

THE HUMAN SIDE OF PROCESS STANDARDIZATION

How a leading multinational pharmaceutical company improved manufacturing and quality performance through process harmonization and digitization

UNLEASHING THE POWER OF PEOPLE IN PROCESS TRANSFORMATION

Behind every process is a person – or in the case of this particular global pharmaceutical company, more than 100,000 people.

Operating 50 manufacturing sites in eight countries in Europe, North America and Asia, this organization faced a challenge common to many global enterprises: different facilities had different ways of working, which led to varying outcomes and an inability to scale improvements across the enterprise.

While many companies focus on technology as the primary driver of process standardization, this pharmaceutical company recognized the equal, if not more important, human element at play. They partnered with Capgemini to create a “people-first” approach to transformation. The plan was based on the idea that the effectiveness of processes often relies on the teams who support them: their willingness to adapt, their enthusiasm to innovate, and their constant pursuit of higher performance.

For this reason, the program team focused primarily on the human elements of transformation, using a mix of traditional change management techniques and enabling technology to standardize, digitize, and optimize diverse manufacturing processes for improved efficiency and quality.

Client: A leading multinational pharmaceutical company

Region: Global

Industry: Life Sciences

Client Challenge: This global pharmaceutical organization faced an issue common to many large companies: different manufacturing facilities had different ways of working, which led to varying outcomes and an inability to scale improvements across the enterprise.

Solution: To develop a fit-for-standard approach, the company engaged in a multi-year partnership with Capgemini. Together, the team took a people-first approach to process harmonization and transformation while focusing on the challenges, needs, and best practices of different teams to guide their program.

Benefits:

- Process standardization and digitalization across various regions
- Widespread education related to changes
- Clearer and standardized data visualization
- More effective, action-based analytics

LIVING BY THE 80/20 RULE OF PROCESS STANDARDIZATION AND HARMONIZATION

When it comes to standardizing processes, it is important to understand not just **what** the current process is, but why people developed each specific step within it. This helps leaders recognize the differences between different workflows and, ideally, understand **why** those deviations exist.

For example, during a series of on-site evaluations, the program team realized that production staff at different sites at this company had their own preferences for how to conduct product moisture check steps in a slightly different order and with different roles and responsibilities. In this case, the changes were a matter of habit and standardizing them would enable greater efficiency at the enterprise level.

By contrast, when it comes to the process by which new products flow from R&D to production or from one production site to another, the organization wanted to maintain some specific differences that existed across geographies due to local regulations. In this case, deviations were tied to compliance and existed as a matter of necessity.

Through these two examples, the company was able to highlight the difference between **standardization**, when processes can be made identical or nearly identical, and **harmonization**, when processes are identical at a high level but differ at lower levels as needed.

Many businesses, including this organization, aim to standardize 80% of the total process, while allowing strategic customization for the remaining 20%. Commonly referred to as the Pareto Principle, this enables local teams to reap the

benefits of the fit-for-standard approach while also allowing those teams to maintain certain customizations that are specific to their local needs.

