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.[6]

Braksick's work is founded on the principles of behavioral science presented in her book *Unlock Behavior, Unleash Profits: Developing Leadership Behavior that Drives Profitability in Your Organization*. 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 article outlines these "few simple principles" that can help reinforce good behavior in your teams.

The ABCs of Behavioral Science

Great execution depends on—behavior.[1]

—Leslie Wilk Braksick

The "ABC" model of behavioral science outlined by Braksick (Figure 2) holds that **A**ntecedents lead to **B**ehaviors, which lead to **C**onsequences. 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). Therefore, the sequence is as follows:

- Antecedents trigger behaviors
- Behaviors are followed by consequences, which, in turn, determine whether behaviors will recur

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 80% of the influence on behaviors. However, Braksick maintains 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 that managers "persist in spending 80% or more of their time trying to manage by working on As, leaving Cs largely unmanaged."[6] Braksick advises a combined approach to achieve maximum impact, stating that while 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.

The Rules of Four

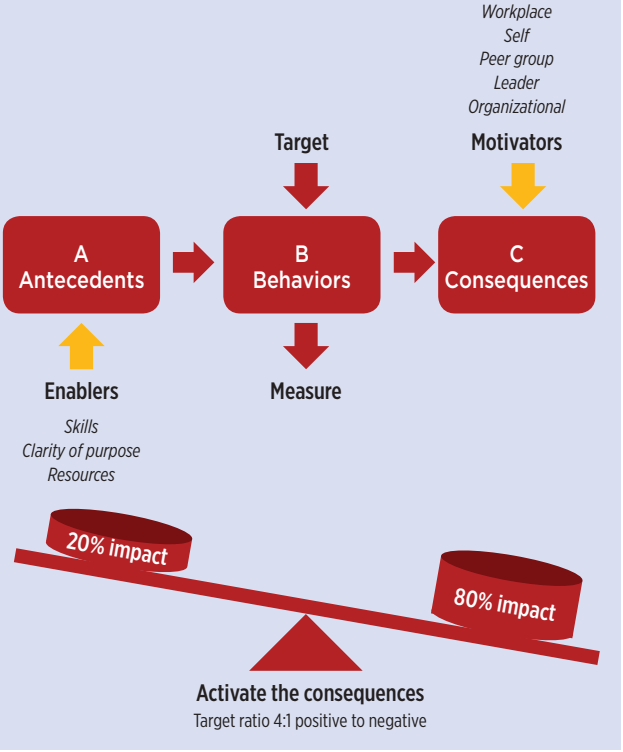
The "consequences rule" defined by Braksick states that consequences have a "4x greater impact on behavior than antecedents." Put simply, this means that consequences are the real motivators (or demotivators) and antecedents are simply the enablers.[1] Research undertaken by Losada and Heaphy in 2004 concludes that peak performance is achieved at a 4:1 ratio of positive to negative consequences.[5]

These rules raise two challenges for pharmaceutical companies that must be considered when targeting desired behaviors within a new learning culture. The traditional culture of compliance has relied heavily on rules-based antecedents to determine behaviors, such as documenting requirements in standard operating procedures and focusing on skills and task training. Within this environment, consequences tend to be those associated with nonachievement of desired behaviors and are largely negative (such as 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 effect 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 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 and 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

Figure 2: The ABCs of behavioral science



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

are simple, but changing minds and attitudes to emphasize *reinforcement* instead of *enforcement* may prove more complex.

Linking Culture, Attitudes, and Behavior: The LQI Model

Industry-based research undertaken by the author 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 both within Ireland and internationally. 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 provides these simple definitions:[3]

- 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."

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."[4]

Based on the truism "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 prevalent attitudes and mindsets 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 the desired behaviors.

