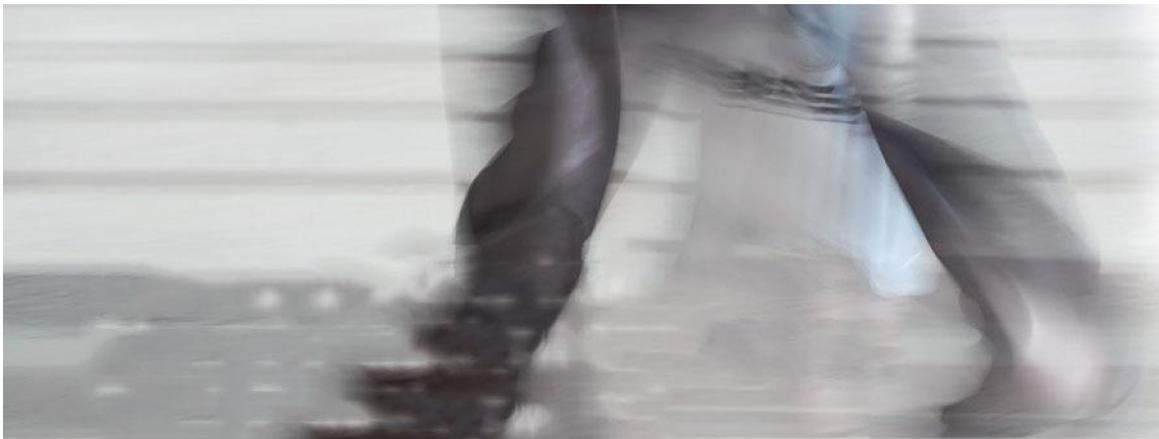


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Gemba Walks in the Pharmaceutical Industry: Best Practices and Recommendations from Real-Life Experiences

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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.

Table A: Gemba walks
A Gemba walk is:
<ul style="list-style-type: none">▪ 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:
<ul style="list-style-type: none">▪ 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

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.

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.

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

Make the mental shift of asking "Why is this happening?" instead of "Who did it?" to extract valuable existing knowledge from people on the floor.

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

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

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.

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
<ul style="list-style-type: none"> ▪ 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
<ul style="list-style-type: none"> ▪ 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
<ul style="list-style-type: none"> ▪ Site internal customers ▪ Manufacturing/packaging supervisors ▪ Lab managers ▪ Supply chain team leaders ▪ Manufacturing/packaging and lab managers ▪ Lab supervisors ▪ Manufacturing/packaging team leaders 	1 per quarter	1 per year
Site support (e.g. human resources, finance)	2 per year	1 per year

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

You may be surprised to learn that we also recommend Gemba walks for internal customers (e.g., purchasing, supply chain planners) and site-support functions (e.g., human resources, finance). We believe that both the visited areas and 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.

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.

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

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

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.

Table D: Example of a Gemba walk action tracker

Date	Action description	Stakeholder	Action owner	Target date	Status	Comments

For further illustration of some key principles and learnings from reallife 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

Date	Action description	Stakeholder	Action owner	Target date	Status	Comments
	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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Gemba Case Study

Quarterly Report: Quality Culture

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

Quarterly Report: Quality Culture



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