

Replicating success: Scaling up quality transformation across a network

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Quality transformations can have tremendous impact—reducing quality incidents by 30 to 50 percent, for instance, or unleashing the energy and capacity of thousands of employees. Transformation in a small pilot area is often successful, but many pharmacos have struggled to replicate the success of a pilot throughout the network. What are the best replication mechanisms?

Transforming quality in an entire organization that comprises thousands of production steps and employees and tens of thousands of SKUs is one of the most difficult challenges for any pharmaceutical company. By nature, every pharmaceutical product is unique, which means its production process cannot be standardized. By nature, every person working on a line is unique, which means a standardized intervention will not always work. Although pharmacos have found that significant management attention can foster a successful pilot of a quality transformation on the shop floor, scaling the transformation across a network has been an elusive goal for many.

What elements do successful transformations at scale have in common? They start with a clear aspiration and feature strong and consistent communication. The transformation's leaders lead by example and set ambitious but attainable targets and balanced incentives. And the organization is supported with tools, capability building, better practices, and other factors.

However, although successful transformations have common elements, the approaches that companies use to scale up their quality transformations are quite diverse. The starting points to determine the choice of approach are typically the scope of the transformation (a few pain points versus the whole quality system) and the company's maturity (that is, how much intervention is needed to improve the capabilities and culture). Below are four different approaches, each of which has proven successful in different contexts, and a detailed discussion of how to choose the right one for your company.

Cascading mini-transformations

How it works

This approach breaks down the organization into manageable units (each typically having 50 to 100 full-time equivalents.) The scaling mechanism is a series of heavily structured local transformations, called “mini-transformations” or “mini-T.”¹ Mini-transformations achieve the benefits of scale by repeating the same transformation approach throughout the organization and applying the knowledge gained in early phases to later phases.

Each mini-transformation is achieved through a standardized process conducted in three to four months. It entails simultaneous and radical changes on the three dimensions of operational excellence: operating system, management infrastructure, and mind-sets and capabilities. Intensive engagement of operators and middle management in root-cause problem solving and reducing the gap to best practices can lead to dramatic performance improvements in just a few weeks for a select set of key performance indicators (KPIs)—such as reducing deviations by a factor of 2 or 3 or reducing line clearance events by 40 to 80 percent. The mini-transformation is not only about introducing concrete improvements, however. It also emphasizes leaving behind a mechanism that allows units to continuously develop further improvements.

1 Alvaro Carpintero, Wolf-Christian Gerstner “Stop fighting fires: Transforming quality on the shop floor one unit at a time,” *Flawless: From Measuring Failure to Building Quality Robustness in Pharma*, McKinsey & Company, July 2014.

Why it is successful

The mini-transformation approach succeeds because it creates both tremendous energy in the organization and changes that are visible immediately. Intense coaching, significant attention to capability building, and energy from the bottom up are the ingredients for creating a profound cultural transformation.

When to choose and what it takes

The approach of cascading mini-transformations is best suited to organizations faced with a wide variety of challenges, such as undermotivated teams, an absence of standards or respect for them, too many issues blamed on “human errors,” or a lack of execution discipline. To be fully effective, the approach requires a significant investment in a team of “change agents,” who can help to replicate the transformation throughout the organization. This team (typically representing less than 1 percent of the workforce) is composed of people who have strong skills in problem solving, coaching, and change management. Team members need to be engaged as change agents for two to three years. Often, the speed of the transformation depends on this team’s capacity and effectiveness.

Designing a holistic production system

How it works

The holistic production system, derived from the renowned Toyota Production System, aims to bring together elements of the quality system and standard production processes in a comprehensive management philosophy. A production system defines the guiding principles a company uses to run its operations within a business and continuously improve its performance. It is a set of standards, practices, principles, and tools (including lean, Six Sigma, and other change management methods) that fully describe the best-in-class and expected operating practices across the network. In contrast to the formal setup of quality systems oriented toward compliance, production systems put a stronger emphasis on sharing learning and best practices across the network, training and capability building, and developing people. The best production systems are a living knowledge repository, simple to understand (from top management to shop-floor staff), and easy to access.

Why it is successful

Production systems ensure that everyone in the enterprise shares the same operational culture, speaks the same language, and applies a standard approach to work. Defining a unique way of working and deploying it gradually across the network can foster dramatic operational improvements, transparent performance levels for plants, and strong internal people development.

When to choose and what it takes

Production systems are still relatively rare in pharma but are commonly seen in the automotive, aerospace, and high-tech industries. Benchmarks in those industries have demonstrated that implementing a production system allows companies to build a sustainable competitive advantage.

Production systems are typically implemented in companies after some basic lean or quality skills are in place and well recognized. For example, a company that has gone through the mini-transformation approach will have a significant set of experiences. Best practices emerging from the transformation are then codified into the production system.

Creating a production system requires strong top management involvement, an easy-to-access central repository, and a clear deployment model. To sustain the system, an adequate organization must be in place, along with processes for capability building and practice sharing. Training of new hires, evaluation of people, training modules, and process descriptions all typically need to be closely aligned with the production system. The implementation of the production system is typically accompanied by cultural-change activities.

Setting priorities for process excellence

How it works

In this approach, a company selects a few quality processes as priorities for improvement efforts, such as change controls, line clearance, or cleaning validation. It centrally sets ambitions for the processes to attain a certain level of maturity. The selection of the right processes is quite critical, given that the limited scope of this intervention means major shortcomings could be missed if

the wrong processes are selected. Therefore, the exercise is often preceded by a thorough, global quality-management-system diagnostic.