Pinpointing Behaviors, Measuring Results

Having established that the choice of metrics provides an opportunity to positively influence behaviors (and therefore benefit the patient), this author adapted Braksick's IMPACT model for use in the pharmaceutical industry as a quality metrics tool to design behavior-based LQIs, sometimes referred to as leading behavioral indicators (LBIs). The aim is not to prove the superiority of forward-looking metrics over historical ones

Table A: A worked example of the IMPACT tool for designing behavior-based LQIs

Identify goal	Select the measure to deliver goal	Pinpoint the behaviors	Activate the consequences	Transfer knowledge and skills to sustain change	LQIs
Consistent delivery of high-quality medicinal products	Increase the number of batches which are right first time to X%	Promote and actively coach for enhanced attention to detail where "quality is everyone's job." Encourage a speak-up culture where concerns, issues or suggestions are surfaced in a timely manner in a neutral, constructive forum. Commence proactive daily multidisciplinary interim batch issues reviews.	Organize team briefings on the specific consequences for the business and the patient for rejected or delayed batch approvals. Review outcomes from recent rejected/delayed batches with the team. "Celebrate"/acknowledge each RFT batch by senior leadership and local management during gemba walks. Use of visual management boards for motivation on progress toward goal. Acknowledge improvement efforts by team members in team/public areas/ newsletters. Motivate the team through team awards (e.g., movie tickets, team lunches)	Learning teams use root cause analysis (RCA) tools to proactively identify and document solutions to issues raised. Lessons learned are documented and shared with wider workforce. Lunch and learn sessions are arranged to facilitate Q&A between different improvement teams. Create "improvement" case studies in a shared area on the intranet.	**Leading:** Measure and report on attendance at the multidisciplinary meetings. No. of employee / team RFT improvement suggestions implemented (by period) No. of "good catches" identified at interim batch reviews (by batch) No. of successful root cause analysis exercises completed by the team (by period) **Trended lagging:** % RFT batch approvals/ investigation free lots % RFT batch records (paperwork completion)

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 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, which forms one element of a broader LQI framework developed by the author, was influenced by a successful collaboration with the Pharmaceutical Operational Excellence (OPEX) Benchmarking team based at the 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.

Designing Measures for IMPACT

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

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

Table 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 and agreed upon in conjunction with the team responsible for delivering the identified goal.

The strength of the tool comes not only 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 behavior in the longer 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 team members involved in what Sutton and Rao call spreading their "splendid deeds from the few to the many." [9]

Summary

Designing behavior-based leading indicators of quality is one concrete 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 the consequences that can motivate the desired behaviors that matter to your business and your patients.

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Announcing FDA's Pharmaceutical Manufacturing Quality Metrics Research

Thomas Friedli, PhD, Prabir Basu, PhD, and Nuala Calnan, PhD

In the world of pharmaceutical production, it is universally understood that a robust quality system provides key elements of assurance and oversight for manufacturing processes: It ensures that patients are provided with medications that are safe, effective, and reliably produced at a high level of quality.

Despite recent advances in the manufacturing sector, however, quality issues continue to arise that can result in recalls, withdrawals, or harm to patients. Quality issues have also been linked to the rise in critical drug shortages.[1] Regulatory agencies currently assess the risk profile of manufacturing sites based primarily on their compliance history, as seen in warning letters and field reports, in conjunction with records on product recalls, and market-based quality problems. These are not necessarily the most informative measures and, by their nature, provide historical or lagging data or signal detection.

More relevant data relating to the state of quality, provided in advance, would better inform the risk factors that might predict quality problems and future drug shortages. This could become a valuable source of information for risk-based assessments and inspection scheduling of pharmaceutical manufacturing operations around the world.

The US Food and Drug Administration's (FDA) approach to quality oversight has evolved in recent years. The new Office of Pharmaceutical Quality (OPQ) has made it a priority to establish a more sound basis for ensuring that pharmaceutical products meet high quality standards throughout their life cycle. The FDA draft guidance proposed a set of standardized manufacturing quality metrics. The establishment and collection of these metrics could provide various stakeholders—from industry to regulators—with greater insight into the state of quality at a given manufacturing facility and allow stakeholders to better anticipate and address quality issues and their associated risks while simultaneously reducing unnecessary regulatory burden.

More relevant data relating to the state of quality, provided in advance, would better inform the risk factors that might predict quality problems and future drug shortages

As part of this initiative, the FDA has recently awarded a research grant* to Switzerland's University of St. Gallen to help establish the scientific basis for such metrics and integrate quality in its ongoing operational-excellence (OPEX) efforts.