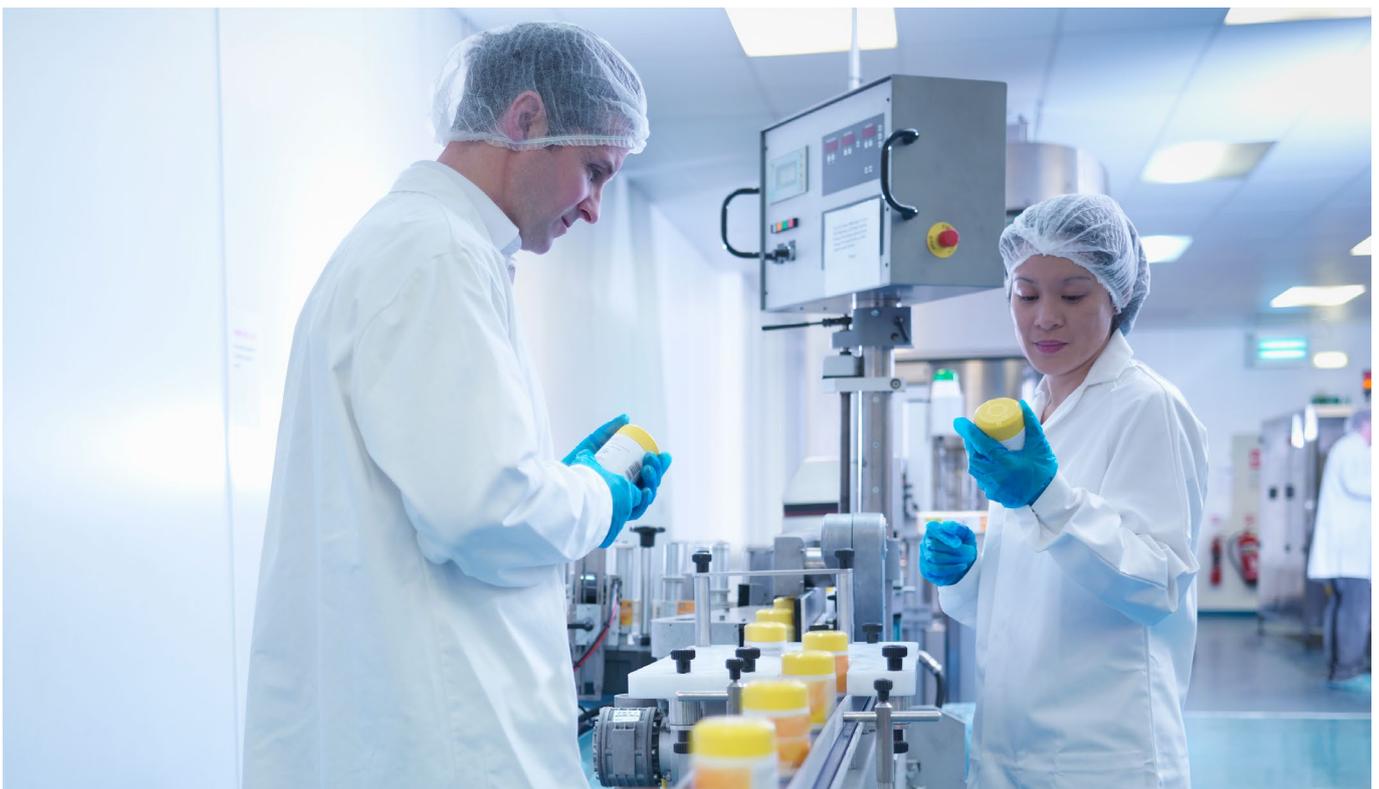
IMPROVING BY REMOVING: A COUNTERINTUITIVE APPROACH TO EFFICIENCY GAINS

Another important aspect of process standardization and improvement embraced by this pharmaceutical company during this engagement is the idea of “improving by removing.” That is, making processes better by eliminating duplicative or unnecessary steps, such as extra checks or the creation of new documents, as well as actively resisting the addition of such steps.

While this may seem counter-intuitive to many pharmaceutical organizations at first, “improving by removing” speaks to the overall efficiency and quality improvement effects gained by identifying non-value-added steps and removing them from the process.

For example, in some markets, this organization needed to maintain critical process parameters as a matter of regulatory compliance, landscape dynamics, or local requirements. These were value added aspects of production monitoring. However, double checks on these values where regulations did not require them would not add value and represent a great opportunity for “improving by removing.”

During this process, the company remained vigilant of this issue and challenged team leaders to find areas where they could remove unnecessary or duplicative steps. In addition, these stakeholders were instructed to avoid adding such steps when creating new processes or refining existing workflows.





FROM DATA TO ACTION: ENABLING ADAPTIVE PROCESSES

As part of this transformation initiative, the company also wanted to harness data and digital tools to enable adaptive processes so that regional and functional teams could more quickly and effectively respond to market dynamics, business needs, or landscape evolutions.

To that end, during the course of this program, the company worked with Capgemini engineers to develop and deploy several visualization tools and dashboards to make data more accessible and help teams better understand the cause-and-effect relationship between different levers within their manufacturing process. By connecting those dashboards to analytics tools, the organization was able to produce insights that could guide teams in addressing challenges as they arise or even before they present a problem.

At the same time, the real value of process change comes down to execution. While data and insights hold potential, improvement requires action. In addition to setting up advanced data visualization tools, the organization also refined existing processes or developed new ones so that teams were able to act on insights and address issues in a way that maintained the optimal levels of performance, efficacy, safety and quality.

SCALING SUCCESS: THE THREE-STEP SOLUTION

To develop a full understanding of the current processes used by each geography as well as the rationales driving differences among sites, the organization hosted a series of in-person workshops across 20 key locations. Through these sessions, the team was able to identify best practices that could serve as models for process improvement across sites while also addressing the unique challenges local teams were facing and any specific limitations they may have had.

This included, for example, process steps to service equipment proactively in order to reduce downtime—a practice that certain sites had implemented based on their experiences but had not been universally adopted across all locations.

Based on key learnings from these sessions, the company then designed a three-step solution for rolling out a clear sequence of standard and customized process steps:



PILOT: Testing and refining the fit-for-standard process for the very first time



SITE: Implementing the pilot model at a manufacturing site on one piece of equipment



SCALE: Replicating the fit-for-standard process across several machines at the same site

Now deployed at 20 different sites in several countries, the company has successfully harmonized processes, leading to the optimal performance of equipment as well as the ability to avoid common supply chain issues, such as bottlenecks, material shortages, or transportation disruptions.

THE MOST CRITICAL KPI: VALUE TO THE PATIENT

For a pharmaceutical company, the goal of any business initiative is to help the organization reach as many patients as possible, as fast as possible, and at the lowest possible cost.

This particular organization was guided by the fact that there is a clear link between how equipment is maintained and operated, and the speed, efficacy, safety, and quality of treatments manufactured by it. In standardizing and digitizing processes, the team also unlocked great potential to reduce costs, which could potentially lead to lower prices for customers.

By focusing on the human aspect of process standardization, the company successfully brought to life the concept that change is meant to improve the lives of people.



About Capgemini

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