From every site in the network, subject matter experts for each process are selected on the basis of their technical skills and their skills as change agents (in particular, collaboration and change management) and are empowered to make decisions. The experts convene for a limited period (up to two weeks) in a “kaizen workshop” to design the process from end to end. The central team travels to the sites, where it checks local against global best practices and prepares the site to adapt the global process design to the local products and processes and to the site’s starting point. The same local quality assurance experts who participated in the global design workshop oversee implementation of the new process in each location.

Why it is successful

The process excellence approach works because it offers very precise prescriptions and best practices that are easy to implement.

Convening subject matter experts from each location allows a company to leverage the best knowledge within the organization. The approach also ensures that this knowledge is broadly shared and aligned with as many people in the organization as possible. Success strongly depends on senior management buy-in, in particular the willingness to hold all organizational units to the same standard. This also makes the approach faster to implement than many others.

When to choose and what it takes

The process excellence approach works best when the organization recognizes that a few processes have clear weaknesses that need to be fixed fast. It requires strong top-down coordination to gather all the subject matter experts and to prepare for efficient and effective one- to two-week kaizen workshops.

Process changes may be more difficult to sustain, because site-level staff have little influence in the practices chosen by the subject matter experts (unlike for mini-transformations). The team of experts also needs to be careful not to create unnecessarily complex or ineffective processes—because one size does not always fit all. Also, the process excellence approach is truly “one off,” seeking to fix one process or set of processes, rather than setting the stage for continuous improvements.

Unit transformation in a box

How it works

“Unit transformation in a box” relies on a structured and fully developed tool kit for a unit or plant that is centrally developed on the basis of benchmarks, existing standards, and best practices among all relevant quality system elements. The tool kit comprises key quality parameters, benchmark metrics, a methodology for target setting, tools for idea generation, and a structure for implementation, among other elements. The organization supports the model through systematic capability building and a leadership development program for the key leaders with on-the-job breakthrough projects pertaining to quality. Such projects, typically almost a year long, help individuals build their leadership skills and learn how to deliver business impact, such as reducing batch failures or improving audit readiness. A continued effort by a central team is vital for this setup to work.

Why it is successful

The approach allows all sites to start the transformation simultaneously and to use it “off the shelf.” The use of benchmarks means that there is less requirement for people to travel and review data at different sites. The most beneficial aspect of this model is the ability to significantly increase the pace and scale of the roll-out with fewer resources. Because the approach focuses on fast improvements, it allows the organization to make early course corrections to ensure a positive trajectory for impact. This also helps to institutionalize the approach.

When to choose and what it takes

Companies should consider choosing this model if they need to accelerate the rollout of a transformation where the challenges are varied but many of the solutions are known. The pace and scale of the transformation make the approach especially useful for high-performing companies engaged in a transformation “from good to great.” Yet the approach does not work as well when the plant still has fundamental issues to be fixed—in that scenario, a more hands-on approach would be required. The approach is also well suited to capturing value in cross-functional areas and in cases in which there are few “low-hanging fruits” for capturing value.

Which approach is right for your company?

The right approach for a company strongly depends on its starting point (Exhibit 1). Companies that face a very significant cultural or capability challenge are better off choosing the mini-transformation approach, because it has the strongest focus on building capabilities and changing mind-sets and behaviors throughout the organization. Companies that want to integrate their lean, Six Sigma, quality, safety, and other approaches throughout the whole organization but that already have reasonably mature culture and capabilities can select a production system approach.

Both these approaches, however, are relatively slower than the others, because they rely on rolling out the transformation across many waves or years and require the organization to dedicate resources over that time period to address all processes throughout the network. The process excellence approach could be called “quick and dirty” in this respect: it is the quickest of the implementation

Exhibit 1

Transformation objective and quality maturity determine the optimal approach for each company



approaches and doesn't depend on the company having advanced skills and mature culture, but it also focuses least on long-term sustainability. As a result, it works best if there is a well-defined problem that is limited in scope and reasonably similar across sites, and if other mechanisms already exist to guarantee sustainability. Unit transformation in a box combines some characteristics of mini-transformations and process excellence. It is not as resource intensive as mini-transformations, but it requires more top-down steering and a more mature culture. Given the use of a broader tool box, it is slightly more bottom up and flexible than the process excellence approach, but it also carries more implementation risk.

Companies often combine elements of the four approaches and emphasize the elements that are most beneficial in their situation. For example, many companies pursuing mini-transformations soon find that their change management process is not equipped to deal with the significantly greater number of changes. In these cases, a quick process excellence intervention on change control processes is often needed to make the mini-transformations effective. Similarly, after running several mini-transformations, some companies choose to put in place systems and approaches for knowledge management that are quite similar to a production system.

To avoid the need for a mid-transformation course change, companies should make a thorough assessment of their starting point before embarking on a transformation. The appropriate scale-up method is easier to evaluate by considering the biggest pain points, the urgency required, and the organization's capacity to invest in a full quality transformation. In some cases, a few brief site visits can highlight similarities and differences across the network. With regard to quality maturity, a reasonably simple survey concentrated on culture elements such as leadership focus, employee ownership, capabilities, and risk attitude could provide good guidance on the organization's ability to undertake each type of transformation.²



2 Katy George, Wolf-Christian Gerstner, Vanya Telpis "Effective quality metrics: The starting point of quality management," *Flawless: From Measuring Failure to Building Quality Robustness in Pharma*, McKinsey & Company, July 2014.

The benefits of quality transformation are substantial—but the energy, willpower, resources, and investment required to get the transformation right can be daunting. To overcome the challenges, pharmacos need to invest in carefully designing the dominant architecture for the transformation. What works in your culture? What works in your enterprise? There are many ways to Rome—but all of them are easier if you have a clear map to guide your approach.

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