OPEX Program

The Institute of Technology Management at the University of St. Gallen (ITEM-HSG) is a global academic leader in establishing solid and meaningful OPEX programs. For more than a decade it has worked hand in hand with the pharmaceutical industry to develop widely accepted global programs. These programs have positioned ITEM-HSG at the forefront of promoting, measuring, and monitoring operational excellence in the pharmaceutical industry.

St. Gallen has been responsible for the largest independent benchmarking project in the pharmaceutical industry since 2004, with 334 global manufacturing sites contributing key performance indicators (KPIs), in addition to providing rich qualitative data on organizational enablers for excellence. The institute's experience in metrics tool development and access to this global industry data set, coupled with experienced independent data analysis resources, uniquely position the St. Gallen OPEX project team to contribute significantly to the FDA/OPQ initiative on quality metrics.

Key Objective

In support of the OPQ's commitment to transform the assessment of drug quality from a qualitative to a quantitative or semi-quantitative expertise-based assessment, the key objective of this project is to evaluate potential quality metrics candidates, including those suggested in the FDA's June 2015 draft guidance,[2] and propose how they may be utilized to monitor the status of product and facility quality across the inventory of FDA-regulated sites. The proposed quality metrics will facilitate the effectiveness of current manufacturing controls, improve delivery of key quality outcomes in manufacturing operations, and seek to establish significant correlations to the underlying quality culture of an organization.

* Grant #1U01FD005675-01: "FDA Pharmaceutical Manufacturing Quality Metrics Research"

FDA has recently awarded a research grant to Switzerland's University of St. Gallen to help establish the scientific basis for such metrics and integrate quality in its ongoing operational-excellence efforts

Based on St. Gallen's extensive global OPEX database and nearly 15 years' experience in research and collaboration with the pharmaceutical industry, the research team will evaluate and propose meaningful, measurable, and reportable potential quality metrics candidates, including quantitative and quality culture–related indicators.

Research Approach

The St. Gallen OPEX model is a comprehensive excellence model able to map site performance from an overall system perspective. It comprises factors related to quality as well as cost- and time-related KPIs, and evaluates dozens of enablers that affect these KPIs. This well-established pharmaceutical program can show, based on data, that the very foundation of superior overall excellence is quality.

The research strategy will be executed in five stages:

Stage 1. The current FDA metrics concepts contained in the "Request for Quality Metrics – Guidance for Industry"[2] will be examined in detail, and the underlying research assumptions will inform further work. For the Stage 1 hypothesis evaluation, the research team will rely on existing data from the St. Gallen global OPEX database.

Stage 2. Researchers will develop a set of quality metrics suitable for overall system performance. Quality will be built in at its very foundation. The system will be described from supplier inputs to final delivery and will also comprise maintenance-related data, enablers, cultural indicators, and classical operational performance figures. This stage will be summarized and evaluated using a gap analysis procedure between the proposed St. Gallen metric sets and the FDA guideline metrics. The main objective is to determine if the limited set of KPIs given in the draft guidance can display a comparable base for an overall system-based evaluation, such as the St. Gallen model.

Stage 3. Based on the gap analysis and Stage 1 outcomes, the research team will propose possible modifications of the set of metrics and examine potential implementation challenges.

Stage 4. The team will use its industry access to check the practicability of the proposed metrics. Implementation hurdles and issues will be discussed and documented, based on case study research. Interaction with industry, however, will commence at the beginning of the project and continue throughout.

Stage 5. The team will create an overall research report to document progress and results and conclude findings. Intermediate and final results will be discussed in open public meetings with the FDA and industry in the United States, Europe, and Singapore.

Collaboration

St. Gallen will collaborate on this project in Ireland with Nuala Calnan, PhD, at the Dublin Institute of Technology (DIT), and in the United States with Prabir Basu, PhD, former Executive Director of the National Institute for Pharmaceutical Technology and Education. ■

The key objective of this project is to evaluate potential quality metrics candidates, including those suggested in the FDA's June 2015 draft guidance